SIEMENS Healthineers

Lactate_3 (Lac_3)

Current Revision and Date[a]	Rev. 05, 2025-10	
Product Name	Atellica CH Lactate_3 (Lac_3)	REF 11537218 (600 tests)
Abbreviated Product Name	Atellica CH Lac_3	
Test Name/ID	Lac_3	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH SPCL CHEM CAL	REF 11099438
Specimen Types	Sodium fluoride/potassium oxalate plasma, sodium heparin plasma, lithium heparin plasma, CSF	
Sample Volume	5.0 µL	
Measuring Interval	1.8–140.0 mg/dL (0.20–15.54 mmol/L)	

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

CE 0197

Intended Use

The Atellica® CH Lactate_3 (Lac_3) assay is for *in vitro* diagnostic use in the quantitative determination of lactate in human plasma (lithium heparin, sodium heparin and sodium fluoride/potassium oxalate) and cerebrospinal fluid (CSF) using the Atellica CH Analyzer. Lactic acid measurements that evaluate the acid-base status are used as an aid in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Summary and Explanation

The Atellica CH Lac_3 assay measures lactate in plasma by an enzymatic assay. It is based on the principle that the analyte concentration is a function of the reaction oxidizing lactate to pyruvate and hydrogen peroxide and the formation of a dye that can be measured spectrophotometrically. Such measurements are used in assessing circulatory function and oxygen status. Increased concentration of lactate in the blood is an indicator of anaerobic metabolism, decreased blood flow to the tissues, and insufficient oxygen delivery. In cases of severe oxygen deprivation, lactic acidosis may occur; therefore, lactate may be used as an indicator of severity of circulatory failure.[1-5]

Measurement of CSF lactate levels parallel but are independent of lactate in plasma. CSF lactate concentrations may be used in patients with clinical signs and symptoms of meningitis to differentiate bacterial from viral meningitis. In general, significantly elevated levels of CSF lactate are suggestive of bacterial meningitis while normal or slightly elevated CSF lactate is suggestive of viral meningitis.[6]

Principles of the Procedure

Atellica CH Lac_3 uses an enzymatic reaction to convert lactate to pyruvate. The hydrogen peroxide produced by this reaction is then used in an enzymatic reaction to generate a colored dye. L-lactate is oxidized to pyruvate by the specific enzyme lactate oxidase (LOD).

$$\text{L-lactate} + O_2 \xrightleftharpoons{\text{LOD}} \text{pyruvate} + H_2O_2$$

Peroxidase (POD) is used to generate a colored dye using the hydrogen peroxide generated in the first reaction.

$$H_2O_2 + \text{H donor} + \text{4-aminoantipyrine}^{+} \xrightleftharpoons{\text{POD}} \text{chromogen}^{+} + 2H_2O$$

The intensity of the color formed is proportional to the L-lactate concentration.

Reagents

Material Description	Storage	Stability[a]
Atellica CH Lac_3	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1) Well 1 (W1) and Well 2 (W2) Reagent 1 (R1) 16.6 mL Buffer (100 mmol/L) (pH 7.8); H donor (> 1.5 mmol/L); ascorbate oxidase (> 10 kU/L); sodium azide (< 0.1%); detergent; stabilizers	Onboard per well	90 days
Pack 2 (P2) Well 1 (W1) and Well 2 (W2) Reagent 2 (R2) 5.9 mL Buffer (100 mmol/L) (pH 7.8); 4-aminoantipyrine (5 mmol/L); LOD (> 5 kU/L); POD (> 10 kU/L); sodium azide (< 0.1%); detergent; stabilizers		

[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-healthineers.com.

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.

Storage and Stability

Store all reagents in an upright position. Do not use products beyond the expiration date printed on the product labeling. Do not freeze reagents. Reagent 1 and Reagent 2 must be clear. Do not use if turbid.

For details about product material description, storage, and stability, refer to *Reagents*.

Onboard Stability

Discard products at the end of the onboard stability interval.

For details about product onboard stability, refer to *Reagents*.

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

Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

Specimen Collection and Handling

Sodium fluoride/potassium oxalate plasma, sodium heparin plasma, lithium heparin plasma, and CSF are the recommended specimen types for this 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.

Collecting the Specimen

Sodium fluoride/potassium oxalate plasma, sodium heparin plasma, lithium heparin plasma, and CSF can be used with this assay. However, sodium fluoride is the preferred anticoagulant, due to its inhibition of glycolysis, which provides a more stable lactate level in the plasma. Collect blood from a stasis-free vein and store it in an ice bath. Separate the plasma by centrifugation within 30 minutes. A delay in separation can lead to an increase in lactate values. Assay the sample immediately.[5]

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[7]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[8]
- Follow the instructions provided with your specimen collection device for use and processing.[9]

- Specimens with high turbidity or particulates should be centrifuged before analysis.
- Keep tubes capped at all times.[10]
- CSF specimens should not contain blood.
- To analyze specimens for this assay, collect and store CSF using your laboratory procedure.[11]

Storing the Specimen

Specimen Type(s)	Storage Condition(s)	Storage Duration
Plasma	2–8°C[12]	up to 169 hours
	-20°C[12]	up to 1 month
CSF	2–8°C[13]	up to 24 hours
	-20°C[13]	up to 1 month

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 5.0 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 system operating instructions.

Do not use samples with apparent contamination.

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[10]

For a complete list of appropriate sample containers, refer to the system operating instructions.

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

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

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11537218	Atellica CH Lac_3	2 x 300
	Pack (P1) Well 1 (W1) 16.6 mL of Reagent 1 Well 2 (W2) 16.6 mL of Reagent 1	
	Pack (P2) Well 1 (W1) 5.9 mL Reagent 2 Well 2 (W2) 5.9 mL Reagent 2	

Materials Required but Not Provided

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

REF	Description	
	Atellica CH Analyzer[a]	
11099438	Atellica CH SPCL CHEM CAL	10 x 5.0 mL calibrator 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 plasma/CSF, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 82.5 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 5 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 16.5 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: 7.4 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

For information about loading reagents, refer to the system operating instructions.

Performing Calibration

For calibration of the Atellica CH Lac_3 assay, use Atellica CH SPCL CHEM CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Calibration Interval	Days
Lot Calibration	180
Pack Calibration	14

In addition, perform a calibration:

- When changing lot numbers of reagents.
- 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 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.

Note When loading new reagents, recalibration is not required if there is a valid lot calibration. For information about the calibration interval, refer to the system operating instructions.

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

Performing Quality Control

At least once each day of use, analyze two levels of quality control (QC) material with known lactate concentration. For assistance in identifying a quality control material, refer to the *Atellica CH Quality Control Material Supplement* available on siemens-healthineers.com. Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

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

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

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 system operating instructions.

Taking Corrective Action

If the quality control results do not fall within the expected control interval, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system operating instructions.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the system operating instructions. The system reports results in mg/dL (conventional units) or mmol/L (SI units [Systèm International d'Unités]), depending on the units defined when setting up the assay.

Conversion formula: mg/dL x 0.111 = 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 following information pertains to limitations of the assay:

- The Atellica CH Lac_3 assay is limited to the detection of lactate in human plasma (lithium heparin, sodium fluoride/potassium oxalate, sodium heparin) and CSF.
- As with any chemical reaction, you must be alert to the possible effect 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 number of substances cause physiological changes in plasma analyte concentrations. A comprehensive discussion of possible interfering substances, their plasma concentrations, and their possible physiological involvements is beyond the scope of this document.Consult the listed reference for specific details on known potential interfering substances.[14]
- Venipuncture should occur prior to N-Acetyl Cysteine (NAC) administration due to the potential for falsely depressed results.[12]
- Metabolites of ethylene glycol, such as glycolate and glyoxylic acid can cross react with methods employing lactate oxidase leading to falsely elevated plasma lactate levels.[15]

Expected Values

Reference Interval

A reference interval for healthy adults was verified in accordance with CLSI Document EP28-A3c [16].

Group	Specimen Type	Reference Interval Conventional Units (SI Units)
Adults	Plasma[12]	4.5–19.8 mg/dL[a] (0.50–2.20 mmol/L)
Adults	CSF[17]	8.1–24.3 mg/dL (0.9–2.7 mmol/L)

[a] These data were verified on the Atellica CH Analyzer.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[16] Consider these values as guidance only.

Performance Characteristics

Measuring Interval

The Atellica CH Lac_3 assay is linear from 1.8 mg/dL (0.20 mmol/L) to 140.0 mg/dL (15.54 mmol/L). The system flags all values that are outside the specified measuring interval.

The lower end of the measuring interval is defined by the limit of quantitation (LoQ). Report results below the measuring interval as < 1.8 mg/dL (0.20 mmol/L).

Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 700.0 mg/dL (77.70 mmol/L) for plasma and CSF. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

Detection Capability

The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ the limit of detection (LoD).

The Limit of Detection (LoD) corresponds to the lowest concentration of lactate that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ Limit of Quantitation (LoQ).

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of lactate in a sample at which the within-laboratory precision is ≤ 20% CV. The assay is designed to have an LoQ ≤ 1.8 mg/dL (0.20 mmol/L).

Detection capability was determined in accordance with CLSI Document EP17-A2.[18]

The following results were obtained:

Specimen Type	Detection Capability	Result mg/dL (mmol/L)
Plasma/CSF	LoB	1.0 (0.11)
	LoD	1.7 (0.19)
	LoQ	1.8 (0.20)

The LoD was determined using 450 determinations, with 225 blank and 225 low-level replicates.

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

The LoQ of the Atellica CH Lac_3 assay is ≤ 1.8 mg/dL (0.20 mmol/L), and was determined using multiple patient samples. All samples were assayed N=5 in each of 1 run per day using 3 reagent lot(s) over a period of 5 days.

Precision

The assay is designed to have the following precision:

- Repeatability: CV ≤ 4.0% at 7.0–140.0 mg/dL
- Within–Laboratory: CV ≤ 6.0% at 7.0–140.0 mg/dL

Precision was determined in accordance with CLSI Document EP05-A3.[19] Samples were assayed on the Atellica CH Analyzer in duplicate in 2 runs per day for 20 days.

The following results were obtained:

Specimen Type	N[a]	Mean mg/dL (mmol/L)	Repeatability SD[b] mg/dL (mmol/L)	Repeatability CV[c] (%)	Within-Laboratory Precision SD mg/dL (mmol/L)	Within-Laboratory Precision CV (%)
Plasma QC1	80	12.3 (1.37)	0.06 (0.007)	0.5	0.15 (0.017)	1.2
Plasma QC2	80	51.5 (5.72)	0.14 (0.016)	0.3	0.31 (0.034)	0.6
Plasma	80	123.9 (13.75)	0.66 (0.073)	0.5	0.82 (0.091)	0.7
CSF QC1	80	13.5 (1.50)	0.06 (0.007)	0.4	0.11 (0.012)	0.8
CSF QC2	80	52.7 (5.85)	0.19 (0.021)	0.4	1.19 (0.132)	2.3
CSF	80	109.1 (12.11)	0.66 (0.073)	0.6	1.29 (0.143)	1.2

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

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

Reproducibility

The assay is designed to have reproducibility of CV ≤ 12% at 7.0–140.0 mg/dL.

Reproducibility was determined in accordance with CLSI Document EP05-A3.[19] Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

Sample	N[a]	Mean mg/dL (mmol/L)	Repeatability SD[b] mg/dL (mmol/L)	Repeatability CV[c] (%)	Between-Day SD mg/dL (mmol/L)	Between-Day CV (%)	Between-Lot SD mg/dL (mmol/L)	Between-Lot CV (%)	Between-Instrument SD mg/dL (mmol/L)	Between-Instrument CV (%)	Total Reproducibility SD mg/dL (mmol/L)	Total Reproducibility CV (%)
CSF 1	225	13.7 (1.52)	0.06 (0.007)	0.5	0.00 (0.000)	0.0	0.13 (0.015)	1.0	0.25 (0.028)	1.9	0.29 (0.033)	2.2
Plasma 1	225	17.9 (1.99)	0.09 (0.010)	0.5	0.04 (0.005)	0.2	0.12 (0.013)	0.7	0.39 (0.043)	2.2	0.42 (0.047)	2.3
QC 1	225	52.6 (5.84)	0.17 (0.019)	0.3	0.00 (0.000)	0.0	0.24 (0.026)	0.5	0.19 (0.021)	0.4	0.34 (0.038)	0.7
CSF 2	225	53.7 (5.96)	0.22 (0.025)	0.4	0.00 (0.000)	0.0	0.29 (0.033)	0.5	0.09 (0.010)	0.2	0.38 (0.042)	0.7
CSF 3	225	110.4 (12.25)	0.52 (0.058)	0.5	0.00 (0.000)	0.0	0.54 (0.060)	0.5	0.18 (0.020)	0.2	0.78 (0.086)	0.7
Plasma 2	225	123.6 (13.72)	0.43 (0.048)	0.4	0.00 (0.000)	0.0	0.70 (0.078)	0.6	0.02 (0.003)	0.0	0.82 (0.091)	0.7

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

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

Assay Comparison

The Atellica CH Lac_3 assay (y) was designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.10 for plasma compared to the Atellica CH Lac_2 assay. The Atellica CH Lac_3 assay (y) was designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.10 for CSF compared to the Dimension Vista® LA assay. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09c.[20] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Atellica CH Lac_2	y = 0.95x + 1.5 mg/dL (y = 0.95x + 0.17 mmol/L)	5.9–106.6 mg/dL (0.65–11.83 mmol/L)	108	0.998
CSF	Dimension Vista LA	y = 0.95x + 0.1 mg/dL (y = 0.95x + 0.01 mmol/L)	11.1–128.1 mg/dL (1.23–14.22 mmol/L)	103	0.998

[a] Number of samples tested.

[b] Correlation coefficient.

Agreement of the assays 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 regression model in accordance with CLSI Document EP09c.[20] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Sodium heparin plasma	Atellica CH Lac_3 lithium heparin plasma	y = 1.00x + 0.1 mg/dL (y = 1.00x + 0.01 mmol/L)	6.9–126.6 mg/dL (0.77–14.05 mmol/L)	53	0.996
Sodium fluoride/ potassium oxalate plasma	Atellica CH Lac sodium fluoride/potassium oxalate plasma	y = 0.98x + 0.8 mg/dL (y = 0.98x + 0.09 mmol/L)	5.1–120.8 mg/dL (0.57–13.41 mmol/L)	50	1.000

[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)

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. The Atellica CH Lac_3 assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Interference testing was performed in accordance with CLSI Document EP07-ED3.[21] The following results were obtained:

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
Hemoglobin	1000 mg/dL (10 g/L) 1000 mg/dL (10 g/L)	9.5 mg/dL (1.05 mmol/L) 16.0 mg/dL (1.78 mmol/L)	-9 -8
Bilirubin, conjugated	14 mg/dL (239 µmol/L) 15 mg/dL (257 µmol/L)	9.7 mg/dL (1.08 mmol/L) 15.2 mg/dL (1.69 mmol/L)	-9 -9
Bilirubin, unconjugated	20 mg/dL (342 µmol/L) 30 mg/dL (513 µmol/L)	9.4 mg/dL (1.04 mmol/L) 15.3 mg/dL (1.70 mmol/L)	-10 -10
Lipemia (Intralipid®)	1000 mg/dL (10 g/L) 1000 mg/dL (10 g/L)	9.3 mg/dL (1.03 mmol/L) 14.1 mg/dL (1.57 mmol/L)	0 -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 Lac_3 assay when present in plasma at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%.

Interference testing was performed in accordance with CLSI Document EP07-ED3.[21] The following results were obtained:

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
Ascorbic Acid	12 mg/dL (682 µmol/L) 12 mg/dL (682 µmol/L)	9.6 mg/dL (1.07 mmol/L) 15.9 mg/dL (1.76 mmol/L)	-1 -1
Etamsylate	5 mg/dL (190 µmol/L) 5 mg/dL (190 µmol/L)	9.8 mg/dL (1.09 mmol/L) 16.1 mg/dL (1.79 mmol/L)	-10 -7

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

Standardization

The assay is traceable to an internal standard manufactured using highly purified material.[12]

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

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

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References

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19. 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.
20. 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; 2018. CLSI Document EP09c.
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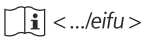
Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]		Revision	Proprietary
RxOnly	Prescription device (US only)	FDA[b]		Unique Device Identifier	5.7.10[c]
	CE Marking with Notified Body	EU IVDR[d]		CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]
	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
	Common Units	Proprietary		International System of Units	Proprietary
YYYY-MM-DD	Date format (year-month-day)	N/A	**YYYY-MM**	Date format (year-month)	N/A
	Document face up[f]	1952[e]		Handheld barcode scanner	Proprietary
	Target	Proprietary		Mixing of substances	5657[g]

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary	←→	Interval	Proprietary
MATERIAL ID	Unique material identification number	Proprietary	MATERIAL	Material	Proprietary
CONTROL TYPE	Type of control	Proprietary	CONTROL NAME	Name of control	Proprietary
CONTROL LOT VAL	Quality control lot value	Proprietary	CAL LOT VAL	Calibrator lot value	Proprietary

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.
[b] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.
[c] ISO 15223-1:2020-04
[d] IVDR REGULATION (EU) 2017/746
[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.
[f] Indicates Assay-eNote
[g] International Electrotechnical Commission (IEC). IEC 60417-1 Graphical symbols for use on equipment – Part 1: Overview and Application

Legal Information

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