SIEMENS Healthineers

Total Bilirubin_2 (TBil_2)

Current Revision and Date[a]	Rev. 04, 2022-06	
Product Name	Atellica CH Total Bilirubin_2 (TBil_2)	REF 11097531 (1792 tests)
Abbreviated Product Name	Atellica CH TBil_2	
Test Name/ID	TBil_2	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica CH CHEM CAL	REF 11099411
Specimen Types	Serum and plasma (lithium heparin)	
Sample Volume	14.3 µL	
Measuring Interval	0.15–35.0 mg/dL (3–599 µmol/L)	

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

CE

Intended Use

The Atellica® CH Total Bilirubin_2 (TBil_2) assay is for *in vitro* diagnostic use in the quantitative determination of total bilirubin in human serum and plasma (lithium heparin) of adults and neonates using the Atellica® CI Analyzer. Measurement of total bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gallbladder block. A total bilirubin measurement in newborn infants is intended to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

Summary and Explanation

The Atellica CH Total Bilirubin_2 (TBil_2) assay is based on a chemical oxidation method using vanadate as an oxidizing agent.[1]

Principles of the Procedure

The bilirubin is oxidized by vanadate at about pH 2.9 to produce biliverdin. In the presence of the detergent and the vanadate, both conjugated (direct) and unconjugated bilirubin are oxidized. This oxidation reaction causes the decrease in the optical density of the yellow color, which is specific to bilirubin. The decrease in optical density at 451/545 nm is proportional to the total bilirubin concentration in the sample. The concentration is measured as an endpoint reaction.

Reaction Equation

Bilirubin + Surfactant + VO_3^- ⟶ Biliverdin

Reagents

Material Description	Storage	Stability[a]
Atellica CH TBil_2	Unopened at 2–30°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	90 days
Well 1 (W1) Reagent 1 (R1) 23.5 mL Citrate buffer (pH 2.9) (0.1 mol/L); detergent		
Well 2 (W2) Reagent 1 (R1) 23.5 mL Citrate buffer (pH 2.9) (0.1 mol/L); detergent		
Pack 2 (P2)		
Well 1 (W1) Reagent 2 (R2) 8.8 mL Phosphate buffer (pH 7.0) (10 mmol/L); sodium metavanadate (4 mmol/L)		
Well 2 (W2) Reagent 2 (R2) 8.8 mL Phosphate buffer (pH 7.0) (10 mmol/L); sodium metavanadate (4 mmol/L)		

[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.

H411 Toxic to aquatic life with long lasting effects.
P273, P391, P501 Avoid release to the environment. Collect spillage. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Cetrimonium bromide (R1)

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 2–30°C.

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

Onboard Stability

Discard reagents 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.

Specimen Collection and Handling

Serum and plasma (lithium heparin) are the recommended sample types for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[2]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[3]
- Follow the instructions provided with your specimen collection device for use and processing.[4]
- Allow blood specimens to clot completely before centrifugation.[5]
- Keep tubes capped at all times.[5]

Storing the Specimen

Specimens may be stored at 4°C and analyzed within 5 days. Bilirubin is extremely photosensitive. Care should be taken to protect sample from both daylight and fluorescent light to avoid photodegradation. Specimens are stable for 3 months when stored frozen at -70°C with no light exposure.[6,7]

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 14.3 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.[5]

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
11097531	**Pack 1 (P1)** Well 1 (W1) 23.5 mL of Atellica CH TBil_2 Reagent 1 Well 2 (W2) 23.5 mL of Atellica CH TBil_2 Reagent 1 **Pack 2 (P2)** Well 1 (W1) 8.8 mL of Atellica CH TBil_2 Reagent 2 Well 2 (W2) 8.8 mL of Atellica CH TBil_2 Reagent 2	4 x 448

Materials Required but Not Provided

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

REF	Description	
	Atellica CI 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. 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 14.3 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
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: 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 TBil_2 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	60
Pack Calibration	60

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 TBil_2 assay, use at least two levels (low and high) of the appropriate quality control material of known analyte 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.

For the assigned values, refer to the lot-specific value sheet provided.

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 online help.

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 µmol/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: mg/dL x 17.1 = µmol/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 TBil_2 assay is limited to the detection of total bilirubin in human serum and plasma (lithium heparin).

When samples with a total bilirubin concentration of 1.0 mg/dL (17.3 µmol/L) are spiked at a therapeutic eltrombopag concentration of 25 µg/mL (56.5 µmol/L) a positive bias of 13.9% is observed. No significant interference is observed when samples with a total bilirubin concentration of 22.8 mg/dL (390 µmol/L) are spiked at a supraphysiological eltrombopag concentration of 75 µg/mL (170 µmol/L), therefore spiking studies at this level of total bilirubin have not been tested at the lower therapeutic concentration of eltrombopag.[8]

Expected Values

Reference Interval

The reference intervals were verified by analysis for the Atellica CI Analyzer in accordance with CLSI Document EP28-A3c.[9]

The expected values for this method by age are shown in the table below.[10]

Age	Expected Values mg/dL (µmol/L)
0–1 day	< 8.0 (137)
1–2 days	< 12.0 (205)
3–5 days	< 16.0 (274)
> 5 days–60 years[a]	0.3–1.2 (5–21)

Age	Expected Values mg/dL (µmol/L)
60–90 years	0.2–1.1 (3–19)
> 90 years	0.2–0.9 (3–15)

[a] > 5 days to < 29 days are neonates; and > 29 days to 60 years are children and adults.

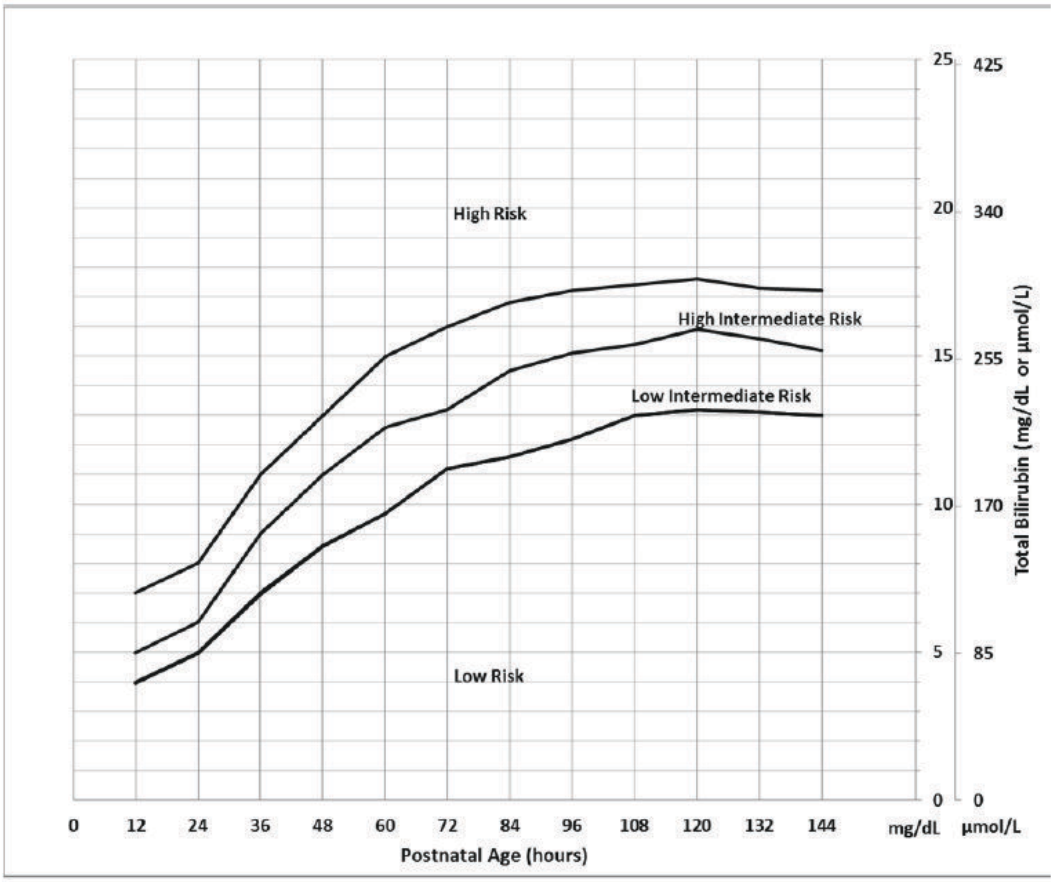
As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.[9]

Clinical Interpretation of Risk for Hyperbilirubinemia in Neonates

Neonatal bilirubin concentrations and development of clinically significant hyperbilirubinemia have been investigated in 2840 well newborns.[11] The 95th percentile concentrations that indicate high risk for developing clinically significant hyperbilirubinemia are presented in the table below along with a nomogram for designation of risk. Neonatal bilirubin concentrations > 95th percentile indicate significant hyperbilirubinemia and generally require close supervision, further evaluation, and/or intervention.

Age	Total Bilirubin mg/dL
24 hours	≥ 8.0
48 hours	≥ 13.0
84 hours	≥ 17.0

Nomogram for predicting risk of development of hyperbilirubinemia by postnatal age and total bilirubin concentration.



Note Solid lines indicate 95th percentile.

Performance Characteristics

Measuring Interval

The Atellica CH TBil_2 assay is linear from 0.15 mg/dL (3 µmol/L) to 35.0 mg/dL (599 µmol/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 70.0 mg/dL (1197 µmol/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.[12] The assay is designed to have a limit of blank (LoB) ≤ limit of detection (LoD) and LoD ≤ 0.1 mg/dL (≤ 2 µmol/L).

The LoD corresponds to the lowest concentration of total bilirubin that can be detected with a probability of 95%. The LoD for the Atellica CH TBil_2 assay is 0.0 mg/dL (0 µmol/L), and was determined using 135 determinations, with 60 blank and 75 low level replicates, and a LoB of 0.0 mg/dL (0 µmol/L).

The LoQ is the lowest amount of total bilirubin that can be determined quantitatively within a defined total error. The LoQ is 0.1 mg/dL (2 µmol/L). All samples were assayed n = 5 using 3 reagent lots, over a period of 3 days.

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

Precision

The Repeatability and Within-Laboratory precision of the Atellica CH TBil_2 assay are designed to have the following characteristics:

Specimen Type	Concentration (mg/dL)	Repeatability Results	Within-Laboratory Results
Serum	0.4–0.99	≤ 6.0%	≤ 9.0%
Serum	1.0–1.9	≤ 5.0%	≤ 6.0%
Serum	2.0–8.0	≤ 4.0%	≤ 5.0%
Serum	20.0–35.0	≤ 3.0%	≤ 4.0%

Precision was determined in accordance with CLSI Document EP05-A3.[13] Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample Type	N	Mean mg/dL (µmol/L)	SD[a] mg/dL (µmol/L)	CV[b] (%)	SD mg/dL (µmol/L)	CV (%)
Serum 1	80	0.7 (12)	0.04 (0.7)	5.7	0.06 (1.0)	8.6
Serum 2	80	1.4 (24)	0.02 (0.3)	1.4	0.06 (1.0)	4.3

Sample Type	N	Mean mg/dL (µmol/L)	Repeatability SD[a] mg/dL (µmol/L)	Repeatability CV[b] (%)	Within-Laboratory Precision SD mg/dL (µmol/L)	Within-Laboratory Precision CV (%)
Serum 3	80	7.2 (123)	0.04 (0.7)	0.6	0.11 (1.9)	1.5
Serum 4	80	24.0 (410)	0.09 (1.5)	0.4	0.41 (7.0)	1.7

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

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

Reproducibility

The assay is designed to have the following reproducibility:

Sample	Concentration mg/dL	Total Reproducibility SD mg/dL	Total Reproducibility CV (%)
Serum	0.4–0.9	N/A	≤ 13.0
Serum	1.0–1.9	N/A	≤ 9.0
Serum	2.0–8.0	N/A	≤ 7.5
Serum	20.0–35.0	N/A	≤ 6.0

Reproducibility was determined in accordance with CLSI Document EP05-A3.[13] 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 (µmol/L)	Repeatability SD[b] mg/dL (µmol/L)	Repeatability CV[c] (%)	Between-Day SD mg/dL (µmol/L)	Between-Day CV (%)	Between-Instrument SD mg/dL (µmol/L)	Between-Instrument CV (%)	Between-Lot SD mg/dL (µmol/L)	Between-Lot CV (%)	Total Reproducibility SD mg/dL (µmol/L)	Total Reproducibility CV (%)
Serum 1	225	0.7 (12)	0.00 (0.0)	0.0	0.00 (0.0)	0.0	0.00 (0.0)	0.0	0.00 (0.0)	0.0	0.00 (0.0)	0.0
Serum 2	225	1.3 (22)	0.04 (0.7)	3.1	0.03 (0.5)	2.3	0.00 (0.0)	0.0	0.00 (0.0)	0.0	0.05 (0.9)	3.8
Serum 3	225	7.1 (121)	0.04 (0.7)	0.6	0.04 (0.7)	0.6	0.00 (0.0)	0.0	0.01 (0.2)	0.1	0.06 (1.0)	0.8
Serum 4	225	22.5 (385)	0.09 (1.5)	0.4	0.10 (1.7)	0.4	0.04 (0.7)	0.2	0.00 (0.0)	0.0	0.14 (2.4)	0.6

[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 performance of the Atellica CH TBil_2 assay on the Atellica CI Analyzer (y) was compared with the performance of the comparison assay on the indicated system (x) and is designed to have a correlation coefficient of > 0.950 and a slope of 1.00 ± 0.10. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09c.[14] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum[c]	ADVIA® Chemistry TBIL_2 on ADVIA 1800 Chemistry System	y = 0.95x + 0.0 mg/dL (y = 0.95x + 0 µmol/L)	0.2–33.9 mg/dL (3–580 µmol/L)	102	0.996
Serum[c]	Atellica CH TBil_2 on Atellica CH Analyzer	y = 0.97x + 0.0 mg/dL (y = 0.97x + 0 µmol/L)	0.2–33.8 mg/dL (3–578 µmol/L)	102	0.995
Serum (neonatal)[d]	ADVIA Chemistry TBIL_2 on ADVIA 1800 Chemistry System	y = 1.00x + 0.1 mg/dL (y = 1.00x + 2 µmol/L)	0.3–29.8 mg/dL (5–510 µmol/L)	120	0.983

[a] Number of samples tested.
[b] Correlation coefficient.
[c] Deming linear regression.
[d] These data were generated using Weighted Deming regression on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer.

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 EP09c.[14] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 0.99x + 0.0 mg/dL (y = 0.99x + 0 µmol/L)	0.1–28.8 mg/dL (2–492 µmol/L)	50	1.000

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

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer. 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

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer.

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH TBil_2 assay is designed to have ≤ 10% interference from hemoglobin 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 TBil_2 assay.[15]

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 (µmol/L)	Percent Bias
Hemoglobin A	500 mg/dL (0.310 mmol/L) 1000 mg/dL (0.621 mmol/L)	1.1 (19) 13.3 (227)	9 -8
Hemoglobin F	1000 mg/dL (10.0 g/L) 1000 mg/dL (10.0 g/L)	1.1 (19) 13.6 (233)	-9 -6
Lipemia (Triglycerides concentrate)	750 mg/dL (8.5 mmol/L) 750 mg/dL (8.5 mmol/L)	1.0 (17) 13.0 (222)	10 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 TBil_2 assay when present in human serum and plasma (lithium heparin) at the concentrations indicated in the table below.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mg/dL (µmol/L)	Percent Bias
Ascorbic acid[a]	50 mg/dL (2.8 mmol/L)	1.3 (22)	0
Indican	10 mg/mL (340 µmol/L) 10 mg/mL (340 µmol/L)	1.1 (19) 14.4 (246)	0 0
Cyanokit	40 µg/mL (30 µmol/L) 40 µg/mL (30 µmol/L)	1.1 (19) 14.4 (246)	0 -2

[a] These data were generated on the ADVIA Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer.[8]

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

Standardization

The Atellica CH TBil_2 assay is traceable to the American Association for Clinical Chemistry (AACC) reference method, which uses reference materials from the National Institute of Standards and Technology (NIST SRM 916).

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

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11. American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. *Pediatrics*. 2004;114(1):297-316.
12. 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.
13. 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.
14. 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-ed3.
15. 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	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Authorized representative in Switzerland
	Catalog number		Batch code
	Consult Instructions for Use		Contains sufficient for <n> tests
 < .../eifu >	Internet URL address to access the electronic instructions for use		Version of Instructions for Use

Symbol	Symbol Title	Symbol	Symbol Title
IVD	*In vitro* diagnostic medical device	Rev. REVISION	Revision
RxOnly	Prescription device (US only)	UDI	Unique Device Identifier
CE XXXX	CE Marking with Notified Body	CE	CE Marking
	Temperature limit		Keep away from sunlight
	Upper limit of temperature		Lower limit of temperature
	Do not re-use		Do not freeze
	Recycle		This way up
	Biological risks		Caution
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	YYYY-MM	Date format (year-month)
	Document face up[a]		Handheld barcode scanner
	Target		Mixing of substances
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Interval
MATERIAL ID	Unique material identification number	MATERIAL	Material
CONTROL TYPE	Type of control	CONTROL NAME	Name of control
CONTROL LOT VAL	Quality control lot value	CAL LOT VAL	Calibrator lot value

[a] Indicates Assay-eNote

Legal Information

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