

Total Iron Binding Capacity (TIBC)

Current Revision and Date ^a	Rev. 03, 2024-06	
Product Name	Atellica CH Total Iron Binding Capacity (TIBC)	REF 11097525 (800 tests)
Abbreviated Product Name	Atellica CH TIBC	
Test Name/ID	TIBC	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica CH SPCL CHEM CAL	REF 11099438
Specimen Types	Serum	
Sample Volume	24 µL	
Measuring Interval	40–670 µg/dL (7.16–119.93 µmol/L)	

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



Intended Use

The Atellica® CH Total Iron Binding Capacity (TIBC) assay is for *in vitro* diagnostic use in the quantitative measurement of total iron binding capacity in human serum on the Atellica® CI Analyzer. Measurement of total iron binding capacity is used in the diagnosis and treatment of anemia.¹⁻⁴

Summary and Explanation

This assay measures total iron binding capacity in a sequential process that is monitored spectrophotometrically. The sample is added to an acidic Reagent 1 (R1) containing iron and an iron binding dye. Bound iron is released by the acidic R1. Neutral Reagent 2 (R2) buffer is added and the shift in pH allows iron to bind and saturate the transferrin from the sample. The decrease in absorbance is directly proportional to the iron binding capacity of the serum sample.

Principles of the Procedure

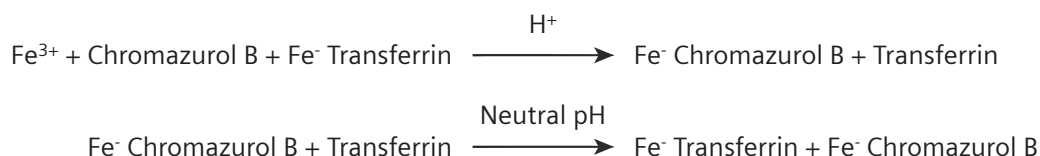
The Atellica CH Total Iron Binding Capacity (TIBC) assay uses two reagents in a sequential process that is monitored spectrophotometrically.

Step 1

1. The system adds R1, an acidic buffer containing an iron-binding dye (Chromazurol B) and ferric chloride, to the serum sample.
2. The low pH of R1 releases iron from transferrin.
3. The iron forms a colored complex with the dye at the end of this first step. The colored complex represents both the serum iron and excess iron already present in R1.

Step 2

1. The system then adds R2, a neutral buffer.
2. The pH shifts, resulting in a large increase in affinity of transferrin for iron.
3. The serum transferrin rapidly binds the iron by abstracting it from the dye-iron complex.
4. The observed decrease in absorbance of the colored dye-iron complex is directly proportional to the total iron-binding capacity of the serum sample.

Reaction Equation**Reagents**

Material Description	Storage	Stability ^a
Atellica CH TIBC	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	5 days
Well 1 (W1)		
Reagent 1 (R1)		
9.2 mL		
Chromazurol B (166 µmol/L); cetrimide (735 µmol/L); ferric chloride (16 µmol/L); acetate buffer; stabilizers; preservatives		
Well 2 (W2)		
Reagent 1 (R1)		
9.2 mL		
Chromazurol B (166 µmol/L); cetrimide (735 µmol/L); ferric chloride (16 µmol/L); acetate buffer; stabilizers; preservatives		
Pack 2 (P2)		
Well 1 (W1)		
Reagent 2 (R2)		
5.5 mL		
Sodium bicarbonate buffer (338 mmol/L); stabilizers; preservatives		
Well 2 (W2)		
Reagent 2 (R2)		
5.5 mL		
Sodium bicarbonate buffer (338 mmol/L); stabilizers; preservatives		

^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](https://www.siemens-healthineers.com).

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.



H317

P280, P302+P352,
P333+P313,
P362+P364

Warning!

May cause an allergic skin reaction.

Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Contains: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (ADVIA Chemistry TIBC R1 and R2)

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

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.

Specimen Collection and Handling

Serum is the recommended sample type 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 4 days at room temperature or for up to 7 days at 2–8°C or stored frozen for up to 2 months at -20°C.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 24 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
11097525	Pack 1 (P1) Well 1 (W1) 9.2 mL of Atellica CH TIBC Reagent 1 Well 2 (W2) 9.2 mL of Atellica CH TIBC Reagent 1 Pack 2 (P2) Well 1 (W1) 5.5 mL of Atellica CH TIBC Reagent 2 Well 2 (W2) 5.5 mL of Atellica CH TIBC Reagent 2	4 x 200

Materials Required but Not Provided

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

REF	Description		
	Atellica CI Analyzer ^a		
11099438	Atellica CH SPCL CHEM CAL (calibrator)	10 x 5.0 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, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 60 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 24 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 24 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 TIBC assay, use Atellica CH SPCL 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	180
Pack Calibration	5

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 TIBC 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](https://www.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 µg/dL (common units) or µmol/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: $\mu\text{g/dL} \times 0.179 = \mu\text{mol/L}$

Use the following formula to obtain serum UIBC from serum TIBC and iron: $\text{TIBC} - \text{Iron} = \text{UIBC}$ (µg/dL or 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 TIBC assay is limited to the detection of total iron binding capacity in human serum.

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.

Expected Values

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified by analysis for the Atellica CI Analyzer.¹⁰

The reference interval for total iron binding capacity is 250–425 µg/dL (44.75–76.08 µmol/L) for adults.¹¹

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.¹⁰

Performance Characteristics

Measuring Interval

The Atellica CH TIBC assay is linear from 40–670 µg/dL (7.16–119.93 µmol/L). The system flags all values that are outside the specified measuring interval.

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 $LoD \leq 40 \mu\text{g/dL}$ (7.16 µmol/L).

The LoD corresponds to the lowest concentration of total iron binding capacity that can be detected with a probability of 95%. The LoD for the Atellica CH TIBC assay is 17 µg/dL (3.04 µmol/L), and was determined using 450 determinations, with 225 blank and 225 low level replicates, and a LoB of 13 µg/dL (2.33 µmol/L).

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

Precision

The Repeatability precision of the Atellica CH TIBC assay is designed to have the following characteristics:

- $CV \leq 5.0\%$ at 200–670 µg/dL

The Within-Laboratory precision of the Atellica CH TIBC assay is designed to have the following characteristics:

- $CV \leq 7.0\%$ at 200–670 µg/dL

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 ($N \geq 80$ for each sample). The following results were obtained:

Sample Type	N ^a	Mean μg/dL (μmol/L)	Repeatability		Within-Laboratory Precision	
			SD ^b μg/dL (μmol/L)	CV ^c (%)	SD μg/dL (μmol/L)	CV (%)
Serum QC 1	80	221 (39.56)	1.8 (0.322)	0.8	4.5 (0.806)	2.0
Serum QC 2	80	362 (64.80)	3.2 (0.573)	0.9	6.6 (1.181)	1.8
Serum 1	80	614 (109.91)	2.1 (0.376)	0.3	6.9 (1.235)	1.1

^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 the following reproducibility:

- $CV \leq 10.0\%$ at 200–670 μg/dL

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 μg/dL (μmol/L)	Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
			SD ^b μg/dL (μmol/L)	CV ^c (%)	SD μg/dL (μmol/L)	CV (%)	SD μg/dL (μmol/L)	CV (%)	SD μg/dL (μmol/L)	CV (%)	SD μg/dL (μmol/L)	CV (%)
Serum QC 1	225	222 (39.74)	1.3 (0.233)	0.6	6.6 (1.181)	3.0	1.2 (0.215)	0.5	2.7 (0.483)	1.2	7.3 (1.307)	3.3
Serum 1	225	319 (57.10)	1.1 (0.197)	0.3	5.1 (0.913)	1.6	2.1 (0.376)	0.7	1.2 (0.215)	0.4	5.7 (1.020)	1.8
Serum 2	225	547 (97.91)	3.4 (0.609)	0.6	10.2 (1.826)	1.9	0.8 (0.143)	0.1	0.0 (0.000)	0.0	10.8 (1.933)	2.0

^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 TIBC 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 for serum. 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	ADVIA® Chemistry TIBC on ADVIA® 1800 Chemistry System	$y = 1.06x - 24 \mu\text{g/dL}$ ($y = 1.06x - 4.30 \mu\text{mol/L}$)	87– 613 $\mu\text{g/dL}$ (15.57– 109.73 $\mu\text{mol/L}$)	107	0.994
Serum	Atellica CH TIBC on Atellica CH Analyzer	$y = 0.98x + 5 \mu\text{g/dL}$ ($y = 0.98x + 0.90 \mu\text{mol/L}$)	61– 609 $\mu\text{g/dL}$ (10.92– 109.01 $\mu\text{mol/L}$)	107	0.998

^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.

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 TIBC assay is designed to have $\leq 10\%$ interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH TIBC 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 $\mu\text{g/dL}$ ($\mu\text{mol/L}$)	Percent Bias
Hemoglobin	1000 mg/dL (0.624 mmol/L)	413 (73.93)	-1
	1000 mg/dL (0.624 mmol/L)	631 (112.95)	-3
Bilirubin, conjugated	25 mg/dL (428 $\mu\text{mol/L}$)	428 (76.61)	-3
	19 mg/dL (325 $\mu\text{mol/L}$)	628 (112.41)	-1
Bilirubin, unconjugated	25 mg/dL (428 $\mu\text{mol/L}$)	428 (76.61)	-1
	25 mg/dL (428 $\mu\text{mol/L}$)	587 (105.07)	-5
Lipemia (Intralipid®)	375 mg/dL (4.2 mmol/L)	430 (76.97)	10
	250 mg/dL (2.8 mmol/L)	608 (108.83)	10
Lipemia (Triglycerides)	1000 mg/dL (11.3 mmol/L)	412 (73.75)	7
	500 mg/dL (5.7 mmol/L)	627 (112.23)	9

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

Standardization

The Atellica CH TIBC assay is traceable to an internal standard.

Assigned values for calibrators are traceable to this standardization.¹⁶

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.

siemens-healthineers.com

References

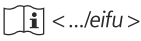
1. Burtis CA, Ashwood ER. *Tietz Fundamentals of Clinical Chemistry*. 5th ed. Philadelphia, PA: WB Saunders Company; 2001:992.
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4. Gambino R, Desvarieux E, Orth M. The relation between chemically measured total iron-binding capacity concentrations and immunologically measured transferrin concentrations in human serum. *Clin Chem*. 1997;43:2408–2412.
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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.
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9. Young DS. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. 3rd ed. Washington, DC: AACC Press; 2007:570.
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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.

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16. Data on file at Siemens Healthcare Diagnostics.

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
	<i>In vitro</i> diagnostic medical device	5.5.1 ^a		Revision	Proprietary
	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
	Date format (year-month-day)	N/A		Date format (year-month)	N/A
	Document face up ^f	1952 ^e		Handheld barcode scanner	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Target	Proprietary		Mixing of substances	5657 ^g
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary		Interval	Proprietary
	Unique material identification number	Proprietary		Material	Proprietary
	Type of control	Proprietary		Name of control	Proprietary
	Quality control lot value	Proprietary		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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