SIEMENS Healthineers

Glucose Oxidase (GluO)

Current Revision and Date[a]	Rev. 04, 2021-03	
Product Name	Atellica CH Glucose Oxidase (GluO)	REF 11097621 (5600 tests)
Abbreviated Product Name	Atellica CH GluO	
Test Name/ID	GluO	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH CHEM CAL	REF 11099411
Specimen Types	Serum, cerebrospinal fluid (CSF), plasma (lithium heparin) and urine	
Sample Volume	4 µL	
Measuring Interval	6–750 mg/dL (0.3–41.6 mmol/L)	

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

CE

Intended Use

The Atellica® CH Glucose Oxidase (GluO) assay is for *in vitro* diagnostic use in the quantitative determination of glucose in human serum, cerebrospinal fluid (CSF), plasma (lithium heparin), 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

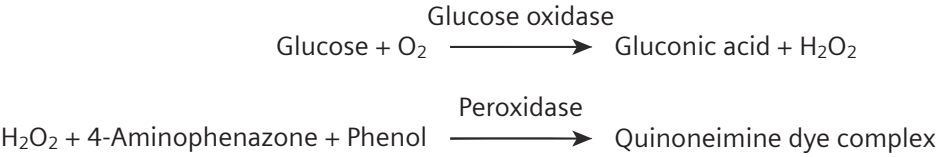
The Atellica CH Glucose Oxidase (GluO) assay is based on the modified method of Keston.[1,2]

The Atellica CH GluO assay utilizes a single reagent. Sample is added to Reagent 1, which initiates the conversion of glucose and the quantitative formation of a dye complex. The absorbance of the dye is measured at 505/694 nm, and is proportional to the glucose concentration.

Principles of the Procedure

Glucose is determined after enzymatic oxidation in the presence of glucose oxidase. The formed hydrogen peroxide reacts under catalysis of peroxidase with phenol and 4-aminophenazone to form a red-violet quinoneimine dye as indicator.

Reaction Equation



Reagents

Material Description	Storage	Stability[a]
Atellica CH GluO	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	51 days
Well 1 (W1) Reagent 1 (R1) 19.3 mL Phenol (55 mmol/L); 4-aminophenazone (3.85 mmol/L); glucose oxidase (microbial) (≥ 7.5 kU/L); peroxidase (horseradish) (≥ 7.5 kU/L); sodium azide (0.04%); buffer		
Well 2 (W2) Reagent 1 (R1) 19.3 mL Phenol (55 mmol/L); 4-aminophenazone (3.85 mmol/L); glucose oxidase (microbial) (≥ 7.5 kU/L); peroxidase (horseradish) (≥ 7.5 kU/L); sodium azide (0.04%); buffer		

[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.

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 51 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

Human serum, cerebrospinal fluid (CSF), plasma (lithium heparin), 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.[3]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[4]
- Follow the instructions provided with your specimen collection device for use and processing.[5]
- Allow blood specimens to clot completely before centrifugation.[6]
- Keep tubes capped at all times.[6]
- 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.[7]
- 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.[7]
- 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.[7]

Storing the Specimen

Room Temperature

Glycolysis decreases serum glucose by approximately 5–7% per hour in normal uncentrifuged, coagulated blood at room temperature. In separated, nonhemolyzed sterile serum, the glucose concentration is generally stable for up to 8 hours at 25°C. Glycolysis can be inhibited and glucose stabilized for up to 3 days at room temperature by addition of sodium iodoacetate or sodium fluoride (NaF) to the specimen.[7]

Refrigerated

In separated, nonhemolyzed sterile serum, the glucose concentration is generally stable for up to 72 hours at 4°C; variable stability is observed with longer storage conditions.[7]

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 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.[6]

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
11097621	**Pack 1 (P1)** Well 1 (W1) 19.3 mL of Atellica CH GluO Reagent 1 Well 2 (W2) 19.3 mL of Atellica CH GluO Reagent 1	4 x 1400

Materials Required but Not Provided

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

REF	Description	
	Atellica CH Analyzer[a]	
11099411	Atellica CH CHEM CAL (calibrator)	12 x 3.0 mL calibrator CAL 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, urine, and CSF, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 24 µL of Reagent 1 and 96 µL of special reagent water into a reaction cuvette.
3. Dispenses 4 µL of pre-diluted sample into a reaction cuvette.
4. Mixes and incubates the mixture at 37°C.
5. Measures the absorbance.
6. Reports results.

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

Test Duration: 10 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 GluO 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	35
Pack Calibration	7
Reagent Onboard Stability	51

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 GluO 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: mg/dL x 0.0555 = 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 GluO assay is limited to the detection of glucose in human serum, cerebrospinal fluid (CSF), plasma (lithium heparin), and urine. Venipuncture should occur prior to N-acetyl cysteine (NAC) or Metamizole (Sulpyrine) administration due to the potential for falsely depressed results.

In the presence of etamsylate at 5 mg/dL (190 µmol/L), falsely depressed results > 10% for glucose oxidase may be observed.

The following substances may interfere with the Atellica CH GluO assay when present in serum at the concentrations indicated in the table below. The observed bias due to these substances is shown in the table below.

Substance	Substance Test Concentration mg/dL (mmol/L)	Analyte Concentration mg/dL (mmol/L)	Percent Bias
Bilirubin, unconjugated	20 (342)	135.0 (7.5)	-11
Bilirubin, conjugated	15 (257)	89.0 (4.9)	-17
Bilirubin, conjugated	15 (257)	130.0 (7.2)	-12

The following substances may interfere with the Atellica CH GluO assay when present in urine at the concentrations indicated in the table below. The observed bias due to these substances is shown in the table below. These data were generated on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[8]

Substance	Substance Test Concentration mg/dL (mmol/L)	Analyte Concentration mg/dL (mmol/L)	Percent Bias
Ascorbic acid	2.5 (0.1)	30 (1.7)	-10
Ascorbic acid	5.0 (0.3)	30 (1.7)	-19
Ascorbic acid	7.5 (0.4)	106 (5.9)	-9
Ascorbic acid	10.0 (0.6)	106 (5.9)	-12

Expected Values

Reference Interval

A reference interval was established in accordance with CLSI Document EP28-A3c and verified on the Atellica CH Analyzer.[9]

Group	Specimen Type	Reference Interval Common Units (SI Units)
Infants and children	CSF[10]	60–80 mg/dL (3.3–4.4 mmol/L)
Adults	Serum/plasma[10]	74–106 mg/dL (4.1–5.9 mmol/L)
	Urine[10]	< 0.5 g/day (< 2.8 mmol/day)
	CSF[10]	40–70 mg/dL (2.2–3.9 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.[9]

Performance Characteristics

Measuring Interval

The Atellica CH GluO assay provides results from 6 mg/dL (0.3 mmol/L) to 750 mg/dL (41.6 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 1500 mg/dL (83.3 mmol/L). 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) < limit of detection (LoD) and LoD ≤ 6 mg/dL (0.3 mmol/L).

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

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		Designed to be ≤	Within-Lab Precision		Designed to be ≤
Sample Type	N	Mean mg/dL (mmol/L)	SD[a] mg/dL (mmol/L)	CV[b] (%)	CV (%)	SD mg/dL (mmol/L)	CV (%)	CV (%)
Serum QC	80	61 (3.4)	0.6 (0.03)	1.0	3.6	1.4 (0.08)	2.3	5.4
Serum QC	80	116 (6.4)	0.5 (0.03)	0.5	3.6	2.2 (0.12)	1.9	5.4
Plasma	80	261 (14.5)	0.8 (0.04)	0.3	2.0	5.3 (0.29)	2.0	3.0
Serum	80	567 (31.5)	1.9 (0.11)	0.3	2.0	16.2 (0.90)	2.9	3.0
Urine QC	80	28 (1.6)	0.4 (0.02)	1.6	3.0	1.2 (0.07)	4.2	4.5
Urine QC	80	299 (16.6)	1.1 (0.06)	0.4	2.0	5.8 (0.32)	2.0	4.0
CSF QC	80	53 (2.9)	0.4 (0.02)	0.8	2.5	1.4 (0.08)	2.6	3.5
CSF QC	80	104 (5.8)	0.5 (0.03)	0.5	2.0	3.6 (0.20)	3.5	3.5

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

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

Assay Comparison

The Atellica CH GluO assay is designed to have a correlation coefficient of > 0.96 and a slope of 1.0 ± 0.05 compared to ADVIA® Chemistry 1800 GLUO for serum, urine, and CSF. Assay comparison was determined using the weighted 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	ADVIA Chemistry 1800 GLUO	y = 0.99x - 3 mg/dL (y = 0.99x - 0.2 mmol/L)	9–724 mg/dL (0.5–40.2 mmol/L)	101	0.999
Urine	ADVIA Chemistry 1800 GLUO	y = 1.00x + 4 mg/dL (y = 1.00x + 0.2 mmol/L)	6–695 mg/dL (0.3–38.6 mmol/L)	105	0.998
CSF	ADVIA Chemistry 1800 GLUO	y = 0.98x + 3 mg/dL (y = 0.98x + 0.2 mmol/L)	34–650 mg/dL (1.9–36.1 mmol/L)	122	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 weighted 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 = 0.97x - 2 mg/dL (y = 0.97x - 0.1 mmol/L)	8–726 mg/dL (0.4–40.3 mmol/L)	50	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 GluO 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 GluO 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 mg/dL (mmol/L)	Percent Bias
Hemoglobin	200 mg/dL (0.156 mmol/L) 200 mg/dL (0.156 mmol/L)	88 (4.9) 134 (7.4)	2 1
Bilirubin, conjugated	7.5 mg/dL (128 µmol/L) 7.5 mg/dL (128 µmol/L)	86 (4.8) 130 (7.2)	-9 -6
Bilirubin, unconjugated	10 mg/dL (171 mmol/L) 10 mg/dL (171 mmol/L)	89.3 (5.0) 135.3 (7.5)	-4 -5
Lipemia (Intralipid®)	250 mg/dL (2.83 mmol/L) 250 mg/dL (2.83 mmol/L)	88 (4.9) 135 (7.5)	9 6

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 GluO assay when present in urine at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%. These data were generated on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[8]

Substance	Substance Test Concentration mg/dL (mmol/L)	Analyte Concentration mg/dL (mmol/L)	Percent Bias
Salicylate	50 (3.1)	20 (1.1)	≤ 10
Caffeine	50 (2.6)	27 (1.5)	≤ 10
Creatinine	500 (44.2)	15 (0.8)	≤ 10
Urea	1000 (166.6)	15 (0.8)	≤ 10

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

Standardization

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

Assigned values for calibrators are traceable to this standardization.[8]

Technical Assistance

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

siemens.com/healthineers

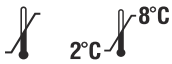
References

1. Keston AS. Specific colorimetric enzymatic analytical reagents for glucose. *American Chemical Society;* 129th meeting. Dallas, TX; 1956:31C-32C. [Abstract of Papers.]
2. Barham D, Trinder P. An improved colour reagent for the determination of blood glucose by the oxidase system. *Analyst*. 1972;97(151):142–145.
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.
4. 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.
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.
6. 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.
7. Burtis CA, Ashwood ER. *Tietz Fundamentals of Clinical Chemistry.* 5th ed. Philadelphia, PA: Saunders; 2001:444-445
8. Data on file at Siemens Healthcare Diagnostics.
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. Wu AHB, ed. *Tietz Clinical Guide to Laboratory Tests.* 4th ed. St. Louis, MO: Saunders; 2006:444–450.
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
	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
	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.

Symbol	Symbol Title and Description
	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
	*In vitro* 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.
RxOnly	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

Symbol	Symbol Title and Description
CE 0088	CE Mark with notified body ID number 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

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