

## Automated Blood Coagulation Analyzer CA-600 series

## Reference Guide

**USA** only

5.02

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We reserve the right to make changes in the course of technical development without previous notice.

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This document is the Siemens Healthineers Reference Guide for the following system: Automated Blood Coagulation Analyzer CA-600 series. It is the only relevant source for assay application information on this system.

The Reference Guide contains a complete list of all assays evaluated and released by Siemens Healthineers. Information in this document supersedes information in earlier versions of the Reference Guide or Application Sheets.

#### **Trademarks**

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#### Disclaimer

Siemens Healthineers has validated the provided instructions, reagents, instrument, software and customizable features for this system to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and test results. It is the responsibility of the user to validate any modifications made to these instructions, instruments, reagents or software provided by Siemens Healthineers.

CA-600 series Revision History

Reference Guide

## **Revision History**

Document	Date	Changes
Reference Guide 5.02	2025-08	New Application Sheets
		None
		Deleted Application Sheets
		None
		Revised Application Sheets
		General changes
		Application Sheets not listed below may contain sections highlighted in blue which indicate editorial corrections without changes to content. These corrections may lead to a higher version of concerned Application Sheets.
		Changes in detail
		<u>Thrombin time / Test Thrombin Reagent</u>
		Additional Notes: modified
Reference Guide 5.01 2025-03		New Application Sheets
		None
		Deleted Application Sheets
		None
		Revised Application Sheets
		General changes
		Application Sheets not listed below may contain sections highlighted in blue which indicate editorial corrections without changes to content. These corrections may lead to a higher version of concerned Application Sheets.
		Changes in detail
		Antithrombin / INNOVANCE® Antithrombin
		Precision: modified
Previous Reference Guide Versions	_	See respective Reference Guide.

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#### **Application Sheet**

## PT seconds / Thromborel® S

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	12		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
Thromborel® S	REF OUHP53			
	10 × → 10 mL			PT THS
Ci-Trol CONTROL 1	<b>REF</b> B4244-10			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244-20			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244-30			
	20 × → 1 mL			n/a
CONTROL	REF ORKE45			
	10 × → 1 mL			n/a
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Thromborel® S	1 <sup>b</sup>	_	24
Ci-Trol CONTROL 1	Any position on sample rack	_	n/a
Ci-Trol CONTROL 2	Any position on sample rack	_	n/a
Ci-Trol CONTROL 3	Any position on sample rack	_	n/a
CONTROL N	Any position on sample rack	_	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	378
Hemoglobin	1 000
Bilirubin	12

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#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	rc
PT seconds / Thromborel® S on CA-6000	$y = 1.00 \times -0.50 \text{ s}$	0.999

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 5 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	1.1	1.0	1.5
CONTROL N	0.7	0.7	0.9

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

			Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	Mean	(s)	(s)
_	158	_	10.2	9.3 – 11.6

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

#### Bibliography

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	PT	STD-Link	No
Manage. ID <sup>d</sup>	5010		
Detector	for PT THS		
End Point	50	) %	
Maximum Time	100	) sec	
Sensitivity	Low Gain		
Sample Vol	50		
Dil.Vol	******	) μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		) μL	
Dil.Vol	******	) μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	180	) sec	
Reag. Vol	PT THS 100	) μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	(	) sec	
Reag. Vol	******	) μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3	(	) sec	
Reag. Vol	******	) μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

 $<sup>^{\</sup>rm d}~$  The Management ID only applies to the CA-600 series.

#### **Data Check**

Special Menu – Settings – **Data Check** 

<ul><li>Mark Limits</li></ul>	Select Param.	PT

#### **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

<ul> <li>Set Replication</li> </ul>	Replicates	1	
Sec itepited tion	repriedes	l •	ı

PT seconds / Thromborel® S (V. 12) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

#### **Application Sheet**

## PT INR /

## Thromborel® S

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

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The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	13		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
Thromborel® S	REF OUHP53			
	10 × → 10 mL			PT THS
Ci-Trol CONTROL 1	<b>REF</b> B4244-10			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244-20			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244-30			
	20 × → 1 mL			n/a
CONTROL	<b>REF</b> ORKE45			
	10 × → 1 mL			n/a
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Thromborel® S	1 <sup>b</sup>	-	24
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
Ci-Trol CONTROL 2	Any position on sample rack	-	n/a
Ci-Trol CONTROL 3	Any position on sample rack	-	n/a
CONTROL N	Any position on sample rack	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	450
Hemoglobin	600
Bilirubin	36

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#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	<b>Regression Equation</b>	rc
PT INR / Thromborel® S on CA-6000	$y = 0.89 \times + 0.11^{d}$	0.999

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	1.0	0.9	1.3
CONTROL	0.6	0.6	0.8

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

#### **Expected Values**

Not applicable.

### **Bibliography**

Refer to the Instructions for Use of the reagent.

d no unit (INR)

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	PT	STD-Link	No
Manage. ID <sup>e</sup>	5010		
Detector	for PT THS		
End Point		50 %	
Maximum Time		100 sec	
Sensitivity	Low G	ain	
Sample Vol		50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		180 sec	
Reag. Vol	PT THS	100 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

Standard Curve Calibration
Calibration Parameter 3

Standard Curve - Select Param.

Param.	PT-INR
Units	_
Number Format	XX.XX
Curve Fit	ISI Input

Standard Curve - Manual Entry

Enter the Normal seconds = MNPT and the ISI.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	PT-INR

#### **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
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#### Remarks

System specific MNPT and ISI have to be used.

The mean normal PT (MNPT) is defined as the mean value of the normal range. Follow the appropriate CLSI guideline for establishing an MNPT.

ISI values for prothrombin time must be entered directly as they appear on the lot-specific table of ISI values. Any changes of the reagent lot, software (upgrades), major service, etc., require verification of the ISI value. Failure to enter the correct ISI value will cause incorrect International Normalization Ratio (INR) results.

For further information, please refer to the Instruction for Use of the reagent.

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

PT INR / Thromborel® S (V. 13) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

#### **Application Sheet**

# Derived Fibrinogen / Thromborel® S

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
Thromborel® S	REF OUHP53			
	10 × → 10 mL			PT THS
Ci-Trol CONTROL 2	<b>REF</b> B4244-20			
	20 × → 1 mL			n/a
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls have to be transferred into appropriate sample cups.

#### **On-board Stability**

Component	Position	Condition	Time (h)
Thromborel® S	1 <sup>b</sup>	-	24
Ci-Trol CONTROL 2	Any position on sample rack	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

b Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	n/a <sup>c</sup>
Hemoglobin	100
Bilirubin	36

Turbid samples are not suitable for Derived Fibrinogen determinations, as they may lead to abnormally low values. Interference of turbid samples may occur even if triglyceride concentrations are within the normal range. Any questionable result should be followed up with a more definitive quantitative method.

#### Limitations

Blood plasma substitutes that contain hydroxyethyl starch (HES) may interfere with the analysis. In a study with a HES solution (130/0.4) no interference was observed up to 6 q HES per liter plasma.

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

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#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> <sup>d</sup>
Fibrinogen / Dade® Thrombin Reagent on CA-500 series	$y = 1.00 \times -0.10 \text{ g/L}$	0.870

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Within-Device CV) on the same lot of control plasma should be as follows:

< 10 %

	Mean	Repeatability CV	Within- Device/Lab CV
	(g/L)	(%)	(%)
Ci-Trol CONTROL 2	2.5	2.3	3.1
Normal plasma pool	2.7	1.6	1.9

#### **Measuring Range**

Results within the measuring range/reference interval can be directly reported. Results outside the measuring range should be re-measured with a standard fibrinogen determination method (e.g., Fibrinogen with Dade® Thrombin Reagent or Fibrinogen with Multifibren® U).

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	(g/L)	(g/L)	(g/L)
_	124	2.8	2.7	1.9 – 4.0

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

#### Bibliography

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	PT	STD-Link	No
Manage. ID <sup>e</sup>	5010		
Detector	for PT THS		
End Point	!	50 %	
Maximum Time	1	00 sec	
Sensitivity	Low Gain		
Sample Vol	!	50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	1:	80 sec	
Reag. Vol	PT THS 1	00 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

**Standard Curve Calibration** 

#### Important!

The recommendation for the Number Format in Calibration Parameter differs from the information that is given in the Instructions for Use of the analyzer. Please check your Host System for correct interpretation of transmitted results whenever the Number Format will be changed.

#### **Calibration Parameter 4**

Standard Curve - Select Param.

Param.	dFbg
Units	g/L or mg/dL
Number Format	XXX.X or XXXX
Curve Fit	_

Standard Curve – Manual Entry – **Next** (if applicable)

Enter the Derived Fibrinogen g/L or mg/dL concentrations and the dH of the Master Curve specified in the "Table of Assigned Values" of the specific Lot of the reagent used for the analyzer.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	dFbg

#### **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
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## **Standard Curve (example only)**

Verify the standard curve with the master curve provided with the PT reagent after each change of the reagent lot, and modify the standard curve if necessary.

#### dFbg

(g/L)	(dH)
1.9	62
4.0	144

**RxOnly** 

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

Derived Fibrinogen / Thromborel® S (V. 14) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

#### **Application Sheet**

# PT seconds / Dade® Innovin®

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

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Version	13		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
Dade® Innovin®	<b>REF</b> B4212-41	<b>REF</b> B4212-51	<b>REF</b> B4212-101	
	10 × → 4 mL	10 × → 10 mL	12 × → 20 mL	PT INN
Ci-Trol CONTROL 1	<b>REF</b> B4244-10			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244-20			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244-30			
	20 × → 1 mL			n/a
CONTROL N	<b>REF</b> ORKE45			
	10 × → 1 mL			n/a
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials.

The required controls have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Dade® Innovin®	1 <sup>b</sup>	-	24
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
Ci-Trol CONTROL 2	Any position on sample rack	-	n/a
Ci-Trol CONTROL 3	Any position on sample rack	-	n/a
CONTROL N	Any position on sample rack	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	373
Hemoglobin	1 000
Bilirubin	48

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#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	rc
PT seconds / Dade® Innovin® on CA-6000	$y = 1.03 \times -0.26 \text{ s}$	0.999

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 5 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	0.9	1.5	1.8
CONTROL N	0.4	0.2	0.4

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

			Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	Mean	(s)	(s)
_	158	_	10.2	9.3 – 11.4

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

#### Bibliography

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – **Test Protocol** 

Test Protocol Name	PT STD-Link	No
Manage. ID <sup>d</sup>	5110	
Detector	for PT INN	
End Point	50 %	
Maximum Time	100 sec	
Sensitivity	Low Gain	
Sample Vol	50 μL	
Dil.Vol	****** 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0
2nd Dil		
D.Samp Vol	0 μL	
Dil.Vol	****** 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0
Reagent 1	180 sec	
Reag. Vol	PT INN 100 μL	
Pre. Rinse	*****	x 0
Post. Rinse	Clean I	x 1
Reagent 2	0 sec	
Reag. Vol	****** 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0
Reagent 3	0 sec	
Reag. Vol	****** Ο μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0

 $<sup>^{\</sup>rm d}~$  The Management ID only applies to the CA-600 series.

#### **Data Check**

Special Menu – Settings – **Data Check** 

– Mark Limits	Select Param.	PT

#### **Standard Curve Calibration**

The assay is not calibrated.

### **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
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#### Remarks

As an alternative protocol it is admitted to extend the Maximum Time to 300 seconds if long coagulation times are expected.

PT seconds / Dade® Innovin® (V. 13) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

#### **Application Sheet**

## PT INR /

## Dade® Innovin®

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14			
Release Date	2024-04			
Software Version	≥ 00-17ª			
USA only				

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order I	No.	0	rder No.	Oı	rder No.	Order No.	Name in Test Pro-
• Component(s)	Package Siz	e 1	Packag	je Size 2	Packag	e Size 3	Package Size 4	
Dade® Innovin®	<b>REF</b> B4212-	41	REF B	4212-51	REF B42	212-101		
	10 × → 4	mL	10 × →	10 mL	12 × →	20 mL		PT INN
Ci-Trol CONTROL 1	<b>REF</b> B4244	10						
	20 × → 1	mL						n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244	20						
	20 × → 1	mL						n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244	30						
	20 × → 1	mL						n/a
CONTROL N	<b>REF</b> ORKE	45						
	10 × → 1	mL						n/a
CA CLEAN I	<b>REF</b> 964-063	1-3						
	1 × 50	mL						Clean I
BC Vial Kit (empty vials for 5 mL)	<b>REF</b> OVKE	03						
	10 p	cs.						n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Dade® Innovin®	1 <sup>b</sup>	_	24
Ci-Trol CONTROL 1	Any position on sample rack	_	n/a
Ci-Trol CONTROL 2	Any position on sample rack	_	n/a
Ci-Trol CONTROL 3	Any position on sample rack	_	n/a
CONTROL N	Any position on sample rack	_	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	300
Hemoglobin	1 000
Bilirubin	60

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#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	rc
PT INR / Dade® Innovin® on CA-6000	$y = 1.08 \times -0.09^{d}$	0.999

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

< 5 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	0.9	1.6	1.8
CONTROL	0.4	0.2	0.4

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

#### **Expected Values**

Not applicable.

### **Bibliography**

Refer to the Instructions for Use of the reagent.

d no unit (INR)

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	PT STD-Link	No
Manage. ID <sup>e</sup>	5110	
Detector	for PT INN	
End Point	50 %	
Maximum Time	100 sec	
Sensitivity	Low Gain	
Sample Vol	50 μL	
Dil.Vol	******* 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0
2nd Dil		
D.Samp Vol	0 μL	
Dil.Vol	******* 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0
Reagent 1	180 sec	
Reag. Vol	PT INN 100 μL	
Pre. Rinse	*****	x 0
Post. Rinse	Clean I	x 1
Reagent 2	0 sec	
Reag. Vol	****** 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0
Reagent 3	0 sec	
Reag. Vol	****** 0 μL	
Pre. Rinse	*****	x 0
Post. Rinse	*****	x 0

Standard Curve Calibration
Calibration Parameter 3

Standard Curve - Select Param.

Param.	PT-INR
Units	_
Number Format	XX.XX
Curve Fit	ISI Input

Standard Curve – Manual Entry – **Next** (if applicable)

Enter the Normal seconds = MNPT and the ISI.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	PT-INR

#### **Number of Replicates**

Special Menu – Settings – **Analysis Settings** 

Ŀ	- Set Replication	Replicates	1	

#### Remarks

System specific MNPT and ISI have to be used.

The mean normal PT (MNPT) is defined as the mean value of the normal range. Follow the appropriate CLSI guideline for establishing an MNPT.

ISI values for prothrombin time must be entered directly as they appear on the lot-specific table of ISI values. Any changes of the reagent lot, software (upgrades), major service, etc., require verification of the ISI value. Failure to enter the correct ISI value will cause incorrect International Normalization Ratio (INR) results.

As an alternative protocol it is admitted to extend the Maximum Time to 300 seconds if long coagulation times are expected.

For further information, please refer to the Instruction for Use of the reagent.

RxOnly

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

PT INR / Dade® Innovin® (V. 14) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

#### **Application Sheet**

# Derived Fibrinogen / Dade® Innovin®

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	16		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Or	der No.	0	rder No.	0	rder No.	Order No.	Name in Test Pro-
• Component(s)	Packag	e Size 1	Packag	ge Size 2	Packag	je Size 3	Package Size 4	tocol
Dade® Innovin®	REF B4	1212-41	<b>REF</b> B	4212-51	REF B4	212-101		
	10 × →	4 mL	10 × →	10 mL	12 × →	20 mL		PT INN
Ci-Trol CONTROL 2	REF B4	1244-20						
	20 × →	1 mL						n/a
CA CLEAN I	<b>REF</b> 964	-0631-3						
	1 ×	50 mL						Clean I
BC Vial Kit (empty vials for 5 mL)	REF	OVKE03						
		10 pcs.						n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials.

The required controls have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Dade® Innovin®	1 <sup>b</sup>	-	24
Ci-Trol CONTROL 2	Any position on sample rack	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	n/a <sup>c</sup>
Hemoglobin	100
Bilirubin	36

Turbid samples are not suitable for Derived Fibrinogen determinations, as they may lead to abnormally low values. Interference of turbid samples may occur even if triglyceride concentrations are within the normal range. Any questionable result should be followed up with a more definitive quantitative method.

#### Limitations

Blood plasma substitutes that contain hydroxyethyl starch (HES) may interfere with the analysis. In a study with a HES solution (130/0.4) no interference was observed up to 3 q HES per liter plasma.

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

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#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> <sup>d</sup>
Fibrinogen / Dade® Thrombin Reagent on CA-500 series	$y = 1.25 \times -0.58 \text{ g/L}$	0.857

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Within-Device CV) on the same lot of control plasma should be as follows:

< 10 %

	Mean	Repeatability CV	Within- Device/Lab CV
	(g/L)	(%)	(%)
Ci-Trol CONTROL 2	2.7	2.9	3.3
Normal plasma pool	3.0	2.4	4.1

#### Measuring Range

Results within the measuring range/reference interval can be directly reported. Results outside the measuring range should be re-measured with a standard fibrinogen determination method (e.g., Fibrinogen with Dade® Thrombin Reagent or Fibrinogen with Multifibren® U).

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	(g/L)	(g/L)	(g/L)
_	123	2.9	2.8	2.0 – 4.2

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

#### Bibliography

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	PT	STD-Link	No
Manage. ID <sup>e</sup>	5110		
Detector	for PT INN		-
End Point		50 %	
Maximum Time		100 sec	
Sensitivity	Low G	ain	
Sample Vol		50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		180 sec	
Reag. Vol	PT INN	100 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

**Standard Curve Calibration** 

#### Important!

The recommendation for the Number Format in Calibration Parameter differs from the information that is given in the Instructions for Use of the analyzer. Please check your Host System for correct interpretation of transmitted results whenever the Number Format will be changed.

#### **Calibration Parameter 4**

Standard Curve - Select Param.

Param.	dFbg
Units	g/L or mg/dL
Number Format	XXX.X or XXXX
Curve Fit	_

Standard Curve – Manual Entry – **Next** (if applicable)

Enter the Derived Fibrinogen g/L or mg/dL concentrations and the dH of the Master Curve specified in the "Table of Assigned Values" of the specific Lot of the reagent used for the analyzer.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	dFbg

#### **Number of Replicates**

Special Menu – Settings – **Analysis Settings** 

- Set Replication	Replicates	1
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## **Standard Curve (example only)**

Verify the standard curve with the master curve provided with the PT reagent after each change of the reagent lot, and modify the standard curve if necessary.

#### dFbg

(g/L)	(dH)
2.0	43
4.2	84

Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg/Germany RxOnly

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

<u>Derived Fibrinogen / Dade® Innovin®</u> (V. 16) Page 4 of 4 Reference Guide CA-600 series APTT

Reference Guide



APTT CA-600 series

Reference Guide

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#### **Application Sheet**

## APTT /

## Dade® Actin® Activated Cephaloplastin Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14	
Release Date	2024-04	
Software Version	≥ 00-17ª	
USA only		

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
ACTIN	<b>REF</b> B4218-1	<b>REF</b> B4218-2		
	10 × 2 mL	10 × 10 mL		PTT ACT
Ci-Trol CONTROL 1	<b>REF</b> B4244-10			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244-20			
	20 × → 1 mL			n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244-30			
	20 × → 1 mL			n/a
CONTROL	REF ORKE45			
	10 × → 1 mL			n/a
CaCl <sub>2</sub> SOLUTION	REF ORHO37			
	10 × 15 mL			CaCl2
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a
BC Vial Kit (empty vials for 15 mL)	REF OVKE05			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
ACTIN	2 <sup>b</sup>	-	48
	any non-cooled reagent position	_	24
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
Ci-Trol CONTROL 2	Any position on sample rack	_	n/a
Ci-Trol CONTROL 3	Any position on sample rack	_	n/a
CONTROL N	Any position on sample rack	_	n/a
CaCl <sub>2</sub> SOLUTION	7 <sup>c</sup>	-	48
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

<sup>&</sup>lt;sup>b</sup> Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

Page 2 of 4

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	337
Hemoglobin	40
Bilirubin	12

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> <sup>d</sup>
APTT / Dade® Actin® Activated Cephaloplastin Reagent on CA-6000	$y = 1.00 \times -0.20 \text{ s}$	0.982

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	0.6	1.3	1.4
CONTROL N	1.0	3.4	3.5

#### Measuring Range

Refer to the Instructions for Use of the analyzer for additional information.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile
Comments	n	(s)	(s)	(s)
_	111	25.7	25.6	21.4 – 30.6

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

#### **Bibliography**

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	APTT	STD-Link	No
Manage. ID <sup>e</sup>	5200		
Detector	for PTT ACT		
End Point		50 %	
Maximum Time		190 sec	
Sensitivity	Low G	ain	
Sample Vol		50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		60 sec	
Reag. Vol	PTT ACT	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		240 sec	
Reag. Vol	CaCl2	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

#### **Data Check**

Special Menu – Settings – **Data Check** 

– Mark Limits	Select Param.	APTT

#### **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

Special Menu – Settings – **Analysis Settings** 

- Set Replication	Replicates	1	ı
- set kepiication	neplicates		1

APTT / Dade® Actin® Activated Cephaloplastin Reagent (V. 14) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

## **Application Sheet**

## APTT /

## Dade® Actin® FS Activated PTT Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14			
Release Date	2024-04			
Software Version	≥ 00-17 <sup>a</sup>			
USA only				

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

## **Materials Required**

Product	Order No	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
ACTIN FS	<b>REF</b> B4218-20	<b>REF</b> B4218-100		
	10 × 2 ml	. 10 × 10 mL		PTT FS
Ci-Trol CONTROL 1	<b>REF</b> B4244-10			
	20 × → 1 ml			n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244-20	1		
	20 × → 1 ml	-		n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244-30			
	20 × → 1 ml			n/a
CONTROL N	REF ORKE45			
	10 × → 1 ml	-		n/a
CaCl <sub>2</sub> SOLUTION	REF ORHO37			
	10 × 15 ml			CaCl2
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 ml	-		Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKEO			
	10 pcs			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials.

The required controls have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
ACTIN FS	2 <sup>b</sup>	_	48
	any non-cooled reagent position	_	24
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
Ci-Trol CONTROL 2	Any position on sample rack	_	n/a
Ci-Trol CONTROL 3	Any position on sample rack	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CaCl <sub>2</sub> SOLUTION	7 <sup>c</sup>	-	48
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

b Alternatively, any other cooled reagent position can be used.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

Page 2 of 4 Reference Guide

## Interference Studies

No interferences up to	(mg/dL)
Triglycerides	331
Hemoglobin	1 000
Bilirubin	6

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

## **Method Comparison**

Predicate Device	Regression Equation	r <sup>d</sup>
APTT / Dade® Actin® FS Activated PTT Reagent on CA-6000	$y = 1.00 \times + 0.10 \text{ s}$	0.983

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	0.3	1.5	1.5
CONTROL N	0.5	0.2	0.5

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile	
Comments	n	(s)	(s)	(s)	
_	111	24.8	24.6	21.8 – 28.0	

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

## **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	APTT	STD-Link	No
Manage. ID <sup>e</sup>	5210		
Detector	for PTT FS		
End Point	50	O %	
Maximum Time	190	O sec	
Sensitivity	Low Gain		
Sample Vol	50	D μL	
Dil.Vol	******	O μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		O μL	
Dil.Vol	******	O μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	60	O sec	
Reag. Vol	PTT FS 50	O μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	240	O sec	
Reag. Vol	CaCl2 50	) μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	(	O sec	
Reag. Vol	******	Ο μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – **Data Check** 

– Mark Limits	Select Param.	APTT

## **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

- Set Replication	Replicates	1	ı
oct itcpiication	ricpiicates	'	

 $\frac{\textit{APTT / Dade} \$ \; \textit{Actin} \$ \; \textit{FS Activated PTT Reagent (V. 14)}}{\text{Page 4 of 4}}$ Reference Guide Reference Guide Page 1 of 4

## **Application Sheet**

## APTT /

## Dade® Actin® FSL Activated PTT Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

## **Materials Required**

Product	Order l	No.	Order No	<b>)</b> .	Order No.	Order No.	Name in Test Pro-
• Component(s)	Package Siz	e 1	Package Size	2	Package Size 3	Package Size 4	tocol
ACTIN FSL	<b>REF</b> B421	9-1	<b>REF</b> B4219-	2			
	10 × 2	mL	10 × 10 m	ıL			PTT FSL
Ci-Trol CONTROL 1	<b>REF</b> B4244	-10					
	20 × → 1	mL					n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244	-20					
	20 × → 1	mL					n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244	-30					
	20 × → 1	mL					n/a
CONTROL	<b>REF</b> ORKE	45					
	10 × → 1	mL					n/a
CaCl <sub>2</sub> SOLUTION	REF ORHO	)37					
	10 × 15	mL					CaCl2
CA CLEAN I	<b>REF</b> 964-063	1-3					
	1 × 50	mL					Clean I
BC Vial Kit (empty vials for 5 mL)	<b>REF</b> OVK	<del>-</del> 03					
	10 բ	ocs.					n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials.

The required controls have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
ACTIN FSL	2 <sup>b</sup>	-	48
	any non-cooled reagent position	_	24
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
Ci-Trol CONTROL 2	Any position on sample rack	_	n/a
Ci-Trol CONTROL 3	Any position on sample rack	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CaCl <sub>2</sub> SOLUTION	7 <sup>c</sup>	_	48
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

b Alternatively, any other cooled reagent position can be used.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

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## Interference Studies

No interferences up to	(mg/dL)
Triglycerides	331
Hemoglobin	200
Bilirubin	12

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

## **Method Comparison**

Predicate Device	<b>Regression Equation</b>	r <sup>d</sup>
APTT / Dade® Actin® FSL Activated PTT Reagent on CA-6000	$y = 1.00 \times + 0.10 \text{ s}$	0.990

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 3	0.4	1.4	1.5
CONTROL N	0.4	0.2	0.4

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

## **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile
Comments	n	(s)	(s)	(s)
_	111	27 9	27.7	24 5 - 32 8

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	APTT	STD-Link	No
Manage. ID <sup>e</sup>	5220		
Detector	for PTT FSL		
End Point	50	%	
Maximum Time	190	sec	
Sensitivity	Low Gain		
Sample Vol	50	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol	0	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	60	sec	
Reag. Vol	PTT FSL 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	240	sec	
Reag. Vol	CaCl2 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	0	sec	
Reag. Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	APTT

## **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
-------------------	------------	---

#### Remarks

As an alternative protocol it is admitted to extend the Maximum Time to 300 seconds if long coagulation times are expected.

According to troubleshooting instructions (CA series Measurement Evaluation and Check Methods), the Maximum Time can be extended to 600 seconds, if an Analysis Time Over error still persists with the measurement.

 $\frac{\textit{APTT / Dade}^{\$} \; \textit{Actin}^{\$} \; \textit{FSL Activated PTT Reagent (V. 14)}}{\text{Page 4 of 4}}$ Reference Guide Reference Guide Page 1 of 4

## **Application Sheet**

## APTT /

## **Pathromtin® SL**

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	15		
Release Date	2024-04		
Software Version	≥ 00-17 <sup>a</sup>		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

## **Materials Required**

Product	Order N	o. Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size	1 Package Size 2	Package Size 3	Package Size 4 tocol
Pathromtin® SL	REF OQGS2	9 <b>REF</b> OQGS35		
	10 × 5 n	nL 20 × 5 mL		PTT PSL
Ci-Trol CONTROL 1	<b>REF</b> B4244-1	0		
	20 × → 1 n	nL		n/a
Ci-Trol CONTROL 2	<b>REF</b> B4244-2	0		
	20 × → 1 n	nL		n/a
Ci-Trol CONTROL 3	<b>REF</b> B4244-3	0		
	20 × → 1 n	nL		n/a
CONTROL	REF ORKE4	5		
	10 × → 1 n	nL		n/a
CaCl <sub>2</sub> SOLUTION	REF ORHO	7		
	10 × 15 n	nL		CaCl2
CA CLEAN I	<b>REF</b> 964-0631	3		
	1 × 50 n	nL		Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKEO	3		
	10 pc	S.		n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls have to be transferred into appropriate sample cups.

The reagent must be gently inverted (5 to 8 times) to mix before first use.

## **On-board Stability**

Component	Position	Condition	Time (h)
Pathromtin® SL	2 <sup>b</sup>	-	48
	any non-cooled reagent position	_	24
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
Ci-Trol CONTROL 2	Any position on sample rack	_	n/a
Ci-Trol CONTROL 3	Any position on sample rack	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CaCl <sub>2</sub> SOLUTION	7 <sup>c</sup>	-	48
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

b Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

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## Interference Studies

No interferences up to	(mg/dL)
Triglycerides	378
Hemoglobin	200
Bilirubin	2.4

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

## **Method Comparison**

Predicate Device	Regression Equation	r <sup>d</sup>
APTT / Pathromtin® SL on CA-6000	$y = 0.99 \times -1.10 \text{ s}$	0.968

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 1	0.6	1.2	1.3
Ci-Trol CONTROL 2	0.9	2.4	2.5

## **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

## **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile
Comments	n	(s)	(s)	(s)
_	110	34 1	33.8	29.0 - 40.2

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

## **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	APTT	STD-Link	No
Manage. ID <sup>e</sup>	5230		
Detector	for PTT PSL		
End Point		50 %	
Maximum Time		190 sec	
Sensitivity	Low Ga	in	
Sample Vol		50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		30 sec	
Reag. Vol	PTT PSL	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		150 sec	
Reag. Vol	CaCl2	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – **Data Check** 

- Mark Limits	Select Param.	APTT

## **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

- Set Replication	Replicates	1	ı
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APTT / Pathromtin® SL (V. 15) Page 4 of 4 Reference Guide CA-600 series Fibrinogen

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Fibrinogen CA-600 series

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## **Application Sheet**

## Fibrinogen / Multifibren® U

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	15	
Release Date	2024-04	
Software Version	≥ 00-17ª	
USA only		

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

## **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
Multifibren® U	REF OWZG19	REF OWZG23		
	10 × → 2 mL	10 × → 5 mL		Fbg MFU
FIBRINOGEN CALIBRATOR	REF OQVK11			
• CALIBRATOR 1 b	1 × → 1 mL			Calibrator 1
• CALIBRATOR 2	1 × → 1 mL			Calibrator 2
• CALIBRATOR 3	1 × → 1 mL			Calibrator 3
• CALIBRATOR 4	1 × → 1 mL			Calibrator 4
• CALIBRATOR 5	1 × → 1 mL			Calibrator 5
• CALIBRATOR 6	1 × → 1 mL			Calibrator 6
Ci-Trol CONTROL 1	<b>REF</b> B4244-10			
	20 × → 1 mL			n/a
CONTROL	REF ORKE45			
	10 × → 1 mL			n/a
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I

b **CALIBRATOR** 1 is not used in this test.

#### **Additional Notes**

The required controls and calibrators have to be transferred into appropriate sample cups.

CA CLEAN I has to be transferred into an appropriate vial.

## **On-board Stability**

Component	Position	Condition	Time (h)
Multifibren® U	3°	-	24
CALIBRATOR 1	n/a <sup>d</sup>	-	n/a
CALIBRATOR 2	#1	_	n/a
CALIBRATOR 3	#2	-	n/a
CALIBRATOR 4	#3	_	n/a
CALIBRATOR 5	#4	-	n/a
CALIBRATOR 6	#5	_	n/a
Ci-Trol CONTROL 1	Any position on sample rack	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

<sup>&</sup>lt;sup>c</sup> Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

CALIBRATOR 1 is not used in this test.

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## Interference Studies

No interferences up to	(mg/dL)
Triglycerides	284
Hemoglobin	800
Bilirubin	36

#### Limitations

Blood plasma substitutes that contain hydroxyethyl starch (HES) may interfere with the analysis. In a study with a HES solution (130/0.4) no interference was observed up to 3 g HES per liter plasma.

## **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

## **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> e
Fibrinogen / Multifibren® U on BCT	$y = 1.01 \times -0.28 \text{ g/L}$	0.973

e r = Correlation Coefficient

#### **Precision**

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 10 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL	4.5	3.1	5.3
Pathological plasma pool low	3.5	1.4	3.6

#### Measuring Range

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile
Comments	n	(g/L)	(g/L)	(g/L)
_	124	2.6	2.6	1.9 – 3.5

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## **Bibliography**

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	Fbg	STD-Link	No
Manage. ID <sup>f</sup>	5360		
Detector	for Fbg		
End Point		30 %	
Maximum Time		100 sec	
Sensitivity	Low G	iain	
Sample Vol		100 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		60 sec	
Reag. Vol	Fbg MFU	100 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

f The Management ID only applies to the CA-600 series.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.		Fbg.C	
– Report Limits	lower (<)	1.1 g/L	or	110 mg/dL
	upper (>)	8.0 g/L	or	800 mg/dL

## **Standard Curve Calibration**

#### Important!

The recommendation for the Number Format in Calibration Parameter differs from the information that is given in the Instructions for Use of the analyzer. Please check your Host System for correct interpretation of transmitted results whenever the Number Format will be changed.

#### **Calibration Parameter 1**

Standard Curve - Select Param.

Param.	Fbg.C
Units	g/L or mg/dL
Number Format	XXX.X or XXXX
Curve Fit	Log Curve

#### Standard Curve - Standard Analysis

Select Dilution Set	М
Calibrator	Fib. Calibrator Kit

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	Calibrator 2	2
Calib. or Dil.Ratio 2	Calibrator 3	2
Calib. or Dil.Ratio 3	Calibrator 4	2
Calib. or Dil.Ratio 4	Calibrator 5	2
Calib. or Dil.Ratio 5	Calibrator 6	2
Calib. or Dil.Ratio 6	_	_

## **Number of Replicates**

Special Menu – Settings – **Analysis Settings** 

- Set Replication	Replicates	1

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

Fbg.C

(g/L)	(s)
8.0	7.3
5.4	8.5
3.5	11.4
2.4	14.4
1.1	25.6

#### Remarks

**CALIBRATOR** 1 is not used in this test.

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Reference Guide Page 1 of 6

## **Application Sheet**

# Fibrinogen / Dade® Thrombin Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14	
Release Date	2024-04	
Software Version	≥ 00-17ª	
USA only		

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

## **Materials Required**

Product	Order No.	Order No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4	tocol
THROMBIN REAGENT	<b>REF</b> B4233-25	<b>REF</b> B4233-27			
	10 × → 1 mL	10 × → 5 mL			Fbg
FIBRINOGEN DETERMINATION	<b>REF</b> B4233-17SY				
• THROMBIN REAGENT	6 × 1 mL				Fbg
• FIBRINOGEN STANDARD	1 × → 1 mL				n/a
• OV BUFFER	3 × 15 mL				OVB
Ci-Trol CONTROL 1	<b>REF</b> B4244-10				
	20 × → 1 mL				n/a
CONTROL P	REF OUPZ19				
	10 × → 1 mL				n/a
Data-Fi FIBRINOGEN CONTROL	<b>REF</b> B4233-22				
	10 × → 1 mL				n/a
STANDARD PLASMA	REF ORKL19				
	10 × → 1 mL				SHP
CA SYSTEM BUFFER	<b>REF</b> B4265-37				
	8 × 250 mL				OVB
OV BUFFER	<b>REF</b> B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	<b>REF</b> 964-0631-3				
	1 × 50 mL				Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03				
	10 pcs.				n/a

## **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
THROMBIN REAGENT	3 <sup>b</sup>	_	24
THROMBIN REAGENT	Any position on reagent rack	-	24
FIBRINOGEN STANDARD	#1	_	n/a
OV BUFFER	Buffer position 12	GW 5; SLD Vial	8
Ci-Trol CONTROL 1	Any position on sample rack	_	n/a
CONTROL P	Any position on sample rack	-	n/a
Data-Fi FIBRINOGEN CONTROL	Any position on sample rack	_	n/a
STANDARD PLASMA	#1	-	n/a

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Component	Position	Condition	Time (h)
CA SYSTEM BUFFER	Buffer position 12	GW 5; SLD Vial <sup>c</sup>	8
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	341
Hemoglobin	1 000
Bilirubin	48

#### Limitations

If samples are measured in a 1:5 dilution, any presence of elevated triglycerides or any other turbidity in the sample may interfere the analysis.

#### Performance Characteristics

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> <sup>d</sup>
Fibrinogen / Dade® Thrombin Reagent on CA-1500	$y = 1.05 \times + 0.04 \text{ g/L}$	0.974

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 10 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
Ci-Trol CONTROL 1	1.9	4.1	4.6
Data-Fi FIBRINOGEN CONTROL	3.8	3.0	4.8

#### Measuring Range

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile
Comments	n	(g/L)	(g/L)	(g/L)
-	123	2.73	2.70	2.10 – 3.58

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

For positioning on the analyzer, the buffer has to be transferred into an appropriate vial.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	Fbg	STD-Link	Master
Manage. ID <sup>e</sup>	5300		
Detector	for Fbg		
End Point	[	60 %	
Maximum Time	10	00 sec	
Sensitivity	High Gain		
Sample Vol	1	0 μL	
Dil.Vol	OVB 9	00 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	6	60 sec	
Reag. Vol	Fbg 5	60 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

#### **Data Check**

All samples exceeding the mentioned report limits should be repeated using the appropriate +Fbg or -Fbg setting again. The redilution has to be requested manually.

Special Menu - Settings - Data Check

– Mark Limits	Select Param.		Fbg.C	
– Report Limits	lower (<)	1.00 g/L	or	100 mg/dL
	upper (>)	4.50 g/L	or	450 mg/dL

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### Fbg.C

•	
(g/L)	(s)
5.20	5.5
3.90	6.7
2.60	9.6
1.30	19.2
0.87	34.1

## **Standard Curve Calibration**

#### Important!

The recommendation for the Number Format in Calibration Parameter differs from the information that is given in the Instructions for Use of the analyzer. Please check your Host System for correct interpretation of transmitted results whenever the Number Format will be changed.

#### **Calibration Parameter 1**

Standard Curve - Select Param.

Param.	Fbg.C
Units	g/L or mg/dL
Number Format	XX.XX or XXXX
Curve Fit	Log Curve

#### Standard Curve - Standard Analysis

Select Dilution Set	9
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	2/1	2
Calib. or Dil.Ratio 2	3/2	2
Calib. or Dil.Ratio 3	1/1	2
Calib. or Dil.Ratio 4	1/2	2
Calib. or Dil.Ratio 5	1/3	2
Calib. or Dil.Ratio 6	0/1	0

## **Number of Replicates**

- Set Replication	Replicates	1
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## **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	+Fbg	STD-Link	Fbg
Manage. ID <sup>f</sup>	5310		'
Detector	for Fbg		
End Point		50 %	
Maximum Time		100 sec	
Sensitivity	High G	ain	
Sample Vol		5 μL	
Dil.Vol	OVB	95 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		60 sec	
Reag. Vol	Fbg	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>f</sup> The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – **Data Check** 

- Mark Limits	Select Param.		+Fbg	
– Report Limits	lower (<)	1.80 g/L	or	180 mg/dL
	upper (>)	9.00 g/L	or	900 mg/dL

## **Standard Curve Calibration**

Not applicable - Standard curve created with "Fbg" will be used automatically. For more information refer to the Instructions for Use of the Analyzer.

## **Number of Replicates**

<ul> <li>Set Replication</li> </ul>	Replicates	1

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## **Test Protocol**

Special Menu – Settings – Analysis Settings – **Test Protocol** 

Test Protocol Name	-Fbg	STD-Link	Fbg
Manage. ID <sup>g</sup>	5320		
Detector	for Fbg		
End Point		50 %	
Maximum Time		100 sec	
Sensitivity	High Gair	1	
Sample Vol		20 μL	
Dil.Vol	OVB	80 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		60 sec	
Reag. Vol	Fbg	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

 $<sup>^{\</sup>rm g}~$  The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.		-Fbg	
- Report Limits	lower (<)	0.50 g/L	or	50 mg/dL
	upper (>)	2.50 g/L	or	250 mg/dL

## **Standard Curve Calibration**

Not applicable - Standard curve created with "Fbg" will be used automatically. For more information refer to the Instructions for Use of the Analyzer.

## **Number of Replicates**

- Set Replication	Replicates	1
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Fibrinogen / Dade® Thrombin Reagent (V. 14) Page 6 of 6 Reference Guide Reference Guide

# ■ Thrombin Time/Batroxobin Time

Reference Guide

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## **Application Sheet**

# Thrombin time / Test Thrombin Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	14
Release Date	2025-08
Software Version	≥ 00-17ª
USA only	

<sup>&</sup>lt;sup>a</sup> CA-620,

## **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
TEST THROMBIN	REF OWHM13			
• TEST THROMBIN REAGENT	10 × → 5 mL			TestThr
TEST THROMBIN REAGENT DILUENT	1 × 50 mL			n/a
CONTROL N	REF ORKE45			
	10 × → 1 mL			n/a
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls have to be transferred into appropriate sample cups.

The controls are manufacturer unassigned and are to be used for verifying the normal range.

Each laboratory must establish its own control range by following their internal guidance.

Ensure trueness of results by referring to analyzer specific reference interval.

#### Limitations

If the Thrombin Time is longer than the reference interval, determine the fibrinogen concentration. Report Thrombin Time if the fibrinogen concentration is below or equal to 7 g/L. Do not report the Thrombin Time if the fibrinogen concentration is higher than 7 g/L.

## **On-board Stability**

Component	Position	Condition	Time (h)
TEST THROMBIN REAGENT	2 <sup>b</sup>	-	24
TEST THROMBIN REAGENT DILUENT	n/a	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	341
Hemoglobin	20
Bilirubin	24

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## **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

## **Method Comparison**

Predicate Device	Regression Equation	rc
TT / Test Thrombin Reagent on BFA	$y = 0.56 \times + 5.69 \text{ s}$	0.946

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 10 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL N	6.2	3.9	7.0

## **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

## **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	(s)	(s)	(s)
_	180	17.8	17.9	16.1 – 19.5

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

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## **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	TT	STD-Link	No
Manage. ID <sup>d</sup>	5330		
Detector	for TT		
End Point		50 %	
Maximum Time		100 sec	
Sensitivity	Low Gain		
Sample Vol		50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		60 sec	
Reag. Vol	TestThr -	100 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

 $<sup>^{\</sup>rm d}~$  The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – **Data Check** 

– Mark Limits	Select Param.	TT

## **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

- Set Replication	Replicates	1	ı
- set kepiication	neplicates		1

Thrombin time / Test Thrombin Reagent (V. 14) Page 4 of 4 Reference Guide Reference Guide Page 1 of 4

## **Application Sheet**

# Batroxobin time / Batroxobin Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	12		
Release Date	2024-04		
Software Version	≥ 00-17ª		
USA only			

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

## **Materials Required**

Product	Order No.	Order No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4	
Batroxobin REAGENT	REF OUOV21				
	2 × → 5 mL				Batrox
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	<b>REF</b> 964-0631-3				
	1 × 50 mL				Clean I

## **Additional Notes**

The required controls have to be transferred into appropriate sample cups.

CA CLEAN I has to be transferred into an appropriate vial.

## **On-board Stability**

Component	Position	Condition	Time (h)
Batroxobin REAGENT	<b>4</b> <sup>b</sup>	-	48
CONTROL	Any position on sample rack	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

<sup>&</sup>lt;sup>b</sup> Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	600
Hemoglobin	1 000
Bilirubin	12

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

## **Method Comparison**

Predicate Device	Regression Equation	rc
Batroxobin time / Batroxobin Reagent on BCT	$y = 0.77 \times + 5.66 \text{ s}$	0.984

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 10%

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	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL	1.0	1.2	1.5
Pathological plasma pool	1.9	0.7	1.9

#### **Measuring Range**

Refer to the Instructions for Use of the analyzer for additional information.

## **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	5 <sup>th</sup> to 95 <sup>th</sup> percentile
Comments	n	(s)	(s)	(s)
_	66	17.6	17.6	16.7 – 18.9

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

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## **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	BXT	STD-Link	No
Manage. ID <sup>d</sup>	5350		
Detector	for BXT		
End Point		50 %	
Maximum Time		100 sec	
Sensitivity	Low Gai	n	
Sample Vol		50 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil		-	
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		60 sec	
Reag. Vol	Batrox	100 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

<sup>&</sup>lt;sup>d</sup> The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – **Data Check** 

<ul><li>Mark Limits</li></ul>	Select Param.	BXT

## **Standard Curve Calibration**

The assay is not calibrated.

## **Number of Replicates**

- Set Replication	Replicates	1	ı
oct itcpiication	ricpiicates	'	

Batroxobin time / Batroxobin Reagent (V. 12) Page 4 of 4 Reference Guide CA-600 series Clotting Assays

Reference Guide

# Clotting Assays

Clotting Assays CA-600 series

Reference Guide

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#### **Application Sheet**

# Coagulation Factor VII / Dade® Innovin®

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	13	
Release Date	2024-04	
Software Version	≥ 00-17ª	
USA only		

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

### **Materials Required**

Product	Or	der No.	0	rder No.	0	rder No.	Order No.	Name in Test Pro-
• Component(s)	Packag	e Size 1	Packag	je Size 2	Packag	ge Size 3	Package Size 4	
FACTOR VII DEFICIENT	REF	OTXV13						
	3 × <b>→</b>	1 mL						VII
Dade® Innovin®	REF B4	1212-41	<b>REF</b> B	4212-51	REF B4	212-101		
	10 × →	4 mL	10 × →	10 mL	12 × →	20 mL		PT INN
STANDARD PLASMA	REF	ORKL19						
	10 × →	1 mL						SHP
CONTROL N	REF	ORKE45						
	10 × →	1 mL						n/a
CONTROL P	REF	OUPZ19						
	10 × →	1 mL						n/a
CA SYSTEM BUFFER	REF B4	1265-37						
	8 ×	250 mL						OVB
OV BUFFER	REF B4	1234-25						
	10 ×	15 mL						OVB
CA CLEAN I	<b>REF</b> 964	-0631-3						
	1 ×	50 mL						Clean I
BC Vial Kit (empty vials for 5 mL)	REF	OVKE03						
		10 pcs.						n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
FACTOR VII DEFICIENT	6 <sup>b</sup>	-	8
Dade® Innovin®	1 <sup>c</sup>	-	24
STANDARD PLASMA	#1	-	n/a
CONTROL	Any position on sample rack	-	n/a
CONTROL P	Any position on sample rack	_	n/a
CA SYSTEM BUFFER	Buffer position 12	-	n/a
OV BUFFER	Buffer position 12	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

<sup>&</sup>lt;sup>b</sup> Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

<sup>&</sup>lt;sup>c</sup> Alternatively, any other cooled reagent position can be used.

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The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	3 000
Hemoglobin	1000
Bilirubin	36

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	r <sup>d</sup>
Coagulation Factor VII / Thromborel® S on BCT	$y = 0.97 \times -1.55 \%$ of Norm	0.976

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows:

< 15 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL N	5.0	1.3	4.9
CONTROL P	3.9	1.8	4.1

#### Measuring Range

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

Refer to the FACTOR VII DEFICIENT Instructions for Use.

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	VII	STD-Link	No
Manage. ID <sup>e</sup>	5410		
Detector	for F-Ext <sup>f</sup>		
End Point	50	%	
Maximum Time	100	sec	
Sensitivity	Low Gain		
Sample Vol	5	μL	
Dil.Vol	OVB 45	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol	0	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	30	sec	
Reag. Vol	VII 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	90	sec	
Reag. Vol	PT INN 100	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	0	sec	
Reag. Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

Standard Curve Calibration
Calibration Parameter 1

Standard Curve - Select Param.

Param.	VII %
Units	%
Number Format	XXX.X
Curve Fit	Log Curve

#### Standard Curve - Standard Analysis

Select Dilution Set	8
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	3/2	2
Calib. or Dil.Ratio 2	1/1	2
Calib. or Dil.Ratio 3	1/2	2
Calib. or Dil.Ratio 4	1/4	2
Calib. or Dil.Ratio 5	1/8	2
Calib. or Dil.Ratio 6	0/1	0

#### **Data Check**

Special Menu – Settings – **Data Check** 

– Mark Limits	Select Param.	VII %

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication Replicates 1
--------------------------------

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### VII %

(%)	(s)
139.5	17.0
93.0	20.1
46.5	26.7
23.3	36.9
11.6	54.4

#### Remarks

#### Important!

The parameters given in the Application Sheet have to be entered into the software carefully. Additionally, there are parameters which have to be entered by the service only. Please contact your local service.

The Management ID only applies to the CA-600 series.

For the CA-600 series, it is also possible to select the detector "for FExtINN".

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### **Application Sheet**

# Coagulation Factor VIII / Dade® Actin® FSL Activated PTT Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	13	
Release Date	2024-04	
Software Version	≥ 00-17ª	
USA only		

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

#### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
FACTOR VIII DEFICIENT	REF OTXW17			
	8 × → 1 mL			VIII
ACTIN FSL	<b>REF</b> B4219-1	<b>REF</b> B4219-2		
	10 × 2 mL	10 × 10 mL		PTT FSL
STANDARD PLASMA	REF ORKL19			
	10 × → 1 mL			SHP
CONTROL N	REF ORKE45			
	10 × → 1 mL			n/a
CONTROL P	REF OUPZ19			
	10 × → 1 mL			n/a
CaCl <sub>2</sub> SOLUTION	REF ORHO37			
	10 × 15 mL			CaCl2
CA SYSTEM BUFFER	<b>REF</b> B4265-37			
	8 × 250 mL			OVB
OV BUFFER	<b>REF</b> B4234-25			
	10 × 15 mL			OVB
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
FACTOR VIII DEFICIENT	8 <sup>b</sup>	-	4
ACTIN FSL	2 <sup>c</sup>	-	48
STANDARD PLASMA	#1	-	n/a
CONTROL N	Any position on sample rack	-	n/a
CONTROL P	Any position on sample rack	-	n/a
CaCl <sub>2</sub> SOLUTION	7 <sup>d</sup>	_	48
CA SYSTEM BUFFER	Buffer position 12	-	n/a

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Component	Position	Condition	Time (h)
OV BUFFER	Buffer position 12	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other non-cooled reagent position can be used.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	3 000
Hemoglobin	40
Bilirubin	24

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	re
Coagulation Factor VIII / Pathromtin® SL on BCT	$y = 1.00 \times + 3.71 \%$ of Norm	0.960

e r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 15%

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL	2.5	3.2	4.0
CONTROL P	3.2	4.2	5.2

#### **Measuring Range**

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

Refer to the **FACTOR VIII DEFICIENT** Instructions for Use.

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

#### Bibliography

Refer to the Instructions for Use of the reagent.

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

d Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	VIII	STD-Link	No
Manage. ID <sup>f</sup>	5430		
Detector	for F-Int <sup>g</sup>		
End Point	50	%	
Maximum Time	150	sec	
Sensitivity	Low Gain		
Sample Vol	5	μL	
Dil.Vol	OVB 45	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol	0	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	30	sec	
Reag. Vol	VIII 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	60	sec	
Reag. Vol	PTT FSL 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	240	sec	
Reag. Vol	CaCl2 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1

The Management ID only applies to the CA-600 series.
 For the CA-600 series, it is also possible to select the detector "for FIntACT".

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	VIII %

#### **Standard Curve Calibration**

For higher concentrations (approx. 150 to 12.5 %) select Dilution Set 8.

#### **Calibration Parameter 1**

Standard Curve - Select Param.

Param.	VIII %
Units	%
Number Format	xxx.x
Curve Fit	Log Curve

#### Standard Curve - Standard Analysis

Select Dilution Set	8
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	3/2	2
Calib. or Dil.Ratio 2	1/1	2
Calib. or Dil.Ratio 3	1/2	2
Calib. or Dil.Ratio 4	1/4	2
Calib. or Dil.Ratio 5	1/8	2
Calib. or Dil.Ratio 6	0/1	0

## **Number of Replicates**

Special Menu - Settings - Analysis Settings

- Set Replication Replicates 1
--------------------------------

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### VIII %

(%)	(s)
129.0	66.7
86.0	72.1
43.0	82.2
21.5	92.9
10.8	104.0

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	VIII	STD-Link	No
Manage. ID <sup>h</sup>	5430		<u>'</u>
Detector	for F-Int <sup>i</sup>		
End Point		50 %	
Maximum Time		150 sec	
Sensitivity	Low G	ain	
Sample Vol		5 μL	
Dil.Vol	OVB	45 µL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		0 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		30 sec	
Reag. Vol	VIII	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		60 sec	
Reag. Vol	PTT FSL	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3		240 sec	
Reag. Vol	CaCl2	50 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1

<sup>&</sup>lt;sup>h</sup> The Management ID only applies to the CA-600 series.

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	VIII %

#### **Standard Curve Calibration**

For lower concentrations (approx. 100 to 3.1 %) select Dilution Set 1.

#### **Calibration Parameter 1**

Standard Curve - Select Param.

Param.	VIII %
Units	%
Number Format	XXX.X
Curve Fit	Log Curve

#### Standard Curve – **Standard Analysis**

Select Dilution Set	1
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	1/1	2
Calib. or Dil.Ratio 2	1/2	2
Calib. or Dil.Ratio 3	1/4	2
Calib. or Dil.Ratio 4	1/8	2
Calib. or Dil.Ratio 5	1/16	2
Calib. or Dil.Ratio 6	1/32	2

### **Number of Replicates**

Special Menu – Settings – Analysis Settings

<ul> <li>Set Replication</li> </ul>	Replicates	1

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### VIII %

(%)	(s)
86.0	70.2
43.0	79.9
21.5	89.7
10.8	100.3
5.4	110.2
2.7	118.7

#### Remarks

Important!

For the CA-600 series, it is also possible to select the detector "for FIntACT".

CA-600 series

Reference Guide Page 5 of 6

The parameters given in the Application Sheet have to be entered into the software carefully. Additionally, there are parameters which have to be entered by the service only. Please contact your local service.

**RxOnly** 

Coagulation Factor VIII / Dade® Actin® FSL Activated PTT Reagent (V. 13) Page 6 of 6 Reference Guide Reference Guide Page 1 of 4

#### **Application Sheet**

## Protein C / Protein C Reagent

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

Version	13	
Release Date	2024-04	
Software Version	≥ 00-17 <sup>a</sup>	
USA only		

<sup>&</sup>lt;sup>a</sup> CA-620, CA-660

### **Materials Required**

Product	Order No.	Order No.	Order No.	Order No. Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4 tocol
PROTEIN C COAG	REF OQYG11			
PROTEIN C COAG ACTIVATOR	1 × → 3 mL			PC.A.cl
PROTEIN C COAG REAGENT APTT	1 × 10 mL			PC.APTT
PROTEIN C COAG DEFICIENT	4 × → 1 mL			PC.DefP
STANDARD PLASMA	REF ORKL19			
	10 × → 1 mL			SHP
CONTROL N	REF ORKE45			
	10 × → 1 mL			n/a
CONTROL P	REF OUPZ19			
	10 × → 1 mL			n/a
CaCl <sub>2</sub> SOLUTION	REF ORHO37			
	10 × 15 mL			CaCl2
CA CLEAN I	<b>REF</b> 964-0631-3			
	1 × 50 mL			Clean I
BC Vial Kit (empty vials for 5 mL)	REF OVKE03			
	10 pcs.			n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
PROTEIN C COAG ACTIVATOR	1 <sup>b</sup>	-	24
PROTEIN C COAG REAGENT APTT	2 <sup>b</sup>	-	24
PROTEIN C COAG DEFICIENT	10	_	6
STANDARD PLASMA	#1	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CONTROL P	Any position on sample rack	-	n/a
CaCl <sub>2</sub> SOLUTION	7 <sup>c</sup>	-	24
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

<sup>&</sup>lt;sup>b</sup> Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

<sup>&</sup>lt;sup>c</sup> Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.

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#### Interference Studies

No interferences up to	(mg/dL)
Triglycerides	3012
Hemoglobin	600
Bilirubin	36

Limitations

Hemolyzed samples are not suitable for protein C determination.

Higher levels of lipids or turbid samples can lead to falsely elevated or decreased values.

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> d
Protein C / Protein C Reagent on BCT (coagulometric)	$y = 1.01 \times + 3.60 \%$ of Norm	0.989

d r = Correlation Coefficient

#### **Precision**

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 15 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL	1.9	4.3	4.7
CONTROL P	2.5	4.5	5.1

#### Measuring Range

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

Refer to the Instructions for Use of the reagent.

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	PCcl	STD-Link	No
Manage. ID <sup>e</sup>	5500		
Detector	for PCc		
End Point	50	%	
Maximum Time	300	sec	
Sensitivity	Low Gain		
Sample Vol	5	μL	
Dil.Vol	PC.DefP 45	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol	0	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	30	sec	
Reag. Vol	PC.A.cl 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	60	sec	
Reag. Vol	PC.APTT 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	300	sec	
Reag. Vol	CaCl2 50	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1

Standard Curve Calibration
Calibration Parameter 1

Standard Curve - Select Param.

Param.	PC.cl %
Units	%
Number Format	XXX.X
Curve Fit	Lin-Lin

#### Standard Curve - Standard Analysis

Select Dilution Set	8
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	3/2	2
Calib. or Dil.Ratio 2	1/1	2
Calib. or Dil.Ratio 3	1/2	2
Calib. or Dil.Ratio 4	1/4	2
Calib. or Dil.Ratio 5	1/8	2
Calib. or Dil.Ratio 6	0/1	2

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	PC.cl %
	50.000. 0.0	1 616. /6

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
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## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### PC.cl%

(%)	(s)
148.5	115.5
99.0	91.7
49.5	66.8
24.8	50.0
12.4	41.3
0.0	34.3

Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg/Germany RxOnly

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

Protein C / Protein C Reagent (V. 13)
Page 4 of 4 Reference Guide CA-600 series Chromogenic Assays

Reference Guide

## Chromogenic Assays

Chromogenic Assays CA-600 series

Reference Guide

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### **Application Sheet**

# Antithrombin / INNOVANCE® Antithrombin

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system;
other combinations are not validated or supported by Siemens Healthineers.

Version	09		
Release Date	2025-03		
Software Version	≥ 00-17ª		
USA only			

CA-660

## **Materials Required**

Product	0	rder No.	(	Order No.		Order No.	Order No.	Name in Test Pro-
Component(s)	Packag	je Size 1	Packa	ige Size 2	Pack	age Size 3	Package Size 4	tocol
INNOVANCE® Antithrombin	REF	OPFH07	REI	OPFH09	RE	F OPFH11		
• INNOVANCE Antithrombin REAGENT	4 ×	2.7 mL	6 ×	6.5 mL	4 ×	2.7 mL		ATReag
• INNOVANCE Antithrombin SUBSTRATE	4 ×	2.7 mL	6 ×	6.5 mL	4 ×	2.7 mL		ATSub
INNOVANCE Antithrombin BUFFER	4 ×	5 mL	6 ×	12 mL	4 ×	12 mL		ATBuf
STANDARD PLASMA	REF	ORKL19						
	10 × →	1 mL						SHP
CONTROL N	REF	ORKE45						
	10 × →	1 mL						n/a
CONTROL P	REF	OUPZ19						
	10 × →	1 mL						n/a
CA SYSTEM BUFFER	<b>REF</b> B	4265-37						
	8 ×	250 mL						OVB
OV BUFFER	<b>REF</b> B	4234-25						
	10 ×	15 mL						OVB
CA CLEAN I	<b>REF</b> 964	1-0631-3						
	1 ×	50 mL						Clean I
BC Vial Kit (empty vials for 5 mL)	REF	OVKE03						
		10 pcs.						n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
INNOVANCE Antithrombin REAGENT	<b>4</b> <sup>b</sup>	_	8
INNOVANCE Antithrombin SUBSTRATE	6 <sup>c</sup>	_	8
INNOVANCE Antithrombin BUFFER	10	_	8
STANDARD PLASMA	#1	-	n/a
CONTROL	Any position on sample rack	_	n/a
CONTROL P	Any position on sample rack	-	n/a
CA SYSTEM BUFFER	Buffer position 12	_	n/a
OV BUFFER	Buffer position 12	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

<sup>&</sup>lt;sup>c</sup> Alternatively, any other non-cooled reagent position can be used.

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The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	681
Hemoglobin	1 000
Bilirubin	60

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> <sup>d</sup>
ATIII / Berichrom® Antithrombin III (A) on CA-500 series	$y = 1.00 \times -0.03 \%$ of Norm	0.972

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Repeatability CV) on the same lot of control plasma should be as follows:

< 10 %

	Mean	Repeatability SD	Repeatability CV	Within-Device/Lab SD	Within-Device/Lab CV
	(% of Norm)	(% of Norm)	(%)	(% of Norm)	(%)
CONTROL N	89.5	-	2.5	-	4.3
CONTROL P	29.1	-	3.2	-	6.9
Normal plasma pool	97.4	-	1.3	_	3.5
Pathological plasma pool 1	56.6	-	1.5	-	4.5
Pathological plasma pool 2	17.34	_	2.31	_	3.05
Pathological plasma pool 3	12.34	0.21	-	0.46	_

#### **Measuring Range**

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	(% of Norm)	(% of Norm)	(% of Norm)
_	150	96.2	96.1	83 – 111

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

### Bibliography

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	AT	STD-Link	. No
Manage. ID <sup>e</sup>	6000		·
Detector	for BCAT3		
Start Point		6 sec	
End Point		21 sec	
Sensitivity	Low Gair	ı	
Wavelength	405 nm	Inc	
Sample Vol		10 μL	
Dil.Vol	ATBuf	110 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		40 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		30 sec	
Reag. Vol	ATReag	80 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		210 sec	
Reag. Vol	ATSub	80 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3		0 sec	
Reag. Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

Standard Curve Calibration
Calibration Parameter 1

Standard Curve - Select Param.

Param.	AT %
Units	%
Number Format	xxx.x
Curve Fit	Log Curve

#### Standard Curve - Standard Analysis

Select Dilution Set	10
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	3/2	2
Calib. or Dil.Ratio 2	1/1	2
Calib. or Dil.Ratio 3	1/2	2
Calib. or Dil.Ratio 4	1/4	2
Calib. or Dil.Ratio 5	1/8	2
Calib. or Dil.Ratio 6	1/16	2

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	AT %

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
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## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### AT%

(%)	(dOD)
135.0	0.299
90.0	0.524
45.0	0.889
22.5	1.137
11.3	1.295
5.6	1.377

<sup>&</sup>lt;sup>e</sup> The Management ID only applies to the CA-600 series.

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### **Application Sheet**

# Antithrombin III / Berichrom® Antithrombin III (A)

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Version	14		
Release Date	2024-04		
Software Version ≥ 00-17 <sup>a</sup>			
USA only			

a CA-660

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

#### **Materials Required**

Product		rder No.		rder No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Packag	e Size 1		ge Size 2	Package Size 3	Package Size 4	tocol
Berichrom AT III	REF C	WWR17	REF	OWWR15			
Berichrom AT III REAGENT THR	6 × <b>→</b>	5 mL	6 × <b>→</b>	15 mL			AT3Thro
Berichrom AT III SUBSTRATE	3 × →	3 mL	6 × <b>→</b>	3 mL			AT3Subs
Berichrom	1 ×	30 mL	1 ×	100 mL			n/a
STANDARD PLASMA	REF	ORKL19					
	10 × →	1 mL					SHP
CONTROL N	REF	ORKE45					
	10 × →	1 mL					n/a
CONTROL P	REF	OUPZ19					
	10 × →	1 mL					n/a
CA SYSTEM BUFFER	REF B	4265-37					
	8 ×	250 mL					OVB
OV BUFFER	REF B	4234-25					
	10 ×	15 mL					OVB
CA CLEAN I	<b>REF</b> 964	-0631-3					
	1 ×	50 mL					Clean I
BC Vial Kit (empty vials for 5 mL)	REF	OVKE03					
		10 pcs.					n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Berichrom AT III REAGENT THR	<b>4</b> <sup>b</sup>	-	8
Berichrom AT III SUBSTRATE	6 <sup>c</sup>	-	8
Berichrom AT III REAGENT THR DILUENT	n/a	-	n/a
STANDARD PLASMA	#1	-	n/a
CONTROL N	Any position on sample rack	-	n/a
CONTROL P	Any position on sample rack	_	n/a
CA SYSTEM BUFFER	Buffer position 12	GW 5; SLD Viald	8
OV BUFFER	Buffer position 12	GW 5; SLD Vial	8
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

<sup>&</sup>lt;sup>b</sup> Alternatively, any other cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

<sup>&</sup>lt;sup>c</sup> Alternatively, any other non-cooled reagent position can be used.

d For positioning on the analyzer, the buffer has to be transferred into an appropriate vial.

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The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	1 200
Hemoglobin	1 000
Bilirubin	60

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	r <sup>e</sup>
ATIII / Berichrom® Antithrombin III (A) on CA-6000	$y = 0.95 \times + 4.50 \%$ of Norm	0.972

e r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 10 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL	2.3	4.5	5.0
CONTROL	2.9	9.5	9.9

#### Measuring Range

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

		Mean	Median	2.5 <sup>th</sup> to 97.5 <sup>th</sup> percentile
Comments	n	(% of Norm)	(% of Norm)	(% of Norm)
_	285	96.1	96.5	79.1 – 114.1

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## **Bibliography**

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	AT3	STD-Link	No
Manage. ID <sup>f</sup>	6010		
Detector	for BCAT3	-	
Start Point		11 sec	
End Point		40 sec	
Sensitivity	Low Ga	in	
Wavelength	405 nm	Inc	
Sample Vol		10 μL	
Dil.Vol	OVB	83 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		20 μL	
Dil.Vol	*****	0 μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1		30 sec	
Reag. Vol	AT3Thro	125 µL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2		90 sec	
Reag. Vol	AT3Subs	33 μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3		0 sec	
Reag. Vol	*****	Ο μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

Standard Curve Calibration
Calibration Parameter 1

Standard Curve - Select Param.

Param.	AT3 %
Units	%
Number Format	XXX.X
Curve Fit	Lin-Lin

#### Standard Curve - Standard Analysis

Select Dilution Set	8
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	3/2	2
Calib. or Dil.Ratio 2	1/1	2
Calib. or Dil.Ratio 3	1/2	2
Calib. or Dil.Ratio 4	1/4	2
Calib. or Dil.Ratio 5	1/8	2
Calib. or Dil.Ratio 6	0/1	2

#### **Data Check**

Special Menu – Settings – Data Check

– Mark Limits	Select Param.	AT3 %

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication	Replicates	1
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## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### AT3 %

(%)	(dOD)
145.5	0.180
97.0	0.507
48.5	0.832
24.3	0.992
12.1	1.065
0.0	1.097

<sup>&</sup>lt;sup>f</sup> The Management ID only applies to the CA-600 series.

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#### **Application Sheet**

# Heparin / INNOVANCE® Heparin

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system;
other combinations are not validated or supported by Siemens Healthineers.

Version	05
Release Date	2024-04
Software Version	≥ 00-27ª
USA only	

CA-660

## **Materials Required**

Product	Order No.	Order No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4	tocol
INNOVANCE <b>HEPARIN</b>	REF OPOA05				
• INNOVANCE HEPARIN REAGENT	5 × 3.2 mL				IHepRea
• INNOVANCE HEPARIN SUBSTRATE	5 × 4.0 mL				IHepSub
INNOVANCE HEPARIN CALIBRATOR	REF OPOB05				
• INNOVANCE HEPARIN CALIBRATOR 1	1 × → 1.0 mL				IHepCal1
• INNOVANCE HEPARIN CALIBRATOR 2	1 × → 1.0 mL				IHepCal2
• INNOVANCE   HEPARIN   CALIBRATOR   3	1 × → 1.0 mL				IHepCal3
• INNOVANCE   HEPARIN   CALIBRATOR   4	1 × → 1.0 mL				IHepCal4
• INNOVANCE   HEPARIN   CALIBRATOR   5	1 × → 1.0 mL				IHepCal5
INNOVANCE HEPARIN LMW CONTROL 1	REF OPOE05				
	5 × → 1 mL				IHepLMW1
INNOVANCE HEPARIN LMW CONTROL 2	REF OPOF05				
	5 × → 1 mL				IHepLMW2
INNOVANCE HEPARIN UF CONTROL 1	REF OPOC05				
	5 × → 1 mL				IHepUF1
INNOVANCE [HEPARIN] UF CONTROL 2	REF OPOD05				
	5 × → 1 mL				IHepUF2
STANDARD PLASMA	REF ORKL19				•
	10 × → 1 mL				SHP
CA SYSTEM BUFFER	<b>REF</b> B4265-37				
	8 × 250 mL				OVB
OV BUFFER	<b>REF</b> B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 964-0631-3				
	1 × 50 mL				Clean I
Sample Cup Conical 4 mL	REF 424-1160-8				Cicali i
Sample cup conical 4 IIIL	100 pcs.				n/a
BC Vial Kit (empty vials for 5 mL)	REF OVKE03				IIId
be viai kit (empty viais ior 5 mt)					,
	10 pcs.				n/a

b Only required when extending the measuring range by sample dilution (please also refer to chapter "Measuring Range").

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

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### **On-board Stability**

Component	Position	Condition	Time (h)
INNOVANCE HEPARIN REAGENT	1 <sup>c</sup>	_	16
INNOVANCE HEPARIN SUBSTRATE	2 <sup>c</sup>	-	16
INNOVANCE HEPARIN CALIBRATOR 1	#1-#5	_	4
INNOVANCE   HEPARIN   CALIBRATOR   2	#1-#5	-	4
INNOVANCE HEPARIN CALIBRATOR 3	#1-#5	-	4
INNOVANCE HEPARIN CALIBRATOR 4	#1-#5	-	4
INNOVANCE HEPARIN CALIBRATOR 5	#1-#5	_	4
INNOVANCE   HEPARIN   LMW CONTROL   1	Any position on sample rack	-	8
INNOVANCE HEPARIN LMW CONTROL 2	Any position on sample rack	_	8
INNOVANCE HEPARIN UF CONTROL 1	Any position on sample rack	-	8
INNOVANCE HEPARIN UF CONTROL 2	Any position on sample rack	-	8
STANDARD PLASMA	n/a	-	n/a
CA SYSTEM BUFFER	Buffer position 12	PV-10 <sup>d</sup>	16
OV BUFFER	Buffer position 12	PV-10	16
CA CLEAN I	Rinse position 11	PV-10	24

<sup>&</sup>lt;sup>c</sup> Alternatively, any other cooled reagent position can be used.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### Interference Studies

No interferences up to	(mg/dL)
Hemoglobin	134
Bilirubin (unconjugated)	20
Bilirubin (conjugated)	28
Triglycerides	267

#### Performance Characteristics

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

The performance of this device has not been established in neonate and pediatric patient populations.

Test results obtained from pediatric patient populations may be age dependent. Therefore, each laboratory must follow their regulatory agency guidelines to qualify additional age groups.

#### **Method Comparison**

A study was performed with frozen samples to compare the INNOVANCE® Heparin assay on the CA-660 System to the INNOVANCE® Heparin assay on the BCS® XP System for the measurement of heparin. The results from the Passing-Bablok regression analysis are summarized in the following table:

Predicate Device	Regression Equation	re
Heparin / INNOVANCE® Heparin on BCS® XP (UFH (n=148) and LMWH (n=132) containing samples)	$y = 0.97 \times -0.04 \text{ IU/mL}$	0.99

e r = Correlation Coefficient

#### Precision

The standard deviation (SD) of the analytical system should be as follows:

Samples with heparin activities of

≤0.50 IU/mL [SD] ≤0.03 IU/mL

Samples with heparin activities of

> 0.50 IU/mL [CV]  $\leq 7.5 \%$ 

Precision studies were conducted on the CA-660 according to CLSI guideline EP05-A2, using

INNOVANCE | HEPARIN | UF CONTROL | 1, INNOVANCE | HEPARIN | UF CONTROL | 2, INNOVANCE | HEPARIN | LMW CONTROL | 1,

INNOVANCE **HEPARIN LMW CONTROL 2** and 6 plasma pools covering the measuring range

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

For positioning on the analyzer, the buffer has to be transferred into an appropriate vial.

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The results from the precision studies are summarized in the following table (Calculation of CV (%): CV (%) = SD (IU/mL) × 100 / Mean (IU/mL)):

	<b>Mean</b> (IU/mL)	Repeatability SD (IU/mL)	Within- Device/Lab SD (IU/mL)
INNOVANCE   HEPARIN   LMW CONTROL   1	0.40	0.013	0.018
INNOVANCE HEPARIN LMW CONTROL 2	1.00	0.030	0.037
INNOVANCE   HEPARIN   UF CONTROL   1	0.28	0.015	0.019
INNOVANCE HEPARIN UF CONTROL 2	0.60	0.018	0.022
Plasma pool 1 containing LMWH	0.10	0.016	0.016
Plasma pool 1 containing UFH	0.13	0.013	0.018
Plasma pool 2 containing LMWH	0.65	0.014	0.019
Plasma pool 2 containing UFH	0.98	0.027	0.038
Plasma pool 3 containing LMWH	1.32	0.024	0.024
Plasma pool 3 containing UFH	1.39	0.027	0.028

#### **Measuring Range**

Comments	(IU/mL)
_	0.10 - 1.50

Samples with low-molecular weight heparin (LMWH) or unfractionated heparin (UFH) concentrations above 1.50 IU/mL can be manually diluted by mixing two parts of sample with one part of **STANDARD PLASMA** and subsequent measurement of the diluted sample.

Prior to reporting the result of the manually diluted sample must be multiplied by the dilution factor of 1.5. This procedure results in an extended measuring range of 0.10 to 2.25 IU/mL.

When applying the above described procedure to dilute samples, the antithrombin activity in samples with pathological low antithrombin activities will be compensated. This may lead to an overestimation of the effect of anticoagulation in these patients.

#### **Expected Values**

n/a

## Bibliography

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – **Test Protocol** 

Test Protocol Name	ІНер	STD-Link	No
Manage. ID	6130		
Detector	for Chrom 1		
Start Time	20	sec	
End Time	60	sec	
Sensitivity	Low Gain		
Wavelength	405 nm Inc		
Sample Vol	10	μL	
Dil.Vol	OVB 11	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol	0	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	30	sec	
Reag. Vol	IHepSub 100	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	90	sec	
Reag. Vol	IHepRea 75	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	0	sec	
Reag. Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

## **Standard Curve Calibration Calibration Parameter 1**

Standard Curve – Select Param.

Param.	IНер
Units	IU/mL
Number Format	XX.XX
Curve Fit	Lin Pt-Pt

#### Standard Curve – **Standard Analysis**

Select Dilution Set	М
Calibrator	INNOVANCE Heparin Calibrator

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	Calibrator 1	2
Calib. or Dil.Ratio 2	Calibrator 2	2
Calib. or Dil.Ratio 3	Calibrator 3	2
Calib. or Dil.Ratio 4	Calibrator 4	2
Calib. or Dil.Ratio 5	Calibrator 5	2

#### **Data Check**

Special Menu – Settings – Data Check

- Mark Limits	Select Param.	IНер
- Replic. Limits	Difference (%)	10
– Report Limits	lower (<)	0.10 IU/mL
	upper (>)	1.50 IU/mL

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

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## **Standard Curve (example only)**

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### lHep

(IU/mL)	(dOD)
1.55	0.376
1.19	0.444
0.79	0.570
0.42	0.724
0.00	0.929

#### Remarks

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Heparin / INNOVANCE® Heparin (V. 05) Page 6 of 6 Reference Guide Reference Guide Page 1 of 4

## **Application Sheet**

## Protein C / Berichrom® Protein C

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Version	15	
Release Date	2024-04	
Software Version	≥ 00-17ª	
USA only		

a CA-660

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

#### **Materials Required**

Product	O	rder No.	0	rder No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Packag	e Size 1	Packag	je Size 2	Package Size 3	Package Size 4	
Berichrom PROTEIN C	REF	OUVV15	REF	OUVV17			
Berichrom PROTEIN C ACTIVATOR	3 × <b>→</b>	10 mL	4 × →	5 mL			BCPCAct
Berichrom PROTEIN C SUBSTRATE	3 × →	3 mL	2 × →	3 mL			BCPCSub
Berichrom PROTEIN C     ACTIVATOR DILUENT	1 ×	30 mL	1 ×	30 mL			n/a
STANDARD PLASMA	REF	ORKL19					
	10 × →	1 mL					SHP
CONTROL N	REF	ORKE45					
	10 × →	1 mL					n/a
CONTROL P	REF	OUPZ19					
	10 × →	1 mL					n/a
CA SYSTEM BUFFER	REF B	4265-37					
	8 ×	250 mL					OVB
OV BUFFER	REF B	4234-25					
	10 ×	15 mL					OVB
CA CLEAN I	<b>REF</b> 964	-0631-3					
	1 ×	50 mL					Clean I
BC Vial Kit (empty vials for 5 mL)	REF	OVKE03					
		10 pcs.					n/a

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropiate vials.

The required controls and calibrators have to be transferred into appropriate sample cups.

## **On-board Stability**

Component	Position	Condition	Time (h)
Berichrom PROTEIN C ACTIVATOR	1 <sup>b</sup>	_	48
Berichrom PROTEIN C SUBSTRATE	2 <sup>b</sup>	-	48
Berichrom PROTEIN C ACTIVATOR DILUENT	n/a	-	n/a
STANDARD PLASMA	#1	-	n/a
CONTROL N	Any position on sample rack	_	n/a
CONTROL P	Any position on sample rack	_	n/a
CA SYSTEM BUFFER	Buffer position 12	_	n/a
OV BUFFER	Buffer position 12	-	n/a
CA CLEAN I	Rinse position 11	PV-10; SLD Vial	24

b Alternatively, any other cooled reagent position can be used.
Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

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The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	284
Hemoglobin	400
Bilirubin	36

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	rc
Protein C / Berichrom® Protein C on BCT	$y = 1.05 \times -1.02 \%$ of Norm	0.963

c r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Total CV) on the same lot of control plasma should be as follows: < 10 %

	Within Run CV	Run to Run CV	Total CV
	(%)	(%)	(%)
CONTROL N	1.6	1.0	1.8
CONTROL P	3.6	1.4	3.6

#### Measuring Range

The measuring range is defined by the concentration of the calibrators used.

#### **Expected Values**

Refer to the Instructions for Use of the reagent.

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## Bibliography

Refer to the Instructions for Use of the reagent.

Reference Guide Page 3 of 4

#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	ВСРС	STD-Link	No
Manage. ID <sup>d</sup>	6200		
Detector	for BCPC		
Start Point	11	sec	
End Point	100	sec	
Sensitivity	Low Gain		
Wavelength	405 nm Inc		
Sample Vol	20	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol	0	μL	
Dil.Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0
Reagent 1	60	sec	
Reag. Vol	BCPCAct 125	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 2	540	sec	
Reag. Vol	BCPCSub 30	μL	
Pre. Rinse	*****		x 0
Post. Rinse	Clean I		x 1
Reagent 3	0	sec	
Reag. Vol	******	μL	
Pre. Rinse	*****		x 0
Post. Rinse	*****		x 0

Standard Curve Calibration
Calibration Parameter 1

Standard Curve - Select Param.

Param.	BCPC%
Units	%
Number Format	XXX.X
Curve Fit	Lin-Lin

#### Standard Curve - Standard Analysis

Select Dilution Set	1
Calibrator	SHP

Refer to the Table of Analytical Values for the lot specific calibrator value.

		Repl.
Calib. or Dil.Ratio 1	1/1	2
Calib. or Dil.Ratio 2	1/2	2
Calib. or Dil.Ratio 3	1/4	2
Calib. or Dil.Ratio 4	1/8	2
Calib. or Dil.Ratio 5	1/16	2
Calib. or Dil.Ratio 6	1/32	2

#### **Data Check**

Special Menu – Settings – Data Check

<ul><li>Mark Limits</li></ul>	Select Param.	BCPC %

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

- Set Replication Replicates	1
------------------------------	---

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### BCPC%

(%)	(dOD)
97.0	0.148
48.5	0.080
24.3	0.039
12.1	0.019
6.1	0.009
3.0	0.004

The Management ID only applies to the CA-600 series.

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CA-600 series Immunoassays

Reference Guide



Immunoassays CA-600 series

Reference Guide

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#### **Application Sheet**

## D-dimer / INNOVANCE® D-Dimer

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthineers to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Release Date	2024-04			
Software Version	≥ 00-17ª			
USA only				

Version 11

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens Healthineers.

#### **Materials Required**

Product	Ore	der No.	0	rder No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Package	e Size 1	Packag	ge Size 2	Package Size 3	Package Size 4	
INNOVANCE® D-Dimer	REF (	OPBP09	REF	OPBP11			
• INNOVANCE D-Dimer REAGENT	3 × →	4 mL	6 × <b>→</b>	4 mL			DDi.REA
• INNOVANCE D-Dimer <b>BUFFER</b>	3 ×	5 mL	6 ×	5 mL			DDi.BUF
• INNOVANCE D-Dimer SUPPLEMENT	3 ×	2.6 mL	6 ×	2.6 mL			DDi.SUP
• INNOVANCE D-Dimer <b>DILUENT</b>	3 ×	5 mL	6 ×	5 mL			DDi.DIL
• INNOVANCE D-Dimer CALIBRATOR	2 × <b>→</b>	1 mL	2 × →	1 mL			n/a
• EMPTY VIAL	1 ×	12 pcs.					n/a
INNOVANCE® D-Dimer Controls	REF (	OPDY09					
• INNOVANCE D-Dimer CONTROL 1	5 × →	1 mL					n/a
• INNOVANCE D-Dimer CONTROL 2	5 × →	1 mL					n/a
INNOVANCE D-Dimer DILUENT	REF (	OPBR03					
	10 ×	5 mL					DDi.DIL
CA SYSTEM BUFFER	REF B4	265-37					
	8 ×	250 mL					OVB
OV BUFFER	REF B4	234-25					
	10 ×	15 mL					OVB

#### **Additional Notes**

If reagents, rinse solutions or buffers are not supplied in vials, which fit on the instrument exactly it is necessary to transfer them into appropriate vials.

The required controls and calibrators have to be transferred into Sample Cup Conical 4 mL, REF 424-1160-8. Push vials (Push Vial PV-10, REF 541-1352-1) and 5 mL vials from the BC Vial Kit (empty vials for 5 mL), REF OVKE03 can be used as appropriate vials for reagents, rinse solutions or buffers that are not supplied in vials that fit exactly on the instrument.

## **On-board Stability**

Component	Position	Condition	Time (h)
INNOVANCE D-Dimer REAGENT	6 <sup>b</sup>	-	16
	6 <sup>b</sup>	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer BUFFER	4 <sup>c</sup>	-	16
	4 <sup>c</sup>	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer SUPPLEMENT	8 <sup>b</sup>	_	16
	8 <sup>b</sup>	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer <b>DILUENT</b>	10	-	16
	10	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer CALIBRATOR	#1	-	n/a
INNOVANCE D-Dimer CONTROL 1	Any position on sample rack	-	n/a
INNOVANCE D-Dimer CONTROL 2	Any position on sample rack	_	n/a

a CA-660

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Component	Position	Condition	Time (h)
CA SYSTEM BUFFER	Buffer position 12	GW 5; SLD Vial	48
OV BUFFER	Buffer position 12	GW 5; SLD Vial	48

Alternatively, any other non-cooled reagent position can be used.

Please note: If reagents recommended for cooling are stored on a non-cooled position, a reduced on-board stability has to be anticipated.

In original vials, the reagents may be left on board the instrument continuously for 16 hours or stored on and off the instrument for intervals of  $7 \times 1$  hour over a maximum period of 14 days.

Storage and stability are described in the Instructions for Use. INNOVANCE® D-Dimer controls need to validate each new test run.

The stability data presented here were established under controlled laboratory conditions. Due to differences in laboratory environmental conditions and reagent vial filling volumes, the on-board stability may deviate from the above-mentioned values.

#### **Interference Studies**

No interferences up to	(mg/dL)
Triglycerides	400
Hemoglobin	200
Bilirubin	12

#### Limitations

Higher levels of lipids or turbid samples can lead to falsely elevated or decreased values. It is therefore recommended to perform an additional centrifugation step of the plasma (10 minutes at approx.  $15\,000\,x\,g$ ) before analyzing lipemic patient specimens.

#### **Performance Characteristics**

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

#### **Method Comparison**

Predicate Device	Regression Equation	<b>r</b> <sup>d</sup>
D-dimer / INNOVANCE® D-Dimer on BCS®	$y = 1.09 \times -0.03 \text{ mg/L FEU}$	0.994

d r = Correlation Coefficient

#### Precision

The coefficient of variation of the analytical system (Within-Device CV) on the same lot of control plasma should be as follows:

< 15 %

	<b>Mean</b> (mg/L FEU)	Repeatability CV	Within- Device/Lab CV (%)
INNOVANCE D-Dimer [CONTROL]1	0.30	5.3	6.7
INNOVANCE D-Dimer [CONTROL]2	2.69	3.9	5.2

#### **Measuring Range**

The INNOVANCE® D-Dimer measuring range is defined by the concentration of the calibrator used and is approximately 0.19 to 4.40 mg/L FEU. The measuring range can be extended to approximately 35.20 mg/L FEU by a manually requested redilution of samples above the measuring range with the +DDi setting.

#### **Clinical Performance**

#### **Exclusion of DVT**

The INNOVANCE® D-Dimer assay was evaluated on the CA-560 Coagulation Analyzer in a multi-center study to validate the exclusion of DVT using fresh specimens collected from 455 consecutive patients presenting to the emergency department with suspected DVT. Of these 455 patients, 31 were excluded for a total of 424 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a likely or unlikely pre-test probability (PTP) of DVT. Patient specimens were tested with the INNOVANCE® D-Dimer assay and results were compared to a cutoff value of

<sup>&</sup>lt;sup>c</sup> Alternatively, any other cooled reagent position can be used.

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0.50 mg/L FEU. A D-dimer result < 0.50 mg/L FEU was considered negative and a D-dimer result  $\ge$  0.50 mg/L FEU was considered positive.

Patients with a positive D-dimer result were evaluated by imaging methods, e.g. compression ultrasound and/or venography. Patients with a negative D-dimer, as well as those with negative imaging results, were followed for three months to evaluate potential development of DVT. All patients were subject to imaging at the physician's discretion.

The overall prevalence of DVT in those patients available for final analysis was 22.2 % (94/424). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95 % confidence limits (CL) were obtained with the INNOVANCE® D-Dimer clinical cutoff of 0.50 mg/L FEU.

	DVT Patients	Cutoff	Sensitivity	Specificity	NPV
	n	[mg/L FEU]	(CL) %	(CL) %	(CL) %
All patients	424	0.50	98.9	37.3	99.2
			(94.2 - 100.0)	(32.0 - 42.7)	(95.6 - 100.0)
Patients with unlikely pre-test probability	267	0.50	100.0	39.8	100.0
			(83.9 - 100.0)	(33.7 - 46.3)	(96.3 - 100.0)

#### **Exclusion of PE**

The INNOVANCE® D-Dimer was evaluated on the CA-500/CA-600 series in a multi-center study to validate the exclusion of PE using fresh specimens collected from 701 consecutive patients presenting to the emergency department with suspected PE. Of these 701 patients, 60 were excluded for a total of 641 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a high, moderate or low pre-test probability (PTP) of PE. Patient specimens were tested with the INNOVANCE® D-Dimer assay and results were compared to a cutoff value of 0.50 mg/L FEU. A D-dimer result < 0.50 mg/L FEU was considered negative and a D-dimer result  $\ge$  0.50 mg/L FEU was considered positive.

Patients with a positive D-dimer result and/or a high PTP were evaluated by imaging methods, e.g. spiral CT and/or VQ scan. Patients with a negative D-dimer result and a low or moderate PTP (these patients underwent imaging at the physician's discretion), and patients with negative imaging results, were followed for three months to evaluate potential development of PE.

The overall prevalence of PE in those patients available for final analysis was 13.7 % (88/641). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95 % confidence limits (CL) were obtained with the INNOVANCE® D-Dimer clinical cutoff of 0.50 mg/L FEU.

	PE Patients	Cutoff	Sensitivity	Specificity	NPV
	n	[mg/L FEU]	(CL) %	(CL) %	(CL) %
All patients	641	0.50	96.6	39.4	98.6
			(90.4 - 99.3)	(35.3 - 43.6)	(96.1 - 99.7)
Patients with low and moderate pre-test	610	0.50	95.8	40.3	98.6
probability			(88.1 - 99.1)	(36.1 - 44.5)	(96.1 - 99.7)

#### **Expected Values**

In a study with ostensibly healthy subjects the following data were obtained:

			Median	90 <sup>th</sup> percentile
Comments	n	Mean	(mg/L FEU)	(mg/L FEU)
-	150	-	0.25	0.59

Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For more information on establishing reference intervals see CLSI document EP28-A3c, "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory"; Approved Guideline.

## **Bibliography**

Refer to the Instructions for Use of the reagent.

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	DDi		STD-Link	Master
Manage. ID <sup>e</sup>	6500			
Detector	for IMMUNO2f			
Sensitivity	Low Gain			
Wavelength	575 nm	Inc		
Sample Vol		8	μL	
Dil.Vol	DDi.DIL	12	μL	
Pre. Rinse	OVB			x 1
Post. Rinse	*****			x 0
2nd Dil				
D.Samp Vol		0	μL	
Dil.Vol	*****	0	μL	
Pre. Rinse	*****			x 0
Post. Rinse	*****			x 0
Reagent 1		30	sec	
Reag. Vol	DDi.SUP	16	μL	
Pre. Rinse	*****			x 0
Post. Rinse	OVB			x 1
Reagent 2		60	sec	
Reag. Vol	DDi.BUF	80	μL	
Pre. Rinse	*****			x 0
Post. Rinse	OVB			x 1
Reagent 3		180	sec	
Reag. Vol	DDi.REA	44	μL	
Pre. Rinse	OVB			x 1
Post. Rinse	OVB			x 1

#### <sup>e</sup> The Management ID only applies to the CA-600 series.

## **Data Check**

Special Menu – Settings – Data Check

– Replic. Limits	Difference (%)	20
– Report Limits	lower (<)	0.19 mg/L
	upper (>)	4.40 mg/L

## Standard Curve Calibration Calibration Parameter 1

Standard Curve - Select Param.

Param.	DDi
Units	mg/L
Number Format	XX.XX
Curve Fit	Log Curve

#### Standard Curve - Standard Analysis

Select Dilution Set	1
Calibrator	DDi.CAL

Refer to the Table of Analytical Values for the lot specific D-Dimer concentration of INNOVANCE D-Dimer CALIBRATOR.

		Repl.
Calib. or Dil.Ratio 1	1/1	2
Calib. or Dil.Ratio 2	1/2	2
Calib. or Dil.Ratio 3	1/4	2
Calib. or Dil.Ratio 4	1/8	2
Calib. or Dil.Ratio 5	1/16	2
Calib. or Dil.Ratio 6	1/32	2

#### **Number of Replicates**

Special Menu – Settings – Analysis Settings

<ul> <li>Set Replication</li> </ul>	Replicates	1

## Standard Curve (example only)

A new standard curve must be established when changing a reagent lot, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

#### DDi

(mg/L)	(dOD)
5.30	0.1896
2.65	0.1401
1.33	0.0768
0.66	0.0345
0.33	0.0143
0.17	0.0074

For the CA-600 series, it is also possible to select the detector "for DD INN".

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#### **Test Protocol**

Special Menu – Settings – Analysis Settings – Test Protocol

Test Protocol Name	+DDi	STD-Link	DDi
Manage. ID <sup>g</sup>	6510		
Detector	for IMMUNO2h		
Sensitivity	Low Gain		
Wavelength	575 nm	Inc	
Sample Vol		10 μL	
Dil.Vol	DDi.DIL	70 μL	
Pre. Rinse	OVB		x 1
Post. Rinse	*****		x 0
2nd Dil			
D.Samp Vol		8 μL	
Dil.Vol	DDi.DIL	12 µL	
Pre. Rinse	OVB		x 1
Post. Rinse	*****		x 0
Reagent 1		30 sec	
Reag. Vol	DDi.SUP	16 μL	
Pre. Rinse	*****		x 0
Post. Rinse	OVB		x 1
Reagent 2		60 sec	
Reag. Vol	DDi.BUF	80 μL	
Pre. Rinse	*****		x 0
Post. Rinse	OVB		x 1
Reagent 3		180 sec	
Reag. Vol	DDi.REA	44 µL	
Pre. Rinse	OVB		x 1
Post. Rinse	OVB		x 1

**Standard Curve Calibration** 

Not applicable - Standard curve for "DDi" will be used automatically. Ensure that the STD-Link in the test protocol is set to "DDi". For more information refer to Operator`s Manual.

#### **Data Check**

Special Menu – Settings – Data Check

- Replic. Limits	Difference (%)	20
- Report Limits	lower (<)	3.65 mg/L
	upper (>)	35.20 mg/L

## **Number of Replicates**

Special Menu – Settings – Analysis Settings

<ul> <li>Set Replication</li> </ul>	Replicates	1

#### Remarks

The units of measure for INNOVANCE® D-Dimer assay are mg/L FEU. The software of the instrument reports only mg/L. Both, DDi and +DDi should be set in the test group setting to enable manual sample redilution if the standard curve range is exceeded.

All samples above the upper report limit should be repeated using the appropriate +DDi setting again. The redilution has to be requested manually.

#### Important!

The parameters given in the Application Sheet have to be entered into the software carefully. Additionally, there are parameters which have to be entered by a Siemens Healthineers service representative only. Please contact your local service.

The Management ID only applies to the CA-600 series.

<sup>&</sup>lt;sup>h</sup> For the CA-600 series, it is also possible to select the detector "for DD INN".

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## Addendum I General Information to the Applications On-board Stability

The on-board stability of CA CLEAN I for all applications is 24 hours (in PV-10 or SLD Vial).

## **Reportable Ranges**

The validation of the reportable ranges on the CA-600 series analyzers includes data generated during the clinical evaluations and software defined limits.

Parameter	Unit	Reportable Range
Reagent/Assay		
Prothrombin Time		
Dade® Innovin® Reagent	seconds	8.9-93.6
Thromborel® S Reagent		
Prothrombin Time (Maximum Time extended to 300 seconds)	seconds	8.9–170.9
Dade® Innovin® Reagent	seconds	0.9-170.9
Activated Partial Thromboplastin Time		
Dade®Actin® Activated Cephaloplastin Reagent		
Dade®Actin® FS Activated PTT Reagent	seconds	17.8–176.1
Dade®Actin® FSL Activated PTT Reagent		
Pathromtin ® SL Reagent		
Activated Partial Thromboplastin Time		
(Maximum Time extended to 600 seconds)	seconds	17.8–192.4
Dade®Actin® FSL Activated PTT Reagent		
Fibrinogen (Clauss)	g/L	0.5-8.4
Dade® Thrombin Reagent	9/L	or limits of calibrator
Fibrinogen (Clauss)	g/L	0.7-8.0
Multifibren <sup>®</sup> UReagent	g/L	or limits of calibrator
Thrombin Time	seconds	13.5-70.2
Test Thrombin Reagent	Jeconas	
Batroxobin Time	seconds	15.4-84.2
Batroxobin Reagent	Scconds	
Extrinsic Factors <sup>a</sup>	% of norm	10–147
Coagulation Factor VII with <i>Dade®Innovin®</i> Reagent	/0 OI HOITH	or limits of calibrator
Intrinsic Factors <sup>a</sup>		7–141
Coagulation Factor VIII with Dade®Actin® FSL Activated PTT Reagent	% of norm	or limits of calibrator
Protein C, coagulometric	% of norm	10–150
Protein C Reagent	/0 OI HOITH	or limits of calibrator
Antithrombin	% of norm	3.1–124.2
INNOVANCE® Antithrombin Assay	/0 OF HOTH	or limits of calibrator
Antithrombin III	% of norm	2–142
Berichrom® Antithrombin III (A) Assay	,0 OI HOITH	or limits of calibrator
Heparin	IU/mL	0.035-0.641
Berichrom® Heparin Assay	TO/IIIL	or limits of calibrator
Protein C	% of norm	10–180
Berichrom® Protein C Assay	/0 OI HOITH	or limits of calibrator
D-Dimer	mg/L (FEU)	0.19-4.40 up to 35.20
INNOVANCE® D-Dimer Assay	mg/L (i Lo)	or limits of calibrator

<sup>&</sup>lt;sup>a</sup> Data evaluated for FVII and FVIII only.

# Addendum II Symbol Names of Required Materials, REF and SMN for all products

Symbol names are depicted onto the reagent labels and are not translatable. In the following table symbol names and corresponding product names in the language of this Reference Guide are listed.

Symbol Name	Product Name	REF	SMN
ACTIN FS	Dade® Actin® FS Activated PTT Reagent	B4218-20	10445712
		B4218-100	10445710
ACTIN FSL	Dade® Actin® FSL Activated PTT Reagent	B4219-1	10445713
		B4219-2	10445714
ACTIN	Dade® Actin® Activated Cephaloplastin Reagent	B4218-1	10445709
		B4218-2	10445711
Batroxobin REAGENT	Batroxobin Reagent	OUOV21	10446463
Berichrom AT III	Berichrom® Antithrombin III (A)	OWWR17 OWWR15	10446673 10446672
Berichrom AT III REAGENT THR	Thrombin Reagent		
Berichrom AT III SUBSTRATE	• Substrate Reagent		
Berichrom AT III REAGENT THR DILUENT	Buffer Solution		
Berichrom PROTEIN C	Berichrom® Protein C	OUVV15 OUVV17	10446499 10446500
Berichrom PROTEIN C ACTIVATOR	Protein C Activator		
Berichrom PROTEIN C SUBSTRATE	Substrate Reagent		
Berichrom PROTEIN C ACTIVATOR DILUENT	Hepes Buffer Solution		
CA CLEAN I	CA CLEAN I	964-0631-3	11694304
CA SYSTEM BUFFER	Dade® CA System Buffer	B4265-37	10873440
CONTROL	Control Plasma N	ORKE45	10446235
CONTROL P	Control Plasma P	OUPZ19	10446472
CaCl <sub>2</sub> SOLUTION	Calcium Chloride Solution	ORHO37	10446232
Ci-Trol CONTROL 1	Dade® Ci-Trol® Coagulation Control Level 1	B4244-10	10445731
Ci-Trol CONTROL 2	Dade® Ci-Trol® Coagulation Control Level 2	B4244-20	10445732
Ci-Trol CONTROL 3	Dade® Ci-Trol® Coagulation Control Level 3	B4244-30	10445733
Dade® Innovin®	Dade® Innovin®	B4212-41	10873566
		B4212-51	10873567
		B4212-101	10873568
Data-Fi FIBRINOGEN CONTROL	Dade® Data-Fi® Abnormal Fibrinogen Control Plasma	B4233-22	10445719
FACTOR VII DEFICIENT	Coagulation Factor VII Deficient Plasma	OTXV13	10446407
FACTOR VIII DEFICIENT	Coagulation Factor VIII Deficient Plasma	OTXW17	10446411
FIBRINOGEN CALIBRATOR	Fibrinogen Calibrator Kit	OQVK11	10446148
• CALIBRATOR 1	• Fibrinogen Calibrator, level 1		
CALIBRATOR 2	• Fibrinogen Calibrator, level 2		
• CALIBRATOR 3	• Fibrinogen Calibrator, level 3		
• CALIBRATOR 4	• Fibrinogen Calibrator, level 4		
• CALIBRATOR 5	• Fibrinogen Calibrator, level 5		
• CALIBRATOR 6	• Fibrinogen Calibrator, level 6		
FIBRINOGEN DETERMINATION	Dade® Fibrinogen Determination Reagents	B4233-17SY	10873571
• THROMBIN REAGENT	• Dade® Thrombin Reagent		
• FIBRINOGEN STANDARD	Dade® Fibrinogen Standard		
• OV BUFFER	Dade® Owren's Veronal Buffer		
INNOVANCE D-Dimer DILUENT	INNOVANCE® D-Dimer Sample Diluent	OPBR03	10487039

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Symbol Name	Product Name	REF	SMN
INNOVANCE HEPARIN CALIBRATOR	INNOVANCE® Heparin Calibrator	OPOB05	10873530
• INNOVANCE HEPARIN CALIBRATOR 1	• INNOVANCE® Heparin Calibrator 1		
• INNOVANCE HEPARIN CALIBRATOR 2	• INNOVANCE® Heparin Calibrator 2		
• INNOVANCE HEPARIN CALIBRATOR 3	• INNOVANCE® Heparin Calibrator 3		
• INNOVANCE HEPARIN CALIBRATOR 4	• INNOVANCE® Heparin Calibrator 4		
• INNOVANCE HEPARIN CALIBRATOR 5	• INNOVANCE® Heparin Calibrator 5		
INNOVANCE   HEPARIN   LMW CONTROL   1	INNOVANCE® Heparin LMW Control 1	OPOE05	10873534
INNOVANCE   HEPARIN   LMW CONTROL   2	INNOVANCE® Heparin LMW Control 2	OPOF05	10873533
INNOVANCE   HEPARIN   UF CONTROL   1	INNOVANCE® Heparin UF Control 1	OPOC05	10873531
INNOVANCE   HEPARIN   UF CONTROL   2	INNOVANCE® Heparin UF Control 2	OPOD05	10873532
INNOVANCE HEPARIN	INNOVANCE® Heparin	OPOA05	10873535
• INNOVANCE HEPARIN REAGENT	• INNOVANCE® Heparin Reagent		
• INNOVANCE   HEPARIN   SUBSTRATE	INNOVANCE® Heparin Substrate		
INNOVANCE® Antithrombin	INNOVANCE® Antithrombin	OPFH07	10487304
		OPFH09	10487303
		OPFH11	10709521
• INNOVANCE Antithrombin REAGENT	• INNOVANCE® Antithrombin reagent		
• INNOVANCE Antithrombin SUBSTRATE	• INNOVANCE® Antithrombin substrate		
• INNOVANCE Antithrombin BUFFER	• INNOVANCE® Antithrombin buffer		
INNOVANCE® D-Dimer Controls	INNOVANCE® D-Dimer Controls	OPDY09	10446006
• INNOVANCE D-Dimer CONTROL 1	• INNOVANCE® D-Dimer Control 1		
• INNOVANCE D-Dimer CONTROL 2	• INNOVANCE® D-Dimer Control 2		
INNOVANCE® D-Dimer	INNOVANCE® D-Dimer	OPBP09 OPBP11	10445981 10445982
• INNOVANCE D-Dimer REAGENT	INNOVANCE® D-Dimer reagent		
• INNOVANCE D-Dimer <b>BUFFER</b>	INNOVANCE® D-Dimer buffer		
• INNOVANCE D-Dimer <b>SUPPLEMENT</b>	• INNOVANCE® D-Dimer supplementary reagent		
• INNOVANCE D-Dimer <b>DILUENT</b>	INNOVANCE® D-Dimer Sample Diluent		
• INNOVANCE D-Dimer CALIBRATOR	INNOVANCE® D-Dimer Calibrator		
Multifibren® U	Multifibren® U	OWZG19	10446689
		OWZG23	10446691
OV BUFFER	Dade® Owren's Veronal Buffer	B4234-25	10445724
PROTEIN C COAG	Protein C Reagent	OQYG11	10446185
PROTEIN C COAG ACTIVATOR	Protein C Activator		
PROTEIN C COAG REAGENT APTT	APTT Reagent for Protein C		
PROTEIN C COAG DEFICIENT	Protein C Deficient Plasma		
Pathromtin® SL	Pathromtin® SL	OQGS29 OQGS35	10446066 10446067
STANDARD PLASMA	Standard Human Plasma	ORKL19	10487098
TEST THROMBIN	Test Thrombin Reagent	OWHM13	10446598
• TEST THROMBIN REAGENT	Test Thrombin Reagent		
TEST THROMBIN REAGENT DILUENT	Buffer Solution		
THROMBIN REAGENT	Dade® Thrombin Reagent	B4233-25 B4233-27	10445720 10445721
Thromborel® S	Thromborel® S	OUHP53	10873565
THISHIDOICE 5	THOMBOICE 3	00111 33	10075505