SIEMENS Healthineers

# Alkaline Phosphatase, Concentrated (ALP_2c)

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| **Current Revision and Date**[a] | Rev. 03, 2019-07 | |
| **Product Name** | Atellica CH Alkaline Phosphatase, Concentrated (ALP_2c) | REF 11097600 (4800 tests) |
| **Abbreviated Product Name** | Atellica CH ALP_2c | |
| **Test Name/ID** | ALP_2c | |
| **Systems** | Atellica CH Analyzer | |
| **Materials Required but Not Provided** | Atellica CH ALP_2 CAL | REF 11099316 |
| **Specimen Types** | Serum and plasma (lithium heparin) | |
| **Sample Volume** | 10 µL | |
| **Measuring Interval** | 10–1000 U/L | |

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

## Intended Use

The Atellica® CH Alkaline Phosphatase, Concentrated (ALP_2c) assay is for *in vitro* diagnostic use in the quantitative determination of alkaline phosphatase in human serum and plasma (lithium heparin) using the Atellica® CH Analyzer. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

## Summary and Explanation

The Atellica CH Alkaline Phosphatase, Concentrated (ALP_2c) assay is based on the primary reference procedure for the measurement of catalytic activity of alkaline phosphatase at 37°C as described by the International Federation of Clinical Chemistry (IFCC). The alkaline phosphatase method is based on a procedure published by Bowers and McComb[1] and more recently reviewed by Rej.[2] This assay responds to all alkaline phosphatase isoenzymes in human serum.[3]

# Principles of the Procedure

Alkaline phosphatase catalyzes the transphosphorylation of *p*-nitrophenylphosphate (*p*-NPP) to *p*-nitrophenol (*p*-NP) in the presence of the transphosphorylating buffer, 2-amino-2-methyl-1-propanol (AMP). The reaction is enhanced through the use of magnesium and zinc ions. The change in absorbance at 410 nm due to the formation of *p*-NP is directly proportional to the Atellica CH Alkaline Phosphatase, Concentrated (ALP_2c) activity, since other reactants are present in non-rate limiting quantities. The change is measured using a bichromatic (410/478 nm) rate technique.

## Reaction Equation

$$p\text{-NPP} + \text{AMP} \xrightarrow[\text{pH 10.25 Mg/Zn}]{\text{ALP}} p\text{-NP} + \text{AMP} + PO_4$$

# Reagents

| Material Description | Storage | Stability[a] |
|---|---|---|
| **Atellica CH ALP_2c** | Unopened at 2–8°C | Until expiration date on product |
| **Pack 1 (P1)** | | |
| Well 1 (W1)<br>Reagent 1 (R1)<br>18.4 mL<br>2-amino-2-methyl-1-propanol (AMP) buffer (3.0 mol/L); HEDTA (8.0 mmol/L); magnesium acetate (8.0 mmol/L); zinc sulfate (4.0 mmol/L); sodium azide (0.09%) | Onboard per well | 30 days |
| Well 2 (W2)<br>Reagent 1 (R1)<br>18.4 mL<br>2-amino-2-methyl-1-propanol (AMP) buffer (3.0 mol/L); HEDTA (8.0 mmol/L); magnesium acetate (8.0 mmol/L); zinc sulfate (4.0 mmol/L); sodium azide (0.09%) | | |
| **Pack 2 (P2)** | | |
| Well 1 (W1)<br>Reagent 2 (R2)<br>19.1 mL<br>Paranitrophenyl-phosphate (*p*-NPP) substrate (101.6 mmol/L); sodium azide (0.09%); ProClin 300 (0.024%) | | |
| Well 2 (W2)<br>Reagent 2 (R2)<br>19.1 mL<br>Paranitrophenyl-phosphate (*p*-NPP) substrate (101.6 mmol/L); sodium azide (0.09%); ProClin 300 (0.024%) | | |

[a] Refer to *Storage and Stability*

## Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

**CAUTION**

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

Safety data sheets (SDS) available on siemens.com/healthineers.

**H319, H315, H412**
**P280, P264, P273, P305+P351+P338, P337+P313, P501**

**Warning!**
Causes serious eye irritation. Causes skin irritation. Harmful to aquatic life with long lasting effects.
Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling. Avoid release to the environment. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Dispose of contents and container in accordance with all local, regional, and national regulations.
**Contains:** 2-amino-2-methylpropanol; sulfuric acid; zinc salt (1:1); heptahydrate (R1)

Contains 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (ProClin 300). May produce an allergic reaction.

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

Protect the product from light sources. 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 30 days per well. 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 and plasma (lithium heparin) 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.[4]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[5]
- Follow the instructions provided with your specimen collection device for use and processing.[6]

- Allow blood specimens to clot completely before centrifugation.[7]
- Keep tubes capped at all times.[7]

## Storing the Specimen

Specimens may be stored for up to 8 hours at 25°C or for up to 7 days at 2–8°C or stored frozen for up to 6 months at -20°C or colder. Avoid repeated freezing and thawing.[8]

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 10 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.[7]

**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 |
|---|---|---|
| 11097600 | **Pack 1 (P1)**<br>Well 1 (W1) 18.4 mL of Atellica CH ALP_2c Reagent 1<br>Well 2 (W2) 18.4 mL of Atellica CH ALP_2c Reagent 1<br><br>**Pack 2 (P2)**<br>Well 1 (W1) 19.1 mL of Atellica CH ALP_2c Reagent 2<br>Well 2 (W2) 19.1 mL of Atellica CH ALP_2c Reagent 2 | 4 x 1200 |

## Materials Required but Not Provided

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

| REF | Description | |
|---|---|---|
| | Atellica CH Analyzer[a] | |
| 11099316 | Atellica CH ALP_2 CAL (calibrator) | 6 x 1.0 mL calibrator CAL<br>Calibrator lot-specific value sheet CAL LOT VAL |
| | Commercially available quality control materials | |

[a] 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, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 26.9 µL of Reagent 1 and 53.1 µL of special reagent water into a reaction cuvette.
3. Dispenses 10 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 17 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: 8 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 ALP_2c assay, use Atellica CH ALP_2 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 | 60 |
| Pack Calibration | 17 |
| Reagent Onboard Stability | 30 |

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 ALP_2c 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 U/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 ALP_2c assay is limited to the detection of alkaline phosphatase in human serum and plasma (lithium heparin).

# 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.[9]

The reference interval for alkaline phosphatase is 46–116 U/L for adults. These data were established on the ADVIA® Chemistry system.[10]

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.[9]

# Performance Characteristics

## Measuring Interval

The Atellica CH ALP_2c assay provides results from 10–1000 U/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 2300 U/L for serum and plasma. 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.[11] The assay is designed to have a limit of blank (LoB) < 3 U/L, a limit of detection (LoD) ≤ 8 U/L, and a limit of quantitation (LoQ) 10 U/L with ± 40% total allowable error.

The LoD corresponds to the lowest concentration of alkaline phosphatase that can be detected with a probability of 95%. The LoD for the Atellica CH ALP_2c assay is 0.4 U/L, and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0 U/L.

The LoQ corresponds to the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error ≤ 40%. The LoQ of the Atellica CH ALP_2c assay is 6.2 U/L, based on 180 determinations, and was determined using multiple patient samples that were assayed using total analytical error definition of bias + 2SD.

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

## Precision

Precision was determined in accordance with CLSI Document EP05-A3.[12] Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

| | | | Repeatability | | Within-Lab Precision | |
|---|---|---|---|---|---|---|
| Sample Type | N | Mean U/L | SD[a] U/L | CV[b] (%) | SD U/L | CV (%) |
| Serum Pool | 80 | 87 | 0.37 | 0.4 | 1.17 | 1.3 |
| Control 1 | 80 | 277 | 0.55 | 0.2 | 1.81 | 0.7 |
| Plasma Pool | 80 | 841 | 1.50 | 0.2 | 13.02 | 1.5 |

[a] Standard deviation.
[b] Coefficient of variation.

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

## Assay Comparison

The Atellica CH ALP_2c assay is designed to have a correlation coefficient of > 0.960 and a slope of 1.0 ± 0.10 compared to Dimension® ALPI. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[13] The following results were obtained:

| Specimen | Comparative Assay (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Serum | Dimension ALPI | y = 1.05x - 4 U/L | 26–957 U/L | 104 | 1.000 |

[a] Number of samples tested.
[b] 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.[13] The following results were obtained:

| Specimen (y) | Reference Specimen (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Lithium heparin plasma | Serum | y = 1.01x - 3 U/L | 36–912 U/L | 62 | 0.999 |

[a] Number of samples tested.
[b] Correlation coefficient.

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 ALP_2c assay is designed to have ≤ 10% interference from hemoglobin, 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 ALP_2c assay.[14]

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 U/L | Percent Bias |
|---|---|---|---|
| Hemoglobin | 1000 mg/dL (0.62 mmol/L)<br>1000 mg/dL (0.62 mmol/L) | 264<br>813 | -5<br>-1 |
| Bilirubin, conjugated | 80 mg/dL (1368 µmol/L)<br>80 mg/dL (1368 µmol/L) | 265<br>868 | 6<br>2 |
| Bilirubin, unconjugated | 80 mg/dL (1368 µmol/L)<br>80 mg/dL (1368 µmol/L) | 251<br>827 | 9<br>3 |
| Lipemia (Intralipid®) | 600 mg/dL (6.8 mmol/L)<br>600 mg/dL (6.8 mmol/L) | 250<br>873 | 1<br>-2 |

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 ALP_2c assay when present in human serum and plasma (lithium heparin) at the concentrations indicated in the table below. Bias due to these substances is < 10% at an analyte concentration of 299 U/L. These data were generated on the Dimension Clinical Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[10]

| Substance | Substance Test Concentration Common Units (SI Units) | Percent Bias |
|---|---|---|
| Acetaminophen | 20 mg/dL (1324 µmol/L) | ≤ 10% |
| Amikacin | 8 mg/dL (137 µmol/L) | ≤ 10% |
| Ampicillin | 5.3 mg/dL (152 µmol/L) | ≤ 10% |
| Ascorbic acid | 6 mg/dL (342 µmol/L) | ≤ 10% |
| Caffeine | 6 mg/dL (308 µmol/L) | ≤ 10% |
| Carbamazepine | 3 mg/dL (127 µmol/L) | ≤ 10% |
| Chloramphenicol | 5 mg/dL (155 µmol/L) | ≤ 10% |
| Chlordiazepoxide | 1 mg/dL (33.3 µmol/L) | ≤ 10% |
| Chlorpromazine | 0.2 mg/dL (6.27 µmol/L) | ≤ 10% |
| Cholesterol | 503 mg/dL (13 mmol/L) | ≤ 10% |
| Cimetidine | 2 mg/dL (79.2 µmol/L) | ≤ 10% |
| Creatinine | 30 mg/dL (2.65 mmol/L) | ≤ 10% |
| Dextran 40 | 6000 mg/dL (1500 µmol/L) | ≤ 10% |
| Diazepam | 0.5 mg/dL (18 µmol/L) | ≤ 10% |
| Digoxin | 6.1 ng/mL (7.8 nmol/L) | ≤ 10% |
| Erythromycin | 6 mg/dL (81.6 µmol/L) | ≤ 10% |
| Ethanol | 400 mg/dL (86.8 mmol/L) | ≤ 10% |

| Substance | Substance Test Concentration Common Units (SI Units) | Percent Bias |
|---|---|---|
| Ethosuximide | 25 mg/dL (1770 µmol/L) | ≤ 10% |
| Furosemide | 6 mg/dL (181 µmol/L) | ≤ 10% |
| Gentamicin | 1 mg/dL (21 µmol/L) | ≤ 10% |
| Heparin | 3.0 U/mL (3000 U/L) | ≤ 10% |
| Ibuprofen | 50 mg/dL (2425 µmol/L) | ≤ 10% |
| Immunoglobulin G (IgG) | 5000 mg/dL (50 g/L) | ≤ 10% |
| Lidocaine | 1.2 mg/dL (51.2 µmol/L) | ≤ 10% |
| Lithium | 2.2 mg/dL (3.2 mmol/L) | ≤ 10% |
| Nicotine | 0.1 mg/dL (6.2 µmol/L) | ≤ 10% |
| Penicillin G | 25 U/mL (25000 U/L) | ≤ 10% |
| Pentobarbital | 8 mg/dL (354 µmol/L) | ≤ 10% |
| Phenobarbital | 10 mg/dL (431 µmol/L) | ≤ 10% |
| Phenytoin | 5 mg/dL (198 µmol/L) | ≤ 10% |
| Primidone | 4 mg/dL (183 µmol/L) | ≤ 10% |
| Propoxyphene | 0.16 mg/dL (4.91 µmol/L) | ≤ 10% |
| Protein: Total | 12000 mg/dL (120 g/L) | ≤ 10% |
| Protein: Albumin | 6000 mg/dL (60 g/L) | ≤ 10% |
| Salicylic acid | 60 mg/dL (4.34 mmol/L) | ≤ 10% |
| Theophylline | 4 mg/dL (222 µmol/L) | ≤ 10% |
| Triglycerides | 1500 mg/dL (16.95 mmol/L) | ≤ 10% |
| Urea | 500 mg/dL (83 mmol/L) | ≤ 10% |
| Uric acid | 20 mg/dL (1.2 mmol/L) | ≤ 10% |
| Vancomycin | 10 mg/dL (69 µmol/L) | ≤ 10% |
| Valproic acid | 50 mg/dL (3467 µmol/L) | ≤ 10% |

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

## Standardization

The Atellica CH ALP_2c assay is traceable to the primary reference procedure for the measurement of catalytic activity of alkaline phosphatase at 37°C as described by the International Federation of Clinical Chemistry (IFCC).

Assigned values for calibrators are traceable to this standardization.[10]

# Technical Assistance

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

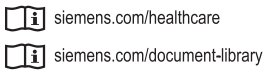
siemens.com/healthineers

# References


1. Bowers GN, McComb RB. A continuous spectrophotometric method for measuring the activity of serum alkaline phosphatase. *Clin Chem*. 1966;12:70.
2. Rej R. Effect of incubation with Mg++ on the measurement of alkaline phosphatase activity. *Clin Chem*. 1977; 23:1903–1911.
3. Schumann G, Bonora R, Ceriotti F, Ferard G, Ferrero CA, Franck PF, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 9: Reference procedure for the measurement of catalytic concentration of alkaline chosphatase. *Clin Chem Lab Med*. 2011;49:1439-1446.
4. 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.
5. Clinical and Laboratory Standards Institute. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.
6. 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.
7. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
8. Young DS. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. 3rd ed. Washington, DC: AACC Press; 2007:87.
9. 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.
10. Data on file at Siemens Healthcare Diagnostics.
11. 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.
12. 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.
13. 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.
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 |
|   | Version of instructions for use |
|   | Internet URL address to access the electronic instructions for use |
| Rev. REVISION | Revision |
|  | Caution<br>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. |
|  | Biological risks<br>Potential biological risks are associated with the medical device. |
|  | Corrosive |
|  | Dangerous to environment |
|  | Irritant<br>Oral, dermal, or inhalation hazard |
|  | Inhalation hazard<br>Respiratory or internal health |
|  | Flammable<br>Flammable to extremely flammable |
|  | Oxidizing |
|  | Explosive |
|  | Toxic |
|  | Compressed gas |
|  | Keep away from sunlight<br>Prevent exposure to sunlight and heat. |

| Symbol | Symbol Title and Description |
|---|---|
|  | Up<br>Store in an upright position. |
|  | Do not freeze |
|  | Temperature limit<br>Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines. |
|  | Handheld barcode scanner |
|  | *In vitro* diagnostic medical device |
|  | Contains sufficient for <n> tests<br>Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol. |
| **RxOnly** | Prescription device (US only)<br>Applies only to United States-registered IVD assays.<br>CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional. |
|  | Mixing of substances<br>Mix product before use. |
|  | Reconstitute and mix lyophilized product before use. |
|  | Target |
|  | Interval |
|  | Legal Manufacturer |
|  | Authorized Representative in the European Community |
|  | Use-by date<br>Use by the designated date. |
|  | Batch code |
|  | Catalog number |
|  | Recycle |
|  | Printed with soy ink |
|  | CE Mark |

| Symbol | Symbol Title and Description |
|---|---|
| CE 0088 | CE Mark with notified body ID number<br>Notified body ID number can vary. |
| YYYY-MM-DD | Date format (year-month-day) |
| CHECKSUM | Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid. |
| UNITS C | Common Units |
| UNITS SI | International System of Units |
| MATERIAL | Material |
| MATERIAL ID | Unique material identification number |
| CONTROL NAME | Name of control |
| CONTROL TYPE | Type of control |

## Legal Information



Siemens Healthcare Diagnostics Inc.
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