IRON

This package insert contains information to run the Iron assay on the AEROSET System and the ARCHITECT® c8000 System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States: 1-877-4ABBOTT
Canada: 1-800-387-8378 (English speaking customers)
1-800-465-2675 (French speaking customers)
International: Call your local Abbott representative

Symbols in Product Labeling

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAL[1-2]</td>
<td>Calibrators 1 and 2</td>
</tr>
<tr>
<td>CONC</td>
<td>Concentration</td>
</tr>
<tr>
<td>EC/REP</td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td>INGRED</td>
<td>Ingredients</td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code/Lot number</td>
</tr>
<tr>
<td>R1</td>
<td>Reagent 1</td>
</tr>
<tr>
<td>R2</td>
<td>Reagent 2</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog number/List number</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>1</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>i</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>♂</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>⬛</td>
<td>Use by/Expiration date</td>
</tr>
</tbody>
</table>
NAME
IRON

INTENDED USE
The Iron assay is used for the quantitation of iron in human serum.

SUMMARY AND EXPLANATION OF TEST
Measurement of iron is used in the diagnosis and treatment of various iron anemias, iron overload, and iron poisonings. Serum iron has been determined by several spectrophotometric methods, including the use of FERROZINE, bathophenanthroline, and FERENE.1,2

PRINCIPLES OF PROCEDURE
The Iron assay utilizes an acidic media to release ferric iron from transferrin. The ferric iron is converted to the ferrous form by the action of hydroxylamine hydrochloride. The released ferrous iron reacts with FERENE to produce a colored iron-FERENE complex. The absorbance of the iron-FERENE complex is measured at 604 nm and is proportional to the concentration of iron present in the sample. Thiourea and detergent are added to prevent copper interference and turbidity, respectively.

Methodology: FERENE without a protein removal step

REAGENTS
Reagent Kit
Iron is supplied as a liquid, ready-to-use, two-reagent kit which contains:

<table>
<thead>
<tr>
<th>REF</th>
<th>7D68-20</th>
<th>7D68-30</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>10 x 84 mL</td>
<td>4 x 84 mL</td>
</tr>
<tr>
<td>R2</td>
<td>10 x 13 mL</td>
<td>4 x 13 mL</td>
</tr>
</tbody>
</table>

Estimated tests per kit: 3,556*  
Estimated tests per kit: 1,422*

*Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients  | Concentration
---|---
R1 Sodium Acetate | 1,027 mmol/L
Acetic Acid | 810 mmol/L
Hypoxylamine HCl | 360 mmol/L
Thiourea (animal carcinogen) | 118 mmol/L

R2 Sodium Acetate | 880 mmol/L
Acetic Acid | 990 mmol/L
FERENE | 14 mmol/L

REAGENT HANDLING AND STORAGE
Reagent Handling
Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles. CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage
Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent stability is 27 days if the reagent is uncapped and onboard.

WARNINGS AND PRECAUTIONS

Precautions for Users
1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.3 Biosafety Level 2 or other appropriate biosafety practices4,5 should be used for materials that contain or are suspected of containing infectious agents.
5. WARNING: This product contains Thiourea. Thiourea is considered to be an animal carcinogen.
6. [R1] contains acetic acid and hydroxylamine hydrochloride and is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:
   - R36 Irritating to eyes.
   - R43 May cause sensitization by skin contact.
   - S24 Avoid contact with skin.
   - S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
   - S35 This material and its container must be disposed of in a safe way.
   - S37/39 Wear suitable gloves and eye/face protection.
   - S46 If swallowed, seek medical advice immediately and show this container or label.
7. [R2] contains acetic acid and is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:
   - R36 Irritating to eyes.
   - S24 Avoid contact with skin.
   - S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
   - S35 This material and its container must be disposed of in a safe way.
   - S37/39 Wear suitable gloves and eye/face protection.
   - S46 If swallowed, seek medical advice immediately and show this container or label.

SPECIMEN COLLECTION AND HANDLING
Suitable Specimens
Serum is the acceptable specimen.

Serum: Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. When processing samples, separate serum from blood cells or gel according to the specimen collection tube manufacturer’s instructions.

Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.

Samples should be drawn in the morning with the patient in a fasting state. A distinct diurnal variation results in serum iron and TIBC concentrations being lower in the afternoon than morning and quite low in the evening in healthy persons.7

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and Section 5 of the instrument-specific operations manual.
Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time interval cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

**PROCEDURE**

**Materials Provided**
- REF 7D68 Iron Reagent Kit

**Materials Required but not Provided**
- 1E69 Iron/Magnesium Calibrator, CAL12 3 x 5 mL
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

**Assay Procedure**

For a detailed description of how to run an assay, refer to Section 5 of the instrument-specific operations manual.

**Specimen Dilution Procedures**

The AEROSET System and the ARCHITECT c8000 System have automatic dilution features; refer to Section 2 of the instrument-specific operations manual for additional information.

**Serum:** Specimens with iron values exceeding 1,779 μg/dL (318.4 μmol/L) are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.

**Automated Dilution Protocol**

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the concentration by multiplying the result by the entered dilution factor. To set up the automatic dilution feature, refer to Section 2 of the instrument-specific operations manual.

**Manual Dilution Procedure**

Manual dilutions should be performed as follows:
- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

**NOTE:** If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to Section 5 of the instrument-specific operations manual.

**CALIBRATION**

Calibration is stable for approximately 27 days (648 hours) and is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For a detailed description of how to calibrate an assay, refer to Section 6 of the instrument-specific operations manual.

For information on calibrator standardization, refer to the Iron/Magnesium Calibrator package insert.

**QUALITY CONTROL**

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions:

- Two levels of controls (normal and abnormal) 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, patient values may be suspect. Follow the established quality control procedures for your laboratory.
- Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**RESULTS**

Refer to the instrument-specific operations manual for information on results calculations.

- **AEROSET System Operations Manual—Appendix A**
- **ARCHITECT System Operations Manual—Appendix C**

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

**EXPECTED VALUES**

**Reference Range**

<table>
<thead>
<tr>
<th></th>
<th>Range (μg/dL)</th>
<th>Range (μmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult, Male</td>
<td>31 to 144</td>
<td>5.5 to 25.78</td>
</tr>
<tr>
<td>Adult, Female</td>
<td>25 to 156</td>
<td>4.48 to 27.92</td>
</tr>
</tbody>
</table>

To convert results from μg/dL to μmol/L, multiply μg/dL by 0.179. It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Linearity**

Iron is linear up to 1,779 μg/dL (318.4 μmol/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP6-P.12

**Limit of Detection (LOD)**

The LOD for Iron is 1.3 μg/dL (0.24 μmol/L). The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample.

**Limit of Quantitation (LOQ)**

The LOQ for Iron is 5.4 μg/dL (0.97 μmol/L). The LOQ is the analyte concentration at which the CV = 20%.
SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Interfering Substances

Interference studies were conducted using CLSI protocol NCCLS EP7-P.\(^{13}\) Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Interferent Concentration (μg/dL)</th>
<th>Target</th>
<th>Observed (μg/dL)</th>
<th>(μg/dL) (%) of Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>60 mg/dL (1.026 μmol/L)</td>
<td>4</td>
<td>142.5</td>
<td>99.3</td>
</tr>
<tr>
<td></td>
<td>750 mg/dL (13.3 mmol/L)</td>
<td>4</td>
<td>152.0</td>
<td>93.5</td>
</tr>
<tr>
<td></td>
<td>900 μg/dL (141 μmol/L)</td>
<td>4</td>
<td>131.9</td>
<td>110.2</td>
</tr>
<tr>
<td></td>
<td>1,200 μg/dL (188 μmol/L)</td>
<td>4</td>
<td>131.9</td>
<td>113.9</td>
</tr>
<tr>
<td>Copper</td>
<td>30 mg/dL (513 μmol/L)</td>
<td>4</td>
<td>142.5</td>
<td>99.3</td>
</tr>
<tr>
<td></td>
<td>60 mg/dL (1.026 μmol/L)</td>
<td>4</td>
<td>142.5</td>
<td>98.4</td>
</tr>
<tr>
<td></td>
<td>125 mg/dL (2.25 g/L)</td>
<td>4</td>
<td>130.7</td>
<td>106.4</td>
</tr>
<tr>
<td></td>
<td>1,000 mg/dL (18.3 mmol/L)</td>
<td>4</td>
<td>152.0</td>
<td>94.1</td>
</tr>
</tbody>
</table>

Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Human triglyceride solutions at the above concentrations were prepared by mixing an elevated triglyceride human serum pool with a normal triglyceride human serum pool. Copper solutions at the above concentrations were prepared by addition of a copper stock to human serum samples.

Interferences from medications or endogenous substances may affect results.\(^{14}\)

Precision

The imprecision of the Iron assay is ≤ 4.7% Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A\(^{15}\) are summarized below.

<table>
<thead>
<tr>
<th>Control</th>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Mean (μg/dL)</td>
<td>239.5</td>
<td>64.3</td>
</tr>
<tr>
<td>Within Run</td>
<td>SD</td>
<td>0.67</td>
</tr>
<tr>
<td></td>
<td>%CV</td>
<td>0.3</td>
</tr>
<tr>
<td>Between Run</td>
<td>SD</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>%CV</td>
<td>0.2</td>
</tr>
<tr>
<td>Between Day</td>
<td>SD</td>
<td>1.99</td>
</tr>
<tr>
<td></td>
<td>%CV</td>
<td>0.8</td>
</tr>
<tr>
<td>Total</td>
<td>SD</td>
<td>2.14</td>
</tr>
<tr>
<td></td>
<td>%CV</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.\(^{16}\)

Serum results from the Iron assay on the AEROSET System were compared with those from a commercially available FERROZINE methodology.

Serum results from the Iron assay on an ARCHITECT c8000 System were compared with the Iron assay on the AEROSET System.

<table>
<thead>
<tr>
<th>N</th>
<th>79</th>
<th>84</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y - Intercept</td>
<td>-2.592</td>
<td>-2.202</td>
</tr>
<tr>
<td>Correlation Coefficient</td>
<td>0.994</td>
<td>1.000</td>
</tr>
<tr>
<td>Slope</td>
<td>0.973</td>
<td>1.012</td>
</tr>
<tr>
<td>Range (μg/dL)*</td>
<td>7.8 to 270.7</td>
<td>15.80 to 1,728.90</td>
</tr>
</tbody>
</table>

*BEROSET Range

BIBLIOGRAPHY


TRADEMARKS

A-GENT, AEROSET, ARCHITECT, and c8000 are registered trademarks of Abbott Laboratories. All other trademarks, brands, product names, and trade names are the property of their respective companies.
# AEROSET SYSTEM ASSAY PARAMETERS

## Iron Serum—Conventional Units

### Assay Configuration: Outline Page

### Assay Configuration: Base Page

### Assay Configuration: Calibration Page

### Assay Configuration: SmartWash Page

## Iron Serum—SI Units

### Assay Configuration: Outline Page

### Assay Configuration: Base Page

### Assay Configuration: Calibration Page

### Assay Configuration: SmartWash Page

Refer to Assay Configuration in Section 2 of the AEROSET System Operations Manual for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.
**Iron Serum—Conventional and SI Units**

### Configure assay parameters — General

<table>
<thead>
<tr>
<th>General</th>
<th>Calibration</th>
<th>SmartWash</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assay:</strong> Iron</td>
<td><strong>Type:</strong> Photometric</td>
<td><strong>Version:</strong> †</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number:</strong> 1030</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reagent:** IRON0

**Diluent dispense mode:** Type 0

**Dilution name:** Standard

**Reaction definition:** Configured as linear model

**Assay number:** 1030

**Component reagent / assay wash:**

- **COMPONENT / REAGENT / ASSAY WASH**
  - **Volume:** Repeats
  - **Reagent:** ALBG0
  - **Water:** 1
  - **Reagent:** ALKP0
  - **Water:** 1
  - **Cuvette:** Trig

**Correlation factor:**

- **Either 0 – 130 (Y)**: 1.0
- **Female 0 – 130 (Y)**: 25.0
- **Male 0 – 130 (Y)**: 130.0

**Gender and age specific ranges:**

- **Male 0 – 130 (Y)**
  - **Normal:** 31.0
  - **Extreme:** 144.0
- **Female 0 – 130 (Y)**
  - **Normal:** 25.0
  - **Extreme:** 156.0
- **Either 0 – 130 (Y)**
  - **Normal:** 25.0
  - **Extreme:** 156.0

**Result units:**

- **Either 0 – 130 (Y)**: 
  - **Normal:** μmol/L
  - **Extreme:** μmol/L
- **Female 0 – 130 (Y)**: 
  - **Normal:** μmol/L
  - **Extreme:** μmol/L
- **Either 0 – 130 (Y)**: 
  - **Normal:** μmol/L
  - **Extreme:** μmol/L

**Decimal places:**

- **Either 0 – 130 (Y)**: 2
- **Female 0 – 130 (Y)**: 2
- **Either 0 – 130 (Y)**: 2

**Expected cal factor tolerance %:**

- **Either 0 – 130 (Y)**: 0.00
- **Female 0 – 130 (Y)**: 0.00
- **Either 0 – 130 (Y)**: 0.00

- **Version:** †

### Configure result units

- **Assay:** Iron
  - **Version:** †
  - **Result units:** μmol/L

**Correlation factor:**

- **Either 0 – 130 (Y)**: 1.0
- **Female 0 – 130 (Y)**: 25.0
- **Male 0 – 130 (Y)**: 130.0

**Gender and age specific ranges:**

- **Male 0 – 130 (Y)**
  - **Normal:** 5.5
  - **Extreme:** 25.8
- **Female 0 – 130 (Y)**
  - **Normal:** 4.5
  - **Extreme:** 27.9
- **Either 0 – 130 (Y)**
  - **Normal:** 4.5
  - **Extreme:** 27.9

**Result units:**

- **Either 0 – 130 (Y)**: 
  - **Normal:** μmol/L
  - **Extreme:** μmol/L
- **Female 0 – 130 (Y)**: 
  - **Normal:** μmol/L
  - **Extreme:** μmol/L
- **Either 0 – 130 (Y)**: 
  - **Normal:** μmol/L
  - **Extreme:** μmol/L

**Decimal places:**

- **Either 0 – 130 (Y)**: 2
- **Female 0 – 130 (Y)**: 2
- **Either 0 – 130 (Y)**: 2

**Expected cal factor tolerance %:**

- **Either 0 – 130 (Y)**: 0.00
- **Female 0 – 130 (Y)**: 0.00
- **Either 0 – 130 (Y)**: 0.00

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† Due to differences in instrument systems and unit configurations, version numbers may vary.

‡‡ Displays the number of decimal places defined in the decimal places parameter field.

‡ Refer to concentration specified on calibrator labeling or value sheet.

†† The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.