SIEMENS Healthineers

# β2-Microglobulin (B2M)

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| **Current Revision and Date**[a] | Rev. 03, 2019-11 | |
| **Product Name** | Atellica CH β2-Microglobulin (B2M) | REF 11097635 (400 tests) |
| **Abbreviated Product Name** | Atellica CH B2M | |
| **Test Name/ID** | B2M | |
| **Systems** | Atellica CH Analyzer | |
| **Materials Required but Not Provided** | Atellica CH B2M CAL | REF 11099442 |
| **Specimen Types** | Serum and plasma (lithium heparin, potassium EDTA) | |
| **Sample Volume** | 5 µL | |
| **Measuring Interval** | 0.25–18.00 mg/L | |

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

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## Intended Use

The Atellica® CH β2-Microglobulin (B2M) assay is for *in vitro* diagnostic use in the quantitative determination of β2-microglobulin in human serum and plasma (lithium heparin, potassium EDTA) using the Atellica® CH Analyzer. The B2M assay aids in the diagnosis of active rheumatoid arthritis and kidney disease.

## Summary and Explanation

β2-Microglobulin has a molecular weight of 11,800 Da and occurs on all nucleated cells as a component of the HLA complex. It is constantly released into the blood in small quantities. β2-Microglobulin is freely filtered in the kidneys where it is reabsorbed and degraded in the renal tubules. Therefore, the serum levels found in healthy individuals remain at consistently low levels.[1]

A rise of serum concentration occurs as a result of a higher release of β2-microglobulin due to increased activity of the immune system, such as in infections or rheumatic diseases, cell death, or diminished elimination due to renal damage. The serum concentration of β2-microglobulin is thus a sensitive marker for the glomerular filtration capacity of the kidneys.[1,2,3]

Because the serum concentration of β2-microglobulin can be elevated in a variety of disease states, its diagnostic application should always follow a clear clinical question and rule out the presence of other relevant diseases.[1] Elevated concentrations of β2-microglobulin in serum or plasma are also found in patients with multiple myeloma and chronic lymphatic leukemia.[1,2] In situations with increased cell proliferation, its specificity can be enhanced by determining the β2-microglobulin to cystatin C ratio.[4]

## Principles of the Procedure

In the Atellica CH β2-Microglobulin (B2M) assay the sample is diluted and reacted with a buffer that contains latex particles coated with antibody specific for β2-microglobulin. The formation of the antibody-antigen complex during the reaction results in an increase in turbidity, the extent of which is measured as the amount of light absorbed at 545 nm. The Atellica CH B2M concentration in a sample is determined by constructing a standard curve from the absorbance of a reagent blank and a single-level calibrator.

## Reagents

| Material Description | Storage | Stability[a] |
|---|---|---|
| **Atellica CH B2M** | Unopened at 2–8°C | Until expiration date on product |
| **Pack 1 (P1)** | Onboard per well | 30 days |
| Well 1 (W1)<br>Reagent 1 (R1)<br>11.6 mL<br>Bovine serum albumin (0.5%); Tris buffer (pH 8.2); Proclin 950 | | |
| Well 2 (W2)<br>Reagent 1 (R1)<br>11.6 mL<br>Bovine serum albumin (0.5%); Tris buffer (pH 8.2); Proclin 950 | | |
| **Pack 2 (P2)** | | |
| Well 1 (W1)<br>Reagent 2 (R2)<br>4.9 mL<br>Latex particles coated with antihuman β2-microglobulin antibodies (goat), lot-specific; Tris buffer (pH 8.0); Proclin 950 | | |
| Well 2 (W2)<br>Reagent 2 (R2)<br>4.9 mL<br>Latex particles coated with antihuman β2-microglobulin antibodies (goat), lot-specific; Tris buffer (pH 8.0); Proclin 950 | | |

[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.

**CAUTION**

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

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

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.[5]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[6]
- Follow the instructions provided with your specimen collection device for use and processing.[7]
- Allow blood specimens to clot completely before centrifugation.[8]
- Keep tubes capped at all times.[8]

## Storing the Specimen

Separated specimens may be stored for up to 7 days at 2–8°C or stored frozen for up to 2 months at -20°C or colder.[9]

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 5 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.[8]

**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 |
|---|---|---|
| 11097635 | **Pack 1 (P1)**<br>Well 1 (W1) 11.6 mL of Atellica CH B2M Reagent 1<br>Well 2 (W2) 11.6 mL of Atellica CH B2M Reagent 1<br><br>**Pack 2 (P2)**<br>Well 1 (W1) 4.9 mL of Atellica CH B2M Reagent 2<br>Well 2 (W2) 4.9 mL of Atellica CH B2M Reagent 2 | 2 x 200 |

## Materials Required but Not Provided

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

| REF | Description | |
|---|---|---|
| | Atellica CH Analyzer[a] | |
| 11099442 | Atellica CH B2M CAL (calibrator) | 3 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 80 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 5 µL of pre-diluted sample into a reaction cuvette.
4. Mixes and incubates the mixture at 37°C.
5. Dispenses 20 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.

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 B2M assay, use Atellica CH B2M 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 | 21 |
| 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 B2M 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).

## 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 B2M assay is limited to the detection of β2-microglobulin in human serum and plasma (lithium heparin, potassium EDTA).

A number of substances cause physiological changes in serum or plasma analyte concentrations. A comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. Consult the listed reference for specific details on known potentially interfering substances.[10]

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.

# 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.[11]

The reference interval for β2-microglobulin is 1.00–2.40 mg/L for adults. These data were established on the ADVIA® Chemistry system.[12]

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.[11]

# Performance Characteristics

## Measuring Interval

The Atellica CH B2M assay provides results from 0.25–18.00 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 90.00 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.[13] The assay is designed to have a limit of blank (LoB) ≤ limit of detection (LoD) and LoD ≤ 0.25 mg/L.

The LoD corresponds to the lowest concentration of β2-microglobulin that can be detected with a probability of 95%. The LoD for the Atellica CH B2M assay is 0.20 mg/L, and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0.10 mg/L.

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

## Precision

Precision was determined in accordance with CLSI Document EP05-A3.[14] 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 | | Designed to be ≤ | Within-Lab Precision | | Designed to be ≤ |
|---|---|---|---|---|---|---|---|---|
| Sample Type | N | Mean mg/L | SD[a] mg/L | CV[b] (%) | CV (%) | SD mg/L | CV (%) | CV (%) |
| Serum QC | 80 | 2.05 | 0.057 | 2.8 | 3.5 | 0.059 | 2.9 | 4.5 |
| Serum | 80 | 4.88 | 0.027 | 0.6 | 2.0 | 0.042 | 0.9 | 4.0 |
| Plasma | 80 | 11.15 | 0.053 | 0.5 | 2.0 | 0.068 | 0.6 | 4.0 |

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

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

## Assay Comparison

The Atellica CH B2M assay is designed to have a correlation coefficient of > 0.950 and a slope of 1.00 ± 0.05 compared to ADVIA Chemistry 1800 B2M. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[15] The following results were obtained:

| Specimen | Comparative Assay (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Serum | ADVIA Chemistry 1800 B2M | y = 1.02x - 0.18 mg/L | 1.36–17.33 mg/L | 101 | 0.999 |

[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.[15] The following results were obtained:

| Specimen (y) | Reference Specimen (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Lithium heparin plasma | Serum | y = 0.98x + 0.08 mg/L | 0.70–16.56 mg/L | 55 | 0.992 |
| Potassium EDTA plasma | Serum | y = 1.01x + 0.02 mg/L | 1.01–15.28 mg/L | 53 | 0.998 |

[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 B2M 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 serum in accordance with CLSI Document EP07-A2 using the Atellica CH B2M assay.[16]

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 | 500 mg/dL (0.312 mmol/L)<br>1000 mg/dL (0.624 mmol/L) | 1.18<br>11.74 | -3<br>-1 |
| Bilirubin, conjugated | 60 mg/dL (1026 µmol/L)<br>60 mg/dL (1026 µmol/L) | 1.12<br>11.11 | 2<br>1 |
| Bilirubin, unconjugated | 60 mg/dL (1026 µmol/L)<br>60 mg/dL (1026 µmol/L) | 1.11<br>11.29 | 8<br>1 |
| Lipemia (Intralipid®) | 1000 mg/dL (11.3 mmol/L)<br>1000 mg/dL (11.3 mmol/L) | 1.21<br>11.65 | -8<br>-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 B2M assay when present in human serum and plasma (lithium heparin, potassium EDTA) at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%. These data were generated in serum on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[12]

| Substance | Substance Test Concentration Common Units | Analyte Concentration | Percent Bias |
|---|---|---|---|
| Rheumatoid Factor | 2500 IU/mL | 1.16 and 10.30 mg/L B2M | ≤ 10 |
| Ascorbic Acid | 50 mg/dL | 1.21 mg/L B2M | ≤ 10 |
| Ascorbic Acid | 150 mg/dL | 10.73 mg/L B2M | ≤ 10 |

| Substance | Substance Test Concentration Common Units | Analyte Concentration | Percent Bias |
|---|---|---|---|
| Acetone | 250 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Cholesterol | 500 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Creatinine | 125 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Ethanol | 1000 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Glucose | 2000 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Immunoglobulin G | 5000 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Immunoglobulin M | 1600 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Riboflavin | 15 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Total Protein | 12 g/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Urea | 60 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |
| Uric Acid | 12 mg/dL | 1, 3, and 11 mg/L B2M | ≤ 10 |

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

## High-Dose Hook Effect

High $\beta_2$-microglobulin levels can cause a paradoxical decrease in signal as a result of the high-dose hook effect. In the Atellica CH B2M assay, $\beta_2$-microglobulin levels as high as 90 mg/dL will read > 18.00 mg/dL.

## Standardization

The Atellica CH B2M assay is traceable to the World Health Organization (WHO) 1st International Standard for β2-microglobulin.

Assigned values for calibrators are traceable to this standardization.[12]

# Technical Assistance

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

siemens.com/healthineers

# References

1. Thomas L. β2-Mikroglobulin. In: Thomas L, ed. *Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results.* Frankfurt, Germany: TH Books; 1998:685-688.
2. Bethea M, Forman DT. Beta 2-microglobulin: its significance and clinical usefulness. *Ann Clin Lab Sci.* 1990;20(3):163-168.
3. Tomlinson PA. Low molecular weight proteins in children with renal disease. *Pediatr Nephrol.* 1992:6(6):565-571.
4. Norlund L, Fex G, Lanke J, *et al.* Reference intervals for the glomerular filtration rate and cell-proliferation markers: Serum cystatin C and serum beta 2-microglobulin/cystatin C-ratio. *Scand J Clin Lab Invest.* 1997;57(6):463-470.
5. 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.

6. 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.
7. 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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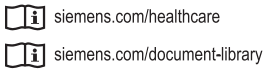
9. Schreiber W, Rausch S, Lammers M. Choice of specimen for immunonephelometric protein assays. *Clin Chim Acta.* 2005;355:S407.
10. Young DS. *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. Washington, DC: AACC Press; 2000.
11. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
12. Data on file at Siemens Healthcare Diagnostics.
13. 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.
14. 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.
15. 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.
16. 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 |
|   | 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. |

| Symbol | Symbol Title and Description |
|---|---|
|  | 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. |
|  | 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 |
| IVD | *In vitro* diagnostic medical device |

| Symbol | Symbol Title and Description |
|---|---|
|  | 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 |
|  | CE Mark with notified body ID number<br>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 |

| Symbol | Symbol Title and Description |
|---|---|
| MATERIAL ID | Unique material identification number |
| CONTROL NAME | Name of control |
| CONTROL TYPE | Type of control |

# Legal Information



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