

## Glucose Hexokinase\_3 (GluH\_3)

<b>Current Revision and Date<sup>a</sup></b>	Rev. 04, 2020-08	
<b>Product Name</b>	Atellica CH Glucose Hexokinase_3 (GluH_3)	<b>REF</b> 11097592 (6240 tests)
<b>Abbreviated Product Name</b>	Atellica CH GluH_3	
<b>Test Name/ID</b>	GluH_3	
<b>Systems</b>	Atellica CH Analyzer	
<b>Materials Required but Not Provided</b>	Atellica CH CHEM CAL	<b>REF</b> 11099411
<b>Specimen Types</b>	Serum, cerebrospinal fluid (CSF), plasma (lithium heparin, potassium EDTA, sodium fluoride/potassium oxalate), and urine	
<b>Sample Volume</b>	3.4 µL	
<b>Measuring Interval</b>	4–700 mg/dL (0.2–38.9 mmol/L)	

<sup>a</sup> A vertical bar in the page margin indicates technical content that differs from the previous version.



## Intended Use

The Atellica® CH Glucose Hexokinase\_3 (GluH\_3) assay is for *in vitro* diagnostic use in the quantitative determination of glucose in human serum, cerebrospinal fluid (CSF), plasma (lithium heparin, potassium EDTA, sodium fluoride/potassium oxalate), and urine using the Atellica® CH Analyzer. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose.

## Summary and Explanation

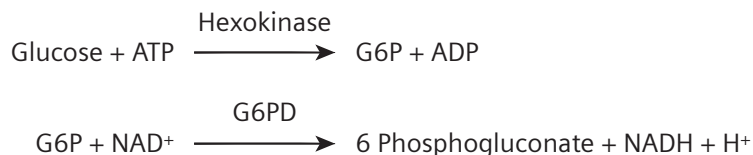
This enzymatic assay is based on the assay by Slein using hexokinase and glucose-6-phosphate dehydrogenase enzymes.<sup>1,2</sup>

Glucose is phosphorylated by adenosine triphosphate (ATP) in the presence of hexokinase. The glucose-6-phosphate that forms is oxidized in the presence of glucose-6-phosphate dehydrogenase causing the reduction of oxidized nicotinamide adenine dinucleotide (NAD) to reduced nicotinamide adenine dinucleotide (NADH).<sup>1,2</sup> The absorbance of NADH is measured as an endpoint reaction at 340/410 nm.

## Principles of the Procedure

The Atellica CH Glucose Hexokinase\_3 (GluH\_3) assay uses a two-component reagent. Sample is added to Reagent 1, which contains the buffer, ATP, and NAD. Absorbance readings of the sample in Reagent 1 are taken and are used to correct for interfering substances in the sample. Reagent 2 is added, which initiates the conversion of glucose and the development of absorbance at 340/410 nm. The difference between the absorbance in Reagent 1 and Reagent 2 is proportional to the glucose concentration.

## Reaction Equation



## Reagents

Material Description	Storage	Stability <sup>a</sup>
<b>Atellica CH GluH_3</b>	Unopened at 2–8°C	Until expiration date on product
<b>Pack 1 (P1)</b>	Onboard per well	62 days
Well 1 (W1)		
Reagent 1 (R1)		
23.3 mL		
ATP (12 mmol/L); NAD (9.63 mmol/L); sodium azide (0.05%); buffer		
Well 2 (W2)		
Reagent 1 (R1)		
23.3 mL		
ATP (12 mmol/L); NAD (9.63 mmol/L); sodium azide (0.05%); buffer		
<b>Pack 2 (P2)</b>		
Well 1 (W1)		
Reagent 2 (R2)		
23.5 mL		
ATP (4 mmol/L); NAD (3.21 mmol/L); sodium azide (0.09%); hexokinase (microbial) (> 6.25 U/mL); G6PDH (microbial) (> 11.25 U/mL); buffer		
Well 2 (W2)		
Reagent 2 (R2)		
23.5 mL		
ATP (4 mmol/L); NAD (3.21 mmol/L); sodium azide (0.09%); hexokinase (microbial) (> 6.25 U/mL); G6PDH (microbial) (> 11.25 U/mL); buffer		

<sup>a</sup> Refer to *Storage and Stability*.

## Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

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**CAUTION**

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

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Safety data sheets (SDS) available on [siemens.com/healthineers](https://www.siemens.com/healthineers).

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

**Note** For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

## Storage and Stability

Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

## Onboard Stability

Reagents are stable onboard the system for 62 days. Discard reagents at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

## Specimen Collection and Handling

Serum, cerebrospinal fluid (CSF), plasma (lithium heparin, potassium EDTA, sodium fluoride/potassium oxalate), and urine are the recommended sample types for this assay.

## Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.<sup>3</sup>
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.<sup>4</sup>
- Follow the instructions provided with your specimen collection device for use and processing.<sup>5</sup>
- Allow blood specimens to clot completely before centrifugation.<sup>6</sup>
- Keep tubes capped at all times.<sup>6</sup>
- In 24-hour collection of urine, glucose may be preserved by adding 5 mL of glacial acetic acid to the container before starting the collection. The final pH of the urine is usually between 4 and 5, which inhibits bacterial activity.<sup>7</sup>
- Urine should be stored at 4°C during collection. Urine samples may lose as much as 40% of their glucose after 24 hours at room temperature.<sup>7</sup>
- CSF may be contaminated with bacteria or other cells and should be analyzed immediately for glucose. If a delay in measurement is unavoidable, the sample should be centrifuged and stored at 4°C or -20°C.<sup>7</sup>

## Storing the Specimen

### Room Temperature

Glycolysis decreases serum glucose by approximately 5% to 7% per hour in normal uncentrifuged, coagulated blood at room temperature. In separated, non-hemolyzed sterile serum, the glucose concentration is generally stable as long as 8 hours at 25°C. Glycolysis can be inhibited and glucose stabilized for as long as 3 days at room temperature by addition of sodium iodoacetate or sodium fluoride (NaF) to the specimen.<sup>7</sup>

### Refrigerated

In separated, nonhemolyzed sterile serum, the glucose concentration is generally stable as long as 72 hours at 4°C; variable stability is observed with longer storage conditions.<sup>7</sup>

Urine should be stored at 4°C during collection. Urine samples may lose as much as 40% of their glucose after 24 hours at room temperature.<sup>7</sup>

CSF may be contaminated with bacteria or other cells and should be analyzed immediately for glucose. If a delay in measurement is unavoidable, the sample should be centrifuged and stored at 4°C or -20°C.<sup>7</sup>

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

## Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

## Preparing the Samples

This assay requires 3.4 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

**Note** Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

**Note** Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.<sup>6</sup>

**Note** For a complete list of appropriate sample containers, refer to the online help.

## Procedure

### Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11097592	<b>Pack 1 (P1)</b> Well 1 (W1) 23.3 mL of Atellica CH GluH_3 Reagent 1 Well 2 (W2) 23.3 mL of Atellica CH GluH_3 Reagent 1  <b>Pack 2 (P2)</b> Well 1 (W1) 23.5 mL of Atellica CH GluH_3 Reagent 2 Well 2 (W2) 23.5 mL of Atellica CH GluH_3 Reagent 2	4 x 1560

### Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description
	Atellica CH Analyzer <sup>a</sup>
11099411	Atellica CH CHEM CAL (calibrator) 12 x 3.0 mL calibrator <b>CAL</b> Calibrator lot-specific value sheet <b>CAL</b> <b>LOT</b> <b>VAL</b>
	Commercially available quality control materials

<sup>a</sup> Additional system fluids are required to operate the system: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. For system fluid instructions for use, refer to the Document Library.

### Assay Procedure

The system automatically performs the following steps:

1. For serum, plasma, urine, and cerebrospinal fluid (CSF), dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 26.7 µL of Reagent 1 and 53.3 µL of special reagent water into a reaction cuvette.
3. Dispenses 3.4 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 16 µL of Reagent 2 into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C.
7. Measures the absorbance after Reagent 2 addition.
8. Reports results.

**Note** For information about special reagent water requirements, refer to the online help.

Test Duration: 7 minutes

### Preparing the Reagents

All reagents are liquid and ready to use.

## Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

## Performing Calibration

For calibration of the Atellica CH GluH\_3 assay, use Atellica CH CHEM CAL. Use the calibrators in accordance with the calibrator instructions for use.

### Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	182
Pack Calibration	30
Reagent Onboard Stability	62

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

## Performing Quality Control

For quality control of the Atellica CH GluH\_3 assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. Use the quality control material in accordance with the quality control instructions for use.

For the assigned values, refer to the lot-specific value sheet provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

### Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

## Results

### Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in mg/dL (common units) or mmol/L (SI units), depending on the units defined when setting up the assay.

Conversion formula:  $\text{mg/dL} \times 0.0555 = \text{mmol/L}$

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

### Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

### Limitations

The Atellica CH GluH\_3 assay is limited to the detection of glucose in human serum, cerebrospinal fluid (CSF), plasma (lithium heparin, potassium EDTA, sodium fluoride/potassium oxalate) and urine.

## Expected Values

### Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified on the Atellica CH Analyzer.<sup>8</sup>

Group	Specimen Type	Reference Interval Common Units (SI Units)
Adults	Serum/plasma <sup>9</sup>	74–106 mg/dL (4.1–5.9 mmol/L)
Newborn	Serum/plasma <sup>9</sup>	40–60 mg/dL (2.2–3.3 mmol/L)
Newborn > 1 day	Serum/plasma <sup>9</sup>	50–80 mg/dL (2.8–4.4 mmol/L)
Child	Serum/plasma <sup>9</sup>	60–100 mg/dL (3.3–5.6 mmol/L)
Adults	Urine <sup>9</sup>	< 0.5 g/day (2.8 mmol/day)
Adults	Cerebral spinal fluid <sup>9</sup>	40–70 mg/dL (2.2–3.9 mmol/L)
Infant/child	Cerebral spinal fluid <sup>9</sup>	60–80 mg/dL (3.3–4.4 mmol/L)

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.<sup>7</sup>

## Performance Characteristics

### Measuring Interval

The Atellica CH GluH\_3 assay provides results from 4 mg/dL (0.2 mmol/L) to 700 mg/dL (38.9 mmol/L). The system flags all values that are outside the specified measuring interval.

## Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 2100 mg/dL (116.6 mmol/L) for serum, plasma, urine and CSF. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

## Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.<sup>10</sup> The assay is designed to have a limit of blank (LoB)  $\leq$  limit of detection (LoD) and  $\text{LoD} \leq 4 \text{ mg/dL}$  ( $\leq 0.2 \text{ mmol/L}$ ) for serum and plasma. The assay is designed to have a  $\text{LoB} \leq \text{LoD}$  and  $\text{LoD} \leq 4 \text{ mg/dL}$  ( $\leq 0.2 \text{ mmol/L}$ ) for urine. The assay is designed to have a  $\text{LoB} \leq \text{LoD}$  and  $\text{LoD} \leq 4 \text{ mg/dL}$  ( $\leq 0.2 \text{ mmol/L}$ ) for CSF.

The LoD corresponds to the lowest concentration of glucose that can be detected with a probability of 95%. The LoD for the Atellica CH GluH\_3 assay is 1 mg/dL (0.1 mmol/L) for serum and plasma, 0 mg/dL (0.0 mmol/L) for urine and 2 mg/dL (0.1 mmol/L) for CSF, and were determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0 mg/dL (0.0 mmol/L) for serum and plasma, 0 mg/dL (0.0 mmol/L) for urine and 1 mg/dL (0.1 mmol/L) for CSF.

Assay results obtained at individual laboratories may vary from the data presented.

## Precision

Precision was determined in accordance with CLSI Document EP05-A3.<sup>11</sup> Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days ( $N \geq 80$  for each sample). The following results were obtained:

Sample Type	N	Mean mg/dL (mmol/L)	Repeatability		Designed to be $\leq$		Within-Lab Precision		Designed to be $\leq$	
			SD <sup>a</sup> mg/dL (mmol/L)	CV <sup>b</sup> (%)	CV (%)		SD mg/dL (mmol/L)	CV (%)	CV (%)	
Serum QC	80	59 (3.3)	0.5 (0.0)	0.8	1.7		1.2 (0.1)	2.0	2.2	
Serum Pool	80	90 (5.0)	0.6 (0.0)	0.7	1.7		1.2 (0.1)	1.4	2.2	
Plasma Pool	80	292 (16.2)	1.4 (0.1)	0.5	1.3		3.3 (0.2)	1.1	2.2	
Serum Pool	80	483 (26.8)	1.8 (0.1)	0.4	1.3		4.6 (0.3)	1.0	2.2	
Urine Pool	80	38 (2.1)	0.7 (0.0)	1.9	3.4		1.4 (0.1)	3.8	4.1	
Urine QC	80	285 (15.8)	1.1 (0.1)	0.4	1.9		3.6 (0.2)	1.3	3.6	
CSF Pool	80	42 (2.3)	0.8 (0.0)	2.0	2.6		1.0 (0.1)	2.3	3.5	
CSF Pool	80	96 (5.3)	0.6 (0.0)	0.7	1.5		1.1 (0.1)	1.2	2.1	

<sup>a</sup> Standard deviation.

<sup>b</sup> Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.



## Assay Comparison

The Atellica CH GluH\_3 assay is designed to have a correlation coefficient of  $> 0.96$  for serum, urine and CSF and a slope of  $1.0 \pm 0.05$  compared to ADVIA® Chemistry 1800 GluH\_3. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.<sup>12</sup> The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N <sup>a</sup>	r <sup>b</sup>
Serum	ADVIA Chemistry 1800 GluH_3	$y = 1.03x - 1 \text{ mg/dL}$ ( $y = 1.03x - 0.1 \text{ mmol/L}$ )	34–665 mg/dL (1.9–36.9 mmol/L)	105	1.00
Urine	ADVIA Chemistry 1800 GluH_3	$y = 1.04x - 1 \text{ mg/dL}$ ( $y = 1.04x - 0.1 \text{ mmol/L}$ )	5–667 mg/dL (0.3–37.0 mmol/L)	100	1.00
CSF	ADVIA Chemistry 1800 GluH_3	$y = 1.03x + 2 \text{ mg/dL}$ ( $y = 1.03x + 0.1 \text{ mmol/L}$ )	6–668 mg/dL (0.3–37.1 mmol/L)	110	1.00

<sup>a</sup> Number of samples tested.

<sup>b</sup> Correlation coefficient.

The agreement of the assay may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

## Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.<sup>12</sup> The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N <sup>a</sup>	r <sup>b</sup>
Lithium heparin plasma	Serum	$y = 0.99x - 1 \text{ mg/dL}$ ( $y = 0.99x + 0.1 \text{ mmol/L}$ )	8–689 mg/dL (0.4–38.2 mmol/L)	53	0.999
Plasma (potassium EDTA)	Serum	$y = 0.97x + 0 \text{ mg/dL}$ ( $y = 0.97x + 0.0 \text{ mmol/L}$ )	5–669 mg/dL (0.3–37.1 mmol/L)	50	0.998
Plasma (sodium fluoride/ potassium oxalate) <sup>c</sup>	Serum	$y = 1.01x + 2 \text{ mg/dL}$ ( $y = 1.01x + 0.1 \text{ mmol/L}$ )	11–589 mg/dL (0.6–32.7 mmol/L)	54	0.999

<sup>a</sup> Number of samples tested.

<sup>b</sup> Correlation coefficient.

<sup>c</sup> These data were generated on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.<sup>13</sup>

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

## Interferences

### Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH GluH\_3 assay is designed to have  $\leq 10\%$  interference from hemolysis, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH GluH\_3 assay.<sup>14</sup>

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Bias  $> 10\%$  is considered interference. Analyte results should not be corrected based on this bias.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mg/dL (mmol/L)	Percent Bias
Hemoglobin	1000 mg/dL (0.62 mmol/L)	82 (4.6)	4
	1000 mg/dL (0.62 mmol/L)	117 (6.5)	3
Bilirubin, conjugated	30 mg/dL (513 µmol/L)	85 (4.7)	-1
	30 mg/dL (513 µmol/L)	124 (6.9)	2
Bilirubin, unconjugated	30 mg/dL (513 µmol/L)	84 (4.7)	1
	30 mg/dL (513 µmol/L)	123 (6.8)	1
Lipemia (Intralipid®)	1000 mg/dL (11.3 mmol/L)	83 (4.6)	-5
	1000 mg/dL (11.3 mmol/L)	116 (6.4)	-1

Assay results obtained at individual laboratories may vary from the data presented.

## Non-Interfering Substances

The following substances do not interfere with the Atellica CH GluH\_3 assay when present in urine at the concentrations indicated in the table below. Bias due to these substances is < 10% at an analyte concentration of 35 mg/dL (1.9 µmol/L). These data were generated on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.<sup>13</sup>

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Ascorbic Acid	200 mg/dL (11.4 mmol/L)	< 10%
Salicylate	50 mg/dL (3.6 mmol/L)	< 10%
Caffeine	50 mg/dL (2.6 mmol/L)	< 10%
Creatinine	500 mg/dL (44.2 mmol/L)	< 10%
Urea	500 mg/dL (83.3 mmol/L)	< 10%

Assay results obtained at individual laboratories may vary from the data presented.

## Standardization

The Atellica CH GluH\_3 assay is traceable to the Standard Reference Material 965a from the National Institute of Standards and Technology (NIST).

Assigned values for calibrators are traceable to this standardization.<sup>13</sup>

## Technical Assistance

For customer support, contact your local technical support provider or distributor.

[siemens.com/healthineers](http://siemens.com/healthineers)







## References



1. Bergmeyer HU, ed. *Methods of Enzymatic Analysis*. New York, NY: Academic Press; 1974:117-130.
2. Slein MW, Cori GT, Cori CF. A comparative study of hexokinase from yeast and animal tissues. *J Biol Chem*. 1950;186(2):763-780.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.



















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5. Clinical and Laboratory Standards Institute. *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP39-A6.
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8. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
9. Wu AHB. *Tietz Clinical Guide to Laboratory Tests*. 4th ed. St. Louis, MO: WB Saunders Company; 2006:444-450.
10. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
11. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
12. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
13. Data on file at Siemens Healthcare Diagnostics.
14. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document EP07-A2.

## Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
 Rev. 01	Version of instructions for use
 <a href="https://www.siemens.com/healthcare">siemens.com/healthcare</a>  <a href="https://www.siemens.com/document-library">siemens.com/document-library</a>	Internet URL address to access the electronic instructions for use
Rev. 	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.

Symbol	Symbol Title and Description
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	<i>In vitro</i> diagnostic medical device

Symbol	Symbol Title and Description
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
<b>RxOnly</b>	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
<b>YYYY-MM-DD</b>	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material

Symbol	Symbol Title and Description
<b>MATERIAL ID</b>	Unique material identification number
<b>CONTROL NAME</b>	Name of control
<b>CONTROL TYPE</b>	Type of control

## Legal Information

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