SIEMENS Healthineers

Automated Blood Coagulation Analyzer CA-600 series

Reference Guide

USA only

5.00

Version: 5.00
Date of Issue: 2024-04

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.

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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.

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Revision History

Document	Date	Changes
Reference Guide 5.00	2024-04	**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. Version, Release Date: modified
Previous Reference Guide Versions	–	See respective Reference Guide.

Table of Contents

Revision bar indicates update to previous version.

PT

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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • **Component(s)**	**Order No.** **Package Size 1**	**Order No.** **Package Size 2**	**Order No.** **Package Size 3**	**Order No.** **Package Size 4**	**Name in Test Protocol**
Thromborel® S	REF OUHP53				
	10 × → 10 mL				PT THS
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	REF 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[b]	–	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

[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	378
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	r[c]
PT seconds / Thromborel® S on CA-6000	y = 1.00 × – 0.50 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:

Comments	n	Mean	Median (s)	2.5th to 97.5th percentile (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.

Test Protocol

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

Test Protocol Name	PT		**STD-Link**	No
Manage. ID[d]	5010			
Detector	for PT THS			
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 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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	PT

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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Application Sheet

PT INR / Thromborel® S

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

[a] CA-620, CA-660

Materials Required

Product • **Component(s)**	**Order No.** **Package Size 1**	**Order No.** **Package Size 2**	**Order No.** **Package Size 3**	**Order No.** **Package Size 4**	**Name in Test Protocol**
Thromborel® S	REF OUHP53				
	10 × → 10 mL				PT THS
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	REF 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[b]	–	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

[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	450
Hemoglobin	600
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[c]
PT INR / Thromborel® S on CA-6000	y = 0.89 × + 0.11[d]	0.999

[c] r = Correlation Coefficient
[d] no unit (INR)

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	1.0	0.9	1.3
CONTROL N	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.

Test Protocol

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

Test Protocol Name	PT	**STD-Link**	No
Manage. ID[e]	5010		
Detector	for PT THS		
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 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

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

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

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.

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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.

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

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Thromborel® S	REF OUHP53				
	10 × → 10 mL				PT THS
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
CA CLEAN I	REF 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[b]	–	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[c]
Hemoglobin	100
Bilirubin	36

[c] 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 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	r[d]
Fibrinogen / Dade® Thrombin Reagent on CA-500 series	y = 1.00 × – 0.10 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 (g/L)	Repeatability CV (%)	Within-Device/Lab CV (%)
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:

Comments	n	Mean (g/L)	Median (g/L)	2.5th to 97.5th percentile (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.

Test Protocol

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

Test Protocol Name	PT	**STD-Link**	No
Manage. ID[e]	5010		
Detector	for PT THS		
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 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

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

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	dFbg

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.

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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

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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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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[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Dade® Innovin®	REF B4212-41	REF B4212-51	REF B4212-101		
	10 × → 4 mL	10 × → 10 mL	12 × → 20 mL		PT INN
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	REF 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)
Dade® Innovin®	1[b]	–	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

[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	373
Hemoglobin	1 000
Bilirubin	48

Performance Characteristics

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

Method Comparison

Predicate Device	Regression Equation	r[c]
PT seconds / Dade® Innovin® on CA-6000	y = 1.03 × – 0.26 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:

Comments	n	Mean	Median (s)	2.5th to 97.5th percentile (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.

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Bibliography

Refer to the Instructions for Use of the reagent.

Test Protocol

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

Test Protocol Name	PT		**STD-Link**	No
Manage. ID[d]	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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	PT

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.

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Application Sheet

PT INR / Dade® Innovin®

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

[a] CA-620, CA-660

Materials Required

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Dade® Innovin®	REF B4212-41	REF B4212-51	REF B4212-101		
	10 × → 4 mL	10 × → 10 mL	12 × → 20 mL		PT INN
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	REF 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)
Dade® Innovin®	1[b]	–	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

[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	300
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[c]
PT INR / Dade® Innovin® on CA-6000	y = 1.08 × – 0.09[d]	0.999

[c] r = Correlation Coefficient
[d] no unit (INR)

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 N	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.

Test Protocol

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

Test Protocol Name	PT	**STD-Link**	No
Manage. ID[e]	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

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

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**

– 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.

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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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Dade® Innovin®	REF B4212-41	REF B4212-51	REF B4212-101		
	10 × → 4 mL	10 × → 10 mL	12 × → 20 mL		PT INN
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
CA CLEAN I	REF 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)
Dade® Innovin®	1[b]	–	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[c]
Hemoglobin	100
Bilirubin	36

[c] 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 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	r[d]
Fibrinogen / Dade® Thrombin Reagent on CA-500 series	y = 1.25 × – 0.58 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 (g/L)	Repeatability CV (%)	Within-Device/Lab CV (%)
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:

Comments	n	Mean (g/L)	Median (g/L)	2.5th to 97.5th percentile (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.

Test Protocol

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

Test Protocol Name	PT		**STD-Link**	No
Manage. ID[e]	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

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

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

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

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APTT

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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
ACTIN	REF B4218-1	REF B4218-2			
	10 × 2 mL	10 × 10 mL			PTT ACT
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
$CaCl_2$ SOLUTION	REF ORHO37				
	10 × 15 mL				CaCl2
CA CLEAN I	REF 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[b]	–	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
$CaCl_2$ SOLUTION	7[c]	–	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.

[c] Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) 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	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**	**r**[d]
APTT / Dade® Actin® Activated Cephaloplastin Reagent on CA-6000	y = 1.00 × – 0.20 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:

< 5 %

	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:

Comments	**n**	**Mean** (s)	**Median** (s)	**5th to 95th percentile** (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.

Test Protocol

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

Test Protocol Name	APTT		**STD-Link**	No
Manage. ID[e]	5200			
Detector	for PTT ACT			
End Point		50 %		
Maximum Time		190 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	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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	APTT

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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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[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
ACTIN FS	REF B4218-20	REF B4218-100			
	10 × 2 mL	10 × 10 mL			PTT FS
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
$CaCl_2$ SOLUTION	REF ORHO37				
	10 × 15 mL				CaCl2
CA CLEAN I	REF 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)
ACTIN FS	2[b]	–	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
$CaCl_2$ SOLUTION	7[c]	–	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.

[c] Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) 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	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**[d]
APTT / Dade® Actin® FS Activated PTT Reagent on CA-6000	y = 1.00 × + 0.10 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:

< 5 %

	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:

Comments	**n**	**Mean** (s)	**Median** (s)	**5th to 95th percentile** (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.

Test Protocol

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

Test Protocol Name	APTT	**STD-Link**	No
Manage. ID[e]	5210		
Detector	for PTT FS		
End Point	50 %		
Maximum Time	190 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	PTT FS	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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	APTT

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
ACTIN FSL	REF B4219-1	REF B4219-2			
	10 × 2 mL	10 × 10 mL			PTT FSL
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
$CaCl_2$ SOLUTION	REF ORHO37				
	10 × 15 mL				CaCl2
CA CLEAN I	REF 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)
ACTIN FSL	2[b]	–	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
$CaCl_2$ SOLUTION	7[c]	–	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.

[c] Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) 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	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	**Regression Equation**	**r**[d]
APTT / Dade® Actin® FSL Activated PTT Reagent on CA-6000	y = 1.00 × + 0.10 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:

< 5 %

	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:

Comments	**n**	**Mean** (s)	**Median** (s)	**5th to 95th percentile** (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.

Test Protocol

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

Test Protocol Name	APTT		**STD-Link**	No
Manage. ID[e]	5220			
Detector	for PTT FSL			
End Point		50 %		
Maximum Time		190 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	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	*******	0 µL		
Pre. Rinse	*******			x 0
Post. Rinse	*******			x 0

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	APTT

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.

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RxOnly

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[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Pathromtin® SL	REF OQGS29	REF OQGS35			
	10 × 5 mL	20 × 5 mL			PTT PSL
Ci-Trol CONTROL 1	REF B4244-10				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 2	REF B4244-20				
	20 × → 1 mL				n/a
Ci-Trol CONTROL 3	REF B4244-30				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
$CaCl_2$ SOLUTION	REF ORHO37				
	10 × 15 mL				CaCl2
CA CLEAN I	REF 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 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[b]	–	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
$CaCl_2$ SOLUTION	7[c]	–	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.

[c] Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) 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	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**[d]
APTT / Pathromtin® SL on CA-6000	y = 0.99 × – 1.10 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:

< 5 %

	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:

Comments	**n**	**Mean** (s)	**Median** (s)	**5th to 95th percentile** (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.

Test Protocol

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

Test Protocol Name	APTT	**STD-Link**	No
Manage. ID[e]	5230		
Detector	for PTT PSL		
End Point	50 %		
Maximum Time	190 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	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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	APTT

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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RxOnly

Fibrinogen

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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
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	REF B4244-10				
	20 × → 1 mL				n/a
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	REF 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[c]	–	24
CALIBRATOR 1	n/a[d]	–	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

[c] 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] CALIBRATOR 1 is not used in this test.

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	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**	**r**[e]
Fibrinogen / Multifibren® U on BCT	y = 1.01 × – 0.28 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 N	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:

Comments	**n**	**Mean** (g/L)	**Median** (g/L)	**5th to 95th percentile** (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.

Test Protocol

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

Test Protocol Name	Fbg		**STD-Link**	No
Manage. ID[f]	5360			
Detector	for Fbg			
End Point		30 %		
Maximum Time		100 sec		
Sensitivity	Low Gain			
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.

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	M
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	—	—

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

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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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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
THROMBIN REAGENT	REF B4233-25	REF B4233-27			
	10 × → 1 mL	10 × → 5 mL			Fbg
FIBRINOGEN DETERMINATION	REF 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	REF B4244-10				
	20 × → 1 mL				n/a
CONTROL P	REF OUPZ19				
	10 × → 1 mL				n/a
Data-Fi FIBRINOGEN CONTROL	REF B4233-22				
	10 × → 1 mL				n/a
STANDARD PLASMA	REF ORKL19				
	10 × → 1 mL				SHP
CA SYSTEM BUFFER	REF B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 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[b]	–	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

Component	Position	Condition	**Time** (h)
CA SYSTEM BUFFER	Buffer position 12	GW 5; SLD Vial[c]	8
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.
[c] For positioning on the analyzer, the buffer has to be transferred into an appropriate vial.

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**	**r**[d]
Fibrinogen / Dade® Thrombin Reagent on CA-1500	y = 1.05 × + 0.04 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:

Comments	**n**	**Mean** (g/L)	**Median** (g/L)	**5th to 95th percentile** (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.

Test Protocol

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

Test Protocol Name	Fbg	**STD-Link**	Master
Manage. ID[e]	5300		
Detector	for Fbg		
End Point	50 %		
Maximum Time	100 sec		
Sensitivity	High Gain		
Sample Vol	10 µL		
Dil.Vol	OVB	90 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

[e] 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 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

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)**
5.20	5.5
3.90	6.7
2.60	9.6
1.30	19.2
0.87	34.1

Test Protocol

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

Test Protocol Name	+Fbg		**STD-Link**	Fbg
Manage. ID[f]	5310			
Detector	for Fbg			
End Point		50 %		
Maximum Time		100 sec		
Sensitivity	High Gain			
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

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

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.

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

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

Test Protocol

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

Test Protocol Name	-Fbg	**STD-Link**	Fbg
Manage. ID[g]	5320		
Detector	for Fbg		
End Point	50 %		
Maximum Time	100 sec		
Sensitivity	High Gain		
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

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

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.

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

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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RxOnly

Thrombin Time/Batroxobin Time

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

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
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	REF 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.

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[b]	–	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

[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	341
Hemoglobin	20
Bilirubin	24

Performance Characteristics

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

Method Comparison

Predicate Device	Regression Equation	r[c]
TT / Test Thrombin Reagent on BFA	y = 0.56 × + 5.69 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:

Comments	n	Mean (s)	Median (s)	2.5th to 97.5th percentile (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.

Test Protocol

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

Test Protocol Name	TT		**STD-Link**	No
Manage. ID[d]	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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	TT

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Batroxobin REAGENT	REF OUOV21				
	2 × → 5 mL				Batrox
CONTROL N	REF ORKE45				
	10 × → 1 mL				n/a
CA CLEAN I	REF 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	4[b]	–	48
CONTROL N	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	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	r[c]
Batroxobin time / Batroxobin Reagent on BCT	y = 0.77 × + 5.66 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 %

	Within Run CV (%)	Run to Run CV (%)	Total CV (%)
CONTROL N	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:

Comments	n	Mean (s)	Median (s)	5^{th} to 95^{th} percentile (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.

Test Protocol

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

Test Protocol Name	BXT	**STD-Link**	No
Manage. ID[d]	5350		
Detector	for BXT		
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	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

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

Standard Curve Calibration

The assay is not calibrated.

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	BXT

Number of Replicates

Special Menu – Settings – **Analysis Settings**

– Set Replication	Replicates	1

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Clotting Assays

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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
FACTOR VII DEFICIENT	REF OTXV13				
	3 × → 1 mL				VII
Dade® Innovin®	REF B4212-41	REF B4212-51	REF B4212-101		
	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 B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 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 VII DEFICIENT	6[b]	–	8
Dade® Innovin®	1[c]	–	24
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 non-cooled reagent position (positions Reagent holder position 5 to 10) can be used.
[c] 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	3 000
Hemoglobin	1 000
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**[d]
Coagulation Factor VII / Thromborel® S on BCT	y = 0.97 × – 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.

Test Protocol

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

Test Protocol Name	VII		**STD-Link**	No
Manage. ID[e]	5410			
Detector	for F-Ext[f]			
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	*******	0 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	*******	0 µL		
Pre. Rinse	*******			x 0
Post. Rinse	*******			x 0

[e] The Management ID only applies to the CA-600 series.
[f] For the CA-600 series, it is also possible to select the detector "for FExtINN".

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.

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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	≥ 00-17[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
FACTOR VIII DEFICIENT	REF OTXW17				
	8 × → 1 mL				VIII
ACTIN FSL	REF B4219-1	REF 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
$CaCl_2$ SOLUTION	REF ORHO37				
	10 × 15 mL				CaCl2
CA SYSTEM BUFFER	REF B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 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[b]	–	4
ACTIN FSL	2[c]	–	48
STANDARD PLASMA	#1	–	n/a
CONTROL N	Any position on sample rack	–	n/a
CONTROL P	Any position on sample rack	–	n/a
$CaCl_2$ SOLUTION	7[d]	–	48
CA SYSTEM BUFFER	Buffer position 12	–	n/a

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

[b] Alternatively, any other non-cooled reagent position can be used.
[c] 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.

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**	**r**[e]
Coagulation Factor VIII / Pathromtin® SL on BCT	y = 1.00 × + 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 N	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.

Test Protocol

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

Test Protocol Name	VIII	**STD-Link**	No
Manage. ID[f]	5430		
Detector	for F-Int[g]		
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	******* 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

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

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

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	VIII %

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

Test Protocol

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

Test Protocol Name	VIII	**STD-Link**	No
Manage. ID[h]	5430		
Detector	for F-Int[i]		
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	******* 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

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

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

Data Check

Special Menu – Settings – **Data Check**

– Mark Limits	Select Param.	VIII %

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)
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!

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.

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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[a]
USA only	

[a] CA-620, CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
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
$CaCl_2$ SOLUTION	REF ORHO37				
	10 × 15 mL				CaCl2
CA CLEAN I	REF 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)
PROTEIN C COAG ACTIVATOR	1[b]	–	24
PROTEIN C COAG REAGENT APTT	2[b]	–	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
$CaCl_2$ SOLUTION	7[c]	–	24
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.

[c] Alternatively, any other non-cooled reagent position (positions Reagent holder position 5 to 10) 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	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**	**r**[d]
Protein C / Protein C Reagent on BCT (coagulometric)	y = 1.01 × + 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 N	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.

Test Protocol

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

Test Protocol Name	PCcl	**STD-Link**	No
Manage. ID[e]	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	*******	0 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

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

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 %

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.

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

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Chromogenic Assays

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	08
Release Date	2024-04
Software Version	≥ 00-17[a]
USA only	

[a] CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
INNOVANCE® Antithrombin	REF OPFH07	REF OPFH09	REF 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	REF B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 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)
INNOVANCE Antithrombin REAGENT	4[b]	–	8
INNOVANCE Antithrombin SUBSTRATE	6[c]	–	8
INNOVANCE Antithrombin BUFFER	10	–	8
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.

[c] 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	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**	**r**[d]
ATIII / Berichrom® Antithrombin III (A) on CA-500 series	y = 1.00 × – 0.03 % of Norm	0.972

[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 (% of Norm)	**Repeatability CV** (%)	**Within-Device/Lab CV** (%)
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	56.6	1.5	4.5

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:

Comments	**n**	**Mean** (% of Norm)	**Median** (% of Norm)	**2.5th to 97.5th percentile** (% 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.

Test Protocol

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

Test Protocol Name	AT	**STD-Link**	No
Manage. ID[e]	6000		
Detector	for BCAT3		
Start Point		6 sec	
End Point		21 sec	
Sensitivity	Low Gain		
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

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

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

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

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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.

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[a]
USA only	

[a] CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Berichrom AT III	REF OWWR17	REF OWWR15			
• Berichrom AT III REAGENT THR	6 × → 5 mL	6 × → 15 mL			AT3Thro
• Berichrom AT III SUBSTRATE	3 × → 3 mL	6 × → 3 mL			AT3Subs
• Berichrom AT III REAGENT THR DILUENT	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 B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 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	4[b]	–	8
Berichrom AT III SUBSTRATE	6[c]	–	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 Vial[d]	8
OV BUFFER	Buffer position 12	GW 5; SLD Vial	8
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.
[c] 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.

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**[e]
ATIII / Berichrom® Antithrombin III (A) on CA-6000	y = 0.95 × + 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 N	2.3	4.5	5.0
CONTROL P	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:

Comments	**n**	**Mean** (% of Norm)	**Median** (% of Norm)	**2.5th to 97.5th percentile** (% 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.

Test Protocol

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

Test Protocol Name	AT3		**STD-Link**	No
Manage. ID[f]	6010			
Detector	for BCAT3			
Start Point		11 sec		
End Point		40 sec		
Sensitivity	Low Gain			
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	*******	0 µL		
Pre. Rinse	*******			x 0
Post. Rinse	*******			x 0

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

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

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

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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	≥ 00–27[a]
USA only	

[a] CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
INNOVANCE HEPARIN	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[b]	REF ORKL19				
	10 × → 1 mL				SHP
CA SYSTEM BUFFER	REF B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF 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				
	100 pcs.				n/a
BC Vial Kit (empty vials for 5 mL)	REF OVKE03				
	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.

On-board Stability

Component	Position	Condition	**Time** (h)
INNOVANCE HEPARIN REAGENT	1[c]	–	16
INNOVANCE HEPARIN SUBSTRATE	2[c]	–	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[d]	16
OV BUFFER	Buffer position 12	PV-10	16
CA CLEAN I	Rinse position 11	PV-10	24

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

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**	**r**[e]
Heparin / INNOVANCE® Heparin on BCS® XP (UFH (n=148) and LMWH (n=132) containing samples)	y = 0.97 × – 0.04 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] ≤ 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

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

	Mean (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.

Test Protocol

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

Test Protocol Name	IHep	**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	******* 0 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	******* 0 µL		
Pre. Rinse	*******		x 0
Post. Rinse	*******		x 0

Standard Curve Calibration

Calibration Parameter 1

Standard Curve – **Select Param.**

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

Standard Curve – **Standard Analysis**

Select Dilution Set	M
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.	IHep
– Replic. Limits	Difference (%)	10
– Report Limits	lower (<)	0.10 IU/mL
	upper (>)	1.50 IU/mL

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.

IHep

(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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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.

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[a]
USA only	

[a] CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
Berichrom PROTEIN C	REF OUVV15	REF OUVV17			
• Berichrom PROTEIN C ACTIVATOR	3 × → 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 B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	10 × 15 mL				OVB
CA CLEAN I	REF 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[b]	–	48
Berichrom PROTEIN C SUBSTRATE	2[b]	–	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.

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**	**r**[c]
Protein C / Berichrom® Protein C on BCT	y = 1.05 × – 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.

Test Protocol

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

Test Protocol Name	BCPC	**STD-Link**	No
Manage. ID[d]	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	*******	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	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	*******	0 µL	
Pre. Rinse	*******		x 0
Post. Rinse	*******		x 0

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

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**

– Mark Limits	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

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Immunoassays

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.

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	11
Release Date	2024-04
Software Version	≥ 00-17[a]
USA only	

[a] CA-660

Materials Required

Product • Component(s)	Order No. Package Size 1	Order No. Package Size 2	Order No. Package Size 3	Order No. Package Size 4	Name in Test Protocol
INNOVANCE® D-Dimer	REF OPBP09	REF OPBP11			
• INNOVANCE D-Dimer REAGENT	3 × → 4 mL	6 × → 4 mL			DDi.REA
• INNOVANCE D-Dimer BUFFER	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 DILUENT	3 × 5 mL	6 × 5 mL			DDi.DIL
• INNOVANCE D-Dimer CALIBRATOR	2 × → 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 B4265-37				
	8 × 250 mL				OVB
OV BUFFER	REF B4234-25				
	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 appropiate 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[b]	–	16
	6[b]	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer BUFFER	4[c]	–	16
	4[c]	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer SUPPLEMENT	8[b]	–	16
	8[b]	Sample Cup Conical 4 mL	4
INNOVANCE D-Dimer DILUENT	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

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

[b] Alternatively, any other non-cooled reagent position can be used.
[c] 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.

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 × 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**	**r**[d]
D-dimer / INNOVANCE® D-Dimer on BCS®	y = 1.09 × – 0.03 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 %

	Mean (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

0.50 mg/L FEU. A D-dimer result < 0.50 mg/L FEU was considered negative and a D-dimer result ≥ 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 n	Cutoff [mg/L FEU]	Sensitivity (CL) %	Specificity (CL) %	NPV (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 ≥ 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 n	Cutoff [mg/L FEU]	Sensitivity (CL) %	Specificity (CL) %	NPV (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:

Comments	n	Mean	Median (mg/L FEU)	90th percentile (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.

Test Protocol

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

Test Protocol Name	DDi	**STD-Link**	Master
Manage. ID[e]	6500		
Detector	for IMMUNO2[f]		
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

[e] The Management ID only applies to the CA-600 series.
[f] For the CA-600 series, it is also possible to select the detector "for DD INN".

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

Data Check

Special Menu – Settings – **Data Check**

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

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.

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

Test Protocol

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

Test Protocol Name	+DDi		**STD-Link**	DDi
Manage. ID[g]	6510			
Detector	for IMMUNO2[h]			
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

[g] The Management ID only applies to the CA-600 series.
[h] For the CA-600 series, it is also possible to select the detector "for DD INN".

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**

– Set Replication	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.

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RxOnly

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

[a] 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	10446673
		OWWR15	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	10446499
		OUVV17	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 N	Control Plasma N	ORKE45	10446235
CONTROL P	Control Plasma P	OUPZ19	10446472
$CaCl_2$ 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

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 OPFH09 OPFH11	10487304 10487303 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 BUFFER	• INNOVANCE® D-Dimer buffer		
• INNOVANCE D-Dimer SUPPLEMENT	• INNOVANCE® D-Dimer supplementary reagent		
• INNOVANCE D-Dimer DILUENT	• INNOVANCE® D-Dimer Sample Diluent		
• INNOVANCE D-Dimer CALIBRATOR	• INNOVANCE® D-Dimer Calibrator		
Multifibren® U	Multifibren® U	OWZG19 OWZG23	10446689 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