PRECISION STUDIES

Total precision data was collected on two concentrations of control sera in 40 runs conducted over 20 days.

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Total SD</th>
<th>Total CV %</th>
<th>Within Run SD</th>
<th>Within Run CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg/dL</td>
<td>µmol/L</td>
<td>µg/dL</td>
<td>µmol/L</td>
<td>µg/dL</td>
</tr>
<tr>
<td>58.1</td>
<td>10.4</td>
<td>2.0</td>
<td>0.36</td>
<td>3.5</td>
</tr>
<tr>
<td>152.4</td>
<td>27.3</td>
<td>3.3</td>
<td>0.59</td>
<td>2.2</td>
</tr>
</tbody>
</table>

ACCURACY

The performance of this method (y) was compared with the performance of a similar method (x) on a Roche/Hitachi® 704. Forty-seven patient serum samples ranging from 12-704 µg/dL (2-126 µmol/L) gave a correlation coefficient was 0.999. Linear regression analysis gave the following equation:

\[
\text{This method} = 1.07 \times \text{(reference method)} - 1.0 \mu g/dL \times (0.16 \mu mol/L).
\]

The information presented was based on results from Sekisui Diagnostics’ studies and is current at the date of publication.

REFERENCES

REAGENT DETERIORATION
The reagent solutions should be clear. Turbidity would indicate deterioration.

DISPOSAL
Reagents must be disposed of in accordance with all Federal, Provincial, State, and local regulations.

SPECIMEN
Fresh, clear, unhemolysed serum. No preservatives are necessary. The tube for iron analysis should be collected before tubes containing anticoagulants to avoid contamination.

If the sample is to be stored for longer than 8 hours, storage at 2-8°C is recommended. The samples should be drawn in the morning following a 12 hour fast. Blood collecting glassware should be free of iron contamination.

GLASSWARE PREPARATION
All glassware and equipment used in an iron or unsaturated iron binding assay must be free of contaminating iron. Glassware may be prepared by soaking overnight in 1 N HCl or sulfuric acid-dichromate cleaning solution. If stronger concentrations of HCl are used the time necessary for decontamination may be decreased. The glassware should be rinsed with deionized water before it is used.

SAMPLE STORAGE
If the sample is to be stored for longer than 8 hours, storage at 2-8°C is recommended.

ANALYTICAL SPECIFICITY
Cross Contamination studies have not been performed on automated instruments. Certain reagent / instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Copper is the only cation of the trace metals normally present in serum and capable of forming a colored complex with ferrozine. Copper interference with ferrozine has been studied by Duffy and Gaudin. Ninety-five percent of copper interference is eliminated by using thiourea which forms a Cu thiourea complex.

Interferences from icterus, lipemia and hemolysis were evaluated for this iron method on a Roche/Hitachi® analyzer using a significance criterion of >10% variance from control. Interference data was collected in serum.

<table>
<thead>
<tr>
<th>Concentration of Analyte</th>
<th>Substance Tested</th>
<th>Concentration of Interferent Where Interference is Insignificant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional Units</td>
<td>SI Units</td>
<td></td>
</tr>
<tr>
<td>98 µg/dL</td>
<td>18 µmol/L</td>
<td>Hemoglobin 500 mg/dL 77.5 µmol/L</td>
</tr>
<tr>
<td>93 µg/dL</td>
<td>17 µmol/L</td>
<td>Bilirubin 60 mg/dL 1026 µmol/L</td>
</tr>
<tr>
<td>97 µg/dL</td>
<td>17 µmol/L</td>
<td>Intralipid 500 mg/dL 1500 mg/dL (17.0 mmol/L) Simulated Triglycerides</td>
</tr>
</tbody>
</table>

The information presented above is based on results from Sekisui Diagnostics’ studies and is current at the date of publication.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.10.

ANALYTICAL PROCEDURE
MATERIALS PROVIDED
Sekisui Diagnostics’ Iron reagents.

MATERIALS REQUIRED (BUT NOT PROVIDED)
1. Automated analyzer capable of accurately measuring absorbance at appropriate wavelength as per instrument application.
2. Calibration material. Calibrators used with this procedure must be protein based. Aqueous calibrators with no buffering agent should NOT be used.
3. Quality Control materials.

TEST CONDITION
For the data presented in this insert, studies using this reagent were performed on an automated analyzer using an endpoint test mode, with a sample to reagent ratio of 1:12.5:2.5 and a wavelength reading of (primary/secondary) 570/700 nm. For assistance with applications on automated analyzers within Canada and the U.S., please contact Sekisui Diagnostics Technical Services at (800)565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION
A protein based calibrator should be used to calibrate the procedure. Aqueous calibrators with no buffering agent should not be used with this reagent. The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used.

QUALITY CONTROL
A normal and abnormal concentration control should be analyzed as required. The results should fall within the acceptable range as established by the laboratory.

CALCULATIONS
The analyzer automatically calculates the iron concentration of each sample.

TEST LIMITATIONS
A sample with an iron concentration exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution faction in the calculation of the value.

REFERENCE INTERVALS
Male: 65-170 µg/dL (11.6-30.4 µmol/L)
Female: 50-170 µg/dL (8.9-30.4 µmol/L)

These values are suggested guidelines. It is recommended that each laboratory establish its own expected range.

There is a diurnal variation in iron concentrations. They are normal in the morning, low in mid-afternoon, and very low near midnight.

PERFORMANCE CHARACTERISTICS
Data presented was collected on an automated analyzer unless otherwise stated.

RESULTS
Iron concentration is reported as µg/dL (µmol/L).

REPORTABLE RANGE
The linearity of the procedure described is 1000 µg/dL (179 µmol/L).