

## High Sensitivity C-Reactive Protein (hsCRP)

<b>Current Revision and Date<sup>a</sup></b>	Rev. 02, 2019-07
<b>Product Name</b>	Atellica CH High Sensitivity C-Reactive Protein (hsCRP) <span style="border: 1px solid black; padding: 0 2px;">REF</span> 11097633 (740 tests)
<b>Abbreviated Product Name</b>	Atellica CH hsCRP
<b>Test Name/ID</b>	hsCRP
<b>Systems</b>	Atellica CH Analyzer
<b>Materials Required but Not Provided</b>	Atellica CH hsCRP CAL <span style="border: 1px solid black; padding: 0 2px;">REF</span> 11099412
<b>Specimen Types</b>	Serum and plasma (lithium heparin, potassium EDTA)
<b>Sample Volume</b>	10 µL
<b>Measuring Interval</b>	0.16–10.00 mg/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 High Sensitivity C-Reactive Protein (hsCRP) assay is for *in vitro* diagnostic use in the quantitative determination of the concentration of C-reactive protein (CRP) in human serum and plasma (lithium heparin, potassium EDTA) using the Atellica® CH Analyzer. In acute phase response, increased levels of a number of plasma proteins, including CRP, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. High sensitivity CRP (hsCRP) measurements may be used as an independent risk marker for the identification of individuals at risk for future cardiovascular disease. Measurement of hsCRP, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndromes.<sup>1-9</sup>

### Summary and Explanation

In most normal individuals, C-reactive protein (CRP) is an acute-phase protein that is present in serum and plasma in very low concentrations. CRP serum concentrations become elevated in response to many pathological conditions, including infection, tissue injury, inflammatory disorders, and associated diseases. Increases in CRP values are non-specific for many disease processes and should not be interpreted without a complete clinical evaluation.

Studies have shown that measurement of CRP by high sensitivity assays is a strong independent predictor of risk for future cardiovascular and peripheral vascular disease.<sup>5,6</sup> High sensitivity CRP measurements have also been shown to add to the predictive value of other markers used to assess the risk of cardiovascular and peripheral vascular disease.<sup>6,8</sup> Elevated CRP values determined by high sensitivity CRP assays may be indicative of the prognosis of individuals with acute coronary syndromes, and may be useful in the management of such individuals.<sup>5</sup>

## Principles of the Procedure

The Atellica CH High Sensitivity C-Reactive Protein (hsCRP) latex reagent is a suspension of uniform polystyrene latex particles coated with anti-CRP antibody. When serum or plasma containing CRP is mixed with the latex reagent, agglutination takes place resulting in an increase in turbidity. This turbidity is measured at 571/658 nm. The CRP concentration in serum or plasma is determined from a calibration curve that is generated with the calibrators.

## Reagents

Material Description	Storage	Stability <sup>a</sup>
<b>Atellica CH hsCRP</b>	Unopened at 2–8°C	Until expiration date on product
<b>Pack 1 (P1)</b>	Onboard per well	30 days
Well 1 (W1) Reagent 1 (R1) 13.5 mL Glycine (170 mmol/L); sodium chloride (100 mmol/L); EDTA disodium salt dihydrate (50 mmol/L); sodium azide (0.09%)		
Well 2 (W2) Reagent 1 (R1) 13.5 mL Glycine (170 mmol/L); sodium chloride (100 mmol/L); EDTA disodium salt dihydrate (50 mmol/L); sodium azide (0.09%)		
<b>Pack 2 (P2)</b>		
Well 1 (W1) Reagent 2 (R2) 13.5 mL CRP antibody synthetic latex (rabbit); sodium azide (0.09%)		
Well 2 (W2) Reagent 2 (R2) 13.5 mL CRP antibody synthetic latex (rabbit); sodium azide (0.09%)		

<sup>a</sup> 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](http://siemens.com/healthineers).

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**CAUTION**

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

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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 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**

Human serum and plasma (lithium heparin, potassium EDTA) 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>10</sup>
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.<sup>11</sup>
- Follow the instructions provided with your specimen collection device for use and processing.<sup>12</sup>
- Allow blood specimens to clot completely before centrifugation.<sup>13</sup>
- Keep tubes capped at all times.<sup>13</sup>

**Storing the Specimen**

Specimens may be stored for up to 3 days at 4–8°C or stored frozen for up to 6 months at -20°C.<sup>15</sup> Avoid repetitive freezing and thawing of specimens. Centrifuge samples containing precipitates before performing the assay.

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.<sup>13</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
11097633	<b>Pack 1 (P1)</b> Well 1 (W1) 13.5 mL of Atellica CH hsCRP Reagent 1 Well 2 (W2) 13.5 mL of Atellica CH hsCRP Reagent 1  <b>Pack 2 (P2)</b> Well 1 (W1) 13.5 mL of Atellica CH hsCRP Reagent 2 Well 2 (W2) 13.5 mL of Atellica CH hsCRP Reagent 2	2 x 370

### 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>														
11099412	Atellica CH hsCRP CAL (calibrator) <table style="margin-left: 20px;"> <tr> <td>1 x 1.0 mL calibrator level 1</td> <td>CAL 1</td> </tr> <tr> <td>1 x 1.0 mL calibrator level 2</td> <td>CAL 2</td> </tr> <tr> <td>1 x 1.0 mL calibrator level 3</td> <td>CAL 3</td> </tr> <tr> <td>1 x 1.0 mL calibrator level 4</td> <td>CAL 4</td> </tr> <tr> <td>1 x 1.0 mL calibrator level 5</td> <td>CAL 5</td> </tr> <tr> <td>1 x 1.0 mL calibrator level 6</td> <td>CAL 6</td> </tr> <tr> <td>Calibrator lot-specific value sheet</td> <td>CAL LOT VAL</td> </tr> </table>	1 x 1.0 mL calibrator level 1	CAL 1	1 x 1.0 mL calibrator level 2	CAL 2	1 x 1.0 mL calibrator level 3	CAL 3	1 x 1.0 mL calibrator level 4	CAL 4	1 x 1.0 mL calibrator level 5	CAL 5	1 x 1.0 mL calibrator level 6	CAL 6	Calibrator lot-specific value sheet	CAL LOT VAL
1 x 1.0 mL calibrator level 1	CAL 1														
1 x 1.0 mL calibrator level 2	CAL 2														
1 x 1.0 mL calibrator level 3	CAL 3														
1 x 1.0 mL calibrator level 4	CAL 4														
1 x 1.0 mL calibrator level 5	CAL 5														
1 x 1.0 mL calibrator level 6	CAL 6														
Calibrator lot-specific value sheet	CAL LOT VAL														
	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, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 50 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 10 µL of pre-diluted sample into a reaction cuvette.
4. Dispenses 50 µL of Reagent 2 into a reaction cuvette.
5. Mixes and incubates the mixture at 37°C.
6. Measures the absorbance after Reagent 2 addition.
7. Reports results.

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 hsCRP assay, use Atellica CH hsCRP 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	30
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 hsCRP 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/L (common units).

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 hsCRP assay is limited to the detection of the concentration of c-reactive protein (CRP) in human serum and plasma (lithium heparin, potassium EDTA).

For diagnostic purposes, CRP results should be used in conjunction with other test results, the overall clinical presentation to the physician, and all other appropriate information. When being used for cardiovascular risk assessment, the following precautions must be noted:<sup>5-9</sup>

- Increases in CRP are non-specific and should not be interpreted without a complete clinical history.
- Siemens does not recommend screening the entire adult population.
- CRP measurements are not a substitute for traditional cardiovascular risk factors.
- Acute coronary syndrome management should not depend on CRP measurement.
- Patients with persistently unexplained CRP levels above 10 mg/L should be evaluated for other non-cardiovascular etiologies.
- Testing for cardiovascular risk assessment should not be performed while there is an indication of active infection, systemic inflammation, or trauma.
- Secondary prevention measures should be based on an array of risk factors (global risk assessment) and not depend on CRP.

- Serial testing of CRP should not be used to monitor effects of treatment.
- The average of CRP results optimally repeated over 2 weeks should be used in performing risk assessment due to the within-subject CRP variability.

As with all immunoassays, there is a potential that heterophilic antibodies may interfere with this method. In these rare patient samples, the presence of heterophilic antibodies could result in an anomalous result. The performance of this method has not been evaluated with patient samples containing heterophilic antibodies. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

As with any chemical reaction, you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient. A comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvement is beyond the scope of this document. Consult listed references for specific details on known potential interfering substances for CRP measurement.<sup>14</sup>

## 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>16</sup>

Group	Specimen Type	Reference Interval mg/L
Healthy individuals	Serum/plasma <sup>5-9</sup>	≤ 3
Low risk for cardiovascular disease prediction	Serum/plasma <sup>5-9</sup>	< 1
Average risk for cardiovascular disease prediction	Serum/plasma <sup>5-9</sup>	> 1 and < 3
High risk for cardiovascular disease prediction	Serum/plasma <sup>5-9</sup>	> 3

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>16</sup>

## Performance Characteristics

### Measuring Interval

The Atellica CH hsCRP assay provides results from 0.16–10.00 mg/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 200.00 mg/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.<sup>17</sup> The assay is designed to have a limit of blank (LoB) < limit of detection (LoD) and LoD ≤ 0.16 mg/L.

The LoD corresponds to the lowest concentration of CRP that can be detected with a probability of 95%. The LoD for the Atellica CH hsCRP assay is 0.07 mg/L, and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0.05 mg/L.

The functional sensitivity (Limit of Quantitation) of this assay is 0.16 mg/L, which is the lowest CRP concentration in a sample where total imprecision is less than 10%.

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

## Precision

Precision was determined in accordance with CLSI Document EP05-A3.<sup>18</sup> 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:

Sample Type	N	Mean mg/L	Repeatability		Within-Lab Precision	
			SD <sup>a</sup> mg/L	CV <sup>b</sup> (%)	SD mg/L	CV (%)
Serum	80	0.24	0.017	6.8	0.018	7.4
QC	80	0.73	0.016	2.2	0.020	2.7
Serum	80	1.52	0.020	1.3	0.026	1.7
Potassium EDTA plasma	80	4.14	0.025	0.6	0.029	0.7
Lithium heparin plasma	80	9.10	0.056	0.6	0.062	0.7

<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 hsCRP assay is designed to have a correlation coefficient of > 0.950 and a slope of  $1.00 \pm 0.07$  compared to ADVIA<sup>®</sup> Chemistry 1800 hsCRP. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.<sup>19</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 hsCRP	$y = 0.96x + 0.02$ mg/L	0.29–9.95 mg/L	100	0.990

<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>19</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	$y = 1.00x + 0.00$ mg/L	0.17–9.19 mg/L	51	0.981
Potassium EDTA plasma	Serum	$y = 1.01x + 0.00$ mg/L	0.17–9.19 mg/L	50	0.978

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

<sup>b</sup> 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 hsCRP assay is designed to have  $\leq 10\%$  interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in serum in accordance with CLSI Document EP07-A2 using the Atellica CH hsCRP assay.<sup>20</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/L	Percent Bias
Hemoglobin	125 mg/dL (0.078 mmol/L)	0.54	-7
	500 mg/dL (0.310 mmol/L)	2.51	-7
Bilirubin, conjugated	30 mg/dL (513 $\mu$ mol/L)	0.43	0
	30 mg/dL (513 $\mu$ mol/L)	2.32	1
Bilirubin, unconjugated	30 mg/dL (513 $\mu$ mol/L)	0.53	-4
	30 mg/dL (513 $\mu$ mol/L)	2.41	2
Lipemia (Intralipid®)	500 mg/dL (5.6 mmol/L)	0.45	-9
	1000 mg/dL (11.3 mmol/L)	2.42	-8

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 hsCRP assay when present in serum at the concentrations indicated in the table below. Bias due to these substances is  $\leq 10\%$  at an analyte concentration of 3 mg/L.

Substance	Substance Test Concentration Common Units	Percent Bias
Rheumatoid factor	1040 IU/mL	8

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

## High-Dose Hook Effect

High CRP levels can cause a paradoxical decrease in signal as a result of the high-dose hook effect. In the Atellica CH hsCRP assay, CRP levels as high as 2000 mg/L will read > 11.25 mg/L.

## Standardization

The assay is traceable to the Institute for Reference Materials and Measurements (IRMM) reference material CRM 470.

Assigned values for calibrators are traceable to this standardization.<sup>21</sup>

## Technical Assistance

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

siemens.com/healthineers









## References
















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9. Heeschen C, Hamm CW, Bruemmer J, Simoons ML. Predictive value of C-reactive protein and troponin T in patients with unstable angina: A comparative analysis. *J Am Coll Cardiol.* 2000;35(6):1535–1542.
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12. 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.
13. 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.
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15. Tietz NW. *Clinical Guide to Laboratory Tests*. 4th ed. Philadelphia, PA. Saunders; 2006:190
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18. 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.
19. 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.
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21. Data on file at Siemens Healthcare Diagnostics.

## 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="http://siemens.com/healthcare">siemens.com/healthcare</a>	Internet URL address to access the electronic instructions for use
 <a href="http://siemens.com/document-library">siemens.com/document-library</a>	
<b>Rev.</b> 	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.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive

Symbol	Symbol Title and Description
	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
	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.

Symbol	Symbol Title and Description
	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.
YYYY-MM-DD	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
	Unique material identification number
	Name of control
	Type of control

## Legal Information

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