Iron2

FOR USE WITH

ARCHITECT

Read Highlighted Changes: Revised March 2022.

REF 04T0220

REF 04T0230

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Iron2

INTENDED USE

The Iron2 assay is used for the direct colorimetric determination of iron without deproteinization in human serum or plasma on the ARCHITECT c Systems.

The Iron2 assay is to be used as an aid in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

SUMMARY AND EXPLANATION OF THE TEST

Iron exists in biological fluids as a component of hemoglobin and myoglobin and is bound in serum and plasma to transferrin, which acts as a carrier protein. Increased iron concentrations are seen in hemolytic anemias, hemochromatosis, and acute liver disease. Decreased iron concentrations are seen in iron deficiency and anemia of chronic disease such as in chronic renal disease.[1] Major causes of iron deficiency include gastrointestinal and menstrual bleeding. For the assessment of the body's iron status, the measurement of transferrin and ferritin can provide more accurate information.[2]

PRINCIPLES OF THE PROCEDURE

The Iron2 assay is an automated clinical chemistry assay.

At an acidic pH, iron is released from transferrin to which it is bound, and then quantitatively reduced to a ferrous state. The iron forms with ferene-S (3-(2-pyridyl)-5,6-bis-[2-(5-furylsulfonic acid)]-1,2,4-triazine), a stable colored complex of which the color intensity is proportional to the amount of iron in the sample.

Particular reaction conditions and a specific masking agent almost entirely eliminate the interference from copper.

Methodology: Ferene

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Iron2 Reagent Kit 04T02

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	04T0220	04T0230
Tests per cartridge set	125	310
Number of cartridge sets per kit	4	4
Tests per kit	500	1240
R1	38.7 mL	91.0 mL
R2	6.5 mL	11.9 mL

R1 Active ingredient: guanidine hydrochloride (382.120 g/L). Preservative: ProClin 300.

R2 Active ingredients: ferene-S (4.944 g/L) and L-ascorbic acid (96.866 g/L). Preservative: ProClin 300.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[3-6]

The following warnings and precautions apply to: R1

WARNING	Contains guanidine hydrochloride, acetic acid, thiourea and methylisothiazolones.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.

Abbott

Prevention	
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P301+P330+P312	IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor / physician if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P337+P313	If eye irritation persists: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

The following warnings and precautions apply to: R2	
	
WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
P273	Avoid release to the environment.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.
- Upon receipt, reagent cartridges can be used immediately or stored in an upright position.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Iron2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the ARCHITECT c Systems Assay Disk Version 17.00 (or higher) and either the MULTIGENT Assay Disk Version 9.00 (or higher) or the Special Chemistry Assay Disk Version 7.00 (or higher) must be completed prior to performing the assay. See below for impacted assays:

Assay Name	Short Name	REF	Assay Number	VERSION	
				Conventional Units / Alternate Units	SI Units / Alternate Units
Ceruloplasmin	Cerul	6K91	2966	10	10 (c8000) 9 (c4000, c16000)
D-Dimer	dDim	7K02	2904	6	6
Immunoglobulin M	IgM	1E01	1059	13	12
Kappa Light Chains	Kappa	6K96	2959	11	11
Microalbumin	uAlb	2K98	2839	8	8
Prealbumin	PAlb	1E02	1062	13	13
Salicylate	Sali	3K01	2860	6	6

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
µg/dL	0.179	µmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum
	Serum separator
Plasma	Lithium heparin
	Lithium heparin separator
	Sodium heparin

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25°C)	10 hours[7]
	2 to 8°C	7 days[8]
	-20°C	12 months[9]

Avoid multiple freeze/thaw cycles.[8]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[10] The storage information provided here is based on references.

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04T02 Iron2 Reagent Kit

Materials Required but not Provided

- Iron2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- Controls containing iron
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 to ensure sufficient specimen is present.

- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 20.0 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Sample dilutions have not been evaluated for the Iron2 assay. Samples with an iron value exceeding 1143 µg/dL (204.6 µmol/L) are flagged with the code "> 1143 µg/dL" ("> 204.6 µmol/L"). The standard dilution factor for the Iron2 assay is 1:1.45.

For details on configuring automated dilutions, refer to the ARCHITECT System Operations Manual, Section 2.

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration is stable for approximately 15 days (360 hours) but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to “Basic QC Practices” by James O. Westgard, Ph.D. for guidance on laboratory quality control practices.[11]

RESULTS

Calculation

The Iron2 assay utilizes the Linear data reduction method to generate a calibration and results.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[12]

	µg/dL	µmol/L
Analytical Measuring Interval (AMI)[a]	7 - 1143	1.3 - 204.6
Reportable Interval[b]	4 - 1143	0.7 - 204.6

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in µg/dL (µmol/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval of 4 µg/dL (0.7 µmol/L). To flag values using the lower limit of the analytical measuring interval of 7 µg/dL (1.3 µmol/L), the operator must edit the Low Linearity value, adjusted by the standard dilution factor.

For detailed information on editing the result settings of assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Falsely elevated iron results may be observed at the low end of the analytical measuring interval in samples with triglyceride concentrations above 200 mg/dL.
- Falsely elevated iron results may be observed at the low end of the analytical measuring interval in samples with unconjugated bilirubin concentrations above 25 mg/dL.
- Iron dextran treatment can result in elevated total iron results.
- Use of the Iron2 assay for patients undergoing treatment with deferoxamine or other iron chelating compounds is not recommended.
- Transiently elevated iron levels can be observed post ingestion of supplements/vitamins that contain iron.[13]
- Rifampicin levels above 5 mg/L may produce artificially low results with the Iron2 assay.
- Substances that demonstrated interference with the Iron2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- SmartWashes for assays impacted by Iron2 must be configured to avoid interference due to reagent carryover. See the INSTRUMENT PROCEDURE section of this package insert for the required assay file updates.

EXPECTED VALUES

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range

Age	Range (µg/dL)	Range (µmol/L)
Pediatric[14]		
0 to < 14 years	16 - 128	2.9 - 22.9*
14 to < 19 years (Female)	20 - 162	3.6 - 29.0*
14 to < 19 years (Male)	31 - 168	5.5 - 30.1*
Adult[15]		
Female	50 - 170	9.0 - 30.4
Male	65 - 175	11.6 - 31.3

* Alternate result units were calculated by Abbott and are not included in the citation provided.

Abbott has not evaluated reference ranges in the pediatric population.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[16] Testing was conducted using 3 lots of the Iron2 reagents, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 human serum panels were tested in a minimum of 2 replicates twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot are paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (µg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	245	0.8	0.3	0.9 (0.9 -1.6)	0.4 (0.4 - 0.7)
Control Level 2	80	71	0.4	0.6	0.5 (0.5 - 0.6)	0.7 (0.7 - 0.9)
Panel A	80	15	0.2	1.0	0.2 (0.2 - 0.4)	1.0 (1.0 - 3.0)
Panel B	80	371	1.2	0.3	2.5 (2.4 - 3.6)	0.7 (0.6 - 1.0)
Panel C	80	954	2.6	0.3	4.4 (2.1 - 5.6)	0.5 (0.2 - 0.6)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across the 3 reagent lot/calibrator lot/instrument combinations.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (µmol/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	43.9	0.14	0.3	0.16 (0.16 - 0.27)	0.4 (0.4 - 0.6)
Control Level 2	80	12.7	0.04	0.4	0.07 (0.07 - 0.11)	0.6 (0.6 - 0.9)
Panel A	80	2.7	0.05	1.9	0.06 (0.06 - 0.09)	2.3 (2.3 - 3.4)
Panel B	80	66.3	0.21	0.3	0.45 (0.44 - 0.63)	0.7 (0.7 - 1.0)
Panel C	80	170.8	0.45	0.3	0.79 (0.38 - 1.00)	0.5 (0.2 - 0.6)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across the 3 reagent lot/calibrator lot/instrument combinations.

Reproducibility

A study was performed based on guidance from CLSI EP05-A3.[16] Testing was conducted using 1 lot of the Iron2 reagents, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Two controls and 3 human serum panels were tested in a minimum of 3 replicates at 2 separate times per day on 5 different days.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (µg/dL)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	245	0.8	0.3	1.1	0.4	1.1	0.4
Control Level 2	90	70	0.3	0.5	0.6	0.8	0.6	0.9
Panel A	90	14	0.4	2.9	0.4	2.9	0.5	3.4
Panel B	90	375	1.0	0.3	1.6	0.4	2.2	0.6
Panel C	90	968	2.3	0.2	2.5	0.3	9.9	1.0

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (µmol/L)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	43.9	0.13	0.3	0.18	0.4	0.18	0.4
Control Level 2	90	12.5	0.06	0.5	0.09	0.8	0.11	0.9
Panel A	90	2.6	0.04	1.6	0.05	2.0	0.06	2.4
Panel B	90	67.1	0.18	0.3	0.28	0.4	0.39	0.6
Panel C	90	173.3	0.41	0.2	0.45	0.3	1.77	1.0

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Accuracy

A study was performed to estimate the bias of the Iron2 assay relative to standard reference material NIST SRM 3126. Testing was conducted using 3 concentrations of the standard across 3 lots of the Iron2 reagents, 2 lots of the Consolidated Chemistry Calibrator, and 3 instruments. The bias ranged from -6.7% to 4.4% across concentrations of the standard, instruments, calibrator and reagent lots.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[17] Testing was conducted using 3 lots of the Iron2 reagents on each of 2 instruments over a minimum of 3 days. The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below. These representative data support the lower limit of the analytical measuring interval.

	µg/dL	µmol/L
LoB[a]	1	0.2
LoD[b]	4	0.7
LoQ[c]	7	1.3

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD presented in the table is in alignment with the low end of the Reportable Interval for the Iron2 assay on the ARCHITECT c System.

[c] The LoQ presented in the table is in alignment with the low end of the AMI for the Iron2 assay on the ARCHITECT c System.

Linearity

A study was performed based on guidance from CLSI EP06-A.[18] This assay is linear across the analytical measuring interval of 7 to 1143 µg/dL (1.3 to 204.6 µmol/L).

Analytical Specificity

Interference

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[19] Each substance was tested at 2 levels of the analyte (approximately 50 µg/dL and 180 µg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

Potentially Interfering Substance	Interferent Level		Analyte Level	
	Default Units	Alternate Units	Default Units	Alternate Units
Bilirubin, conjugated	60 mg/dL	712 µmol/L	50 µg/dL	8.95 µmol/L
			180 µg/dL	32.22 µmol/L
Bilirubin, unconjugated	25 mg/dL	428 µmol/L	50 µg/dL	8.95 µmol/L
	60 mg/dL	1026 µmol/L	180 µg/dL	32.22 µmol/L
Total protein	15 g/dL	150 g/L	50 µg/dL	8.95 µmol/L
			180 µg/dL	32.22 µmol/L
Triglycerides	200 mg/dL	2.26 mmol/L	50 µg/dL	8.95 µmol/L
	1000 mg/dL	11.3 mmol/L	180 µg/dL	32.22 µmol/L

Interference beyond ± 10% (based on 95% Confidence Interval [CI]) was observed at the concentrations shown below for the following substances.

Interference beyond ± 10% (based on 95% Confidence Interval [CI])

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Bilirubin, unconjugated	30 mg/dL	513 µmol/L	50 µg/dL	8.95 µmol/L	12% (11%, 13%)
Triglycerides	250 mg/dL	2.82 mmol/L	50 µg/dL	8.95 µmol/L	11% (10%, 12%)

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[19] Each substance was tested at 2 levels of the analyte (approximately 50 µg/dL and 180 µg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

Potentially Interfering Substance	Interferent Level	
	Default Units	Alternate Units
Acetaminophen	160 mg/L	1059 µmol/L
Acetylcysteine	150 mg/L	920 µmol/L
Acetylsalicylic acid	30 mg/L	167 µmol/L
Ampicillin-Na	80 mg/L	215 µmol/L
Ascorbic acid	60 mg/L	341 µmol/L
Biotin	4250 ng/mL	17.4 µmol/L
Calcium carbonate	900 mg/L	8991 µmol/L
Ca-dobesilate	60 mg/L	143 µmol/L
Cefotaxime	53 mg/dL	1166 µmol/L
Cefoxitin	6600 mg/L	15 mmol/L
Cholecalciferol (Vitamin D3)	0.1 mg/L	0.26 µmol/L
Cyclosporine	2 mg/L	1.66 µmol/L
Deferoxamine	0.03 mg/dL	0.53 µmol/L
Doxycycline	20 mg/L	45.0 µmol/L
Ethanol	600 mg/dL	130.20 mmol/L
Ibuprofen	220 mg/L	1067 µmol/L
Iron dextran	1 mg/L	6.50 µmol/L
Levodopa	8 mg/L	40.6 µmol/L
Mebendazole	2 mg/L	6.78 µmol/L
Methyldopa	25 mg/L	118 µmol/L
Metronidazole	130 mg/L	759 µmol/L
Phenylbutazone	330 mg/L	1069 µmol/L
Rifampicin	5 mg/L	6.10 µmol/L
Sodium heparin	4 U/mL	N/A
Stanozolol	60 mg/L	183 µmol/L
Theophylline (1,3-dimethylxanthine)	60 mg/L	333 µmol/L

N/A = Not applicable

Interference beyond ± 10% (based on 95% Confidence Interval [CI]) was observed at the concentrations shown below for the following substances.

Interference beyond ± 10% (based on 95% Confidence Interval [CI])

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Deferoxamine	0.05 mg/dL	0.89 µmol/L	50 µg/dL	8.95 µmol/L	-11% (-11%, -10%)
Iron dextran	17 mg/L	111 µmol/L	50 µg/dL	8.95 µmol/L	110% (108%, 111%)
Rifampicin	10 mg/L	12.2 µmol/L	50 µg/dL	8.95 µmol/L	-14% (-15%, -13%)

Interferences from medication or endogenous substances may affect results.[20]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3, [21] using the Passing-Bablok regression method.

Iron2 vs Iron on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	113	µg/dL (µmol/L)	1.00	-1 (-0.2)	1.05	16 - 879 (2.9 - 157.2)

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Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

The ARCHITECT c System family of instruments consists of c4000, c8000, and c16000 instruments.

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+353-43-3331000

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Abbott Laboratories
Abbott Park, IL 60064 USA

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For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.

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