Ferritin, in circulation, as measured in serum levels is a satisfactory index of body's iron storage. The iron storage is demonstrated these disorders.

In patients with hemochromatosis and hemosiderosis.

The iron storage is already immobilized on the well.

Each laboratory should assay controls at levels in the low, 0.5-2.5 mg/liter, and high, >5 mg/liter, range in the assay. Duplicates of each calibrator should be run each day.

All products that contain human serum have been inactivated for Hepatitis B Surface Antigen, HIV 1 and 2 and HCV Antibodies by FDA licensed reagents. Since no known test can provide complete assurance that all recipients of these reagents are safe, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory practices for handling and storage of blood products can be found in the Center for Disease Control / National Institutes of Health, " Biosafety in Microbiological and Biomedical Laboratories." 2nd Edition, 1989, p. 283-285.

Safe disposal of kit components must be according to local regulatory and statutory requirement.

For In Vitro Diagnostic Use

For Internal or External Use in Humans or Animals

1. Pipette capable of delivering 0.025ml (25µl) volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100ml (100µl) and 1.000ml (1ml) of solution.
3. Add 0.100 ml (100µl) of the Ferritin Biotin Reagent to each well.
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 30 minutes at room temperature.
6. Discard the contents of the microplate by decantation or aspiration.
7. Vacuum aspirator (optional) for wash steps.
8. Vacuum aspirator (optional) for wash steps.
9. Ultrasonic cleaner.
10. Ultrasonic cleaner.

The specimen will be stored in a refrigerator at 2-8°C and the results will be calculated in ng/mL.

The light signal is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light

The performance of the serum ferritin levels is generated by the addition of a substrate. The intensity of the light
13. Incubate for five (5) minutes at room temperature in the dark.

14. Read the relative light units in each well for 0.2 – 1.0 seconds.

11.0 Q.C. PARAMETERS

(greatest light output). This conversion minimizes differences

* The data presented in Example 1 and Figure 1 is for illustration purposes only and should not be used in lieu of a dose response curve prepared with each assay. In addition, the RLUs of the calorimeter have been normalized to 100,000 RLUs for the F calibrator for each unknown specimen.

11.2 Interpretation

9. The sensitivity (detection limit) was ascertained by determining the lowest serum calibrator and using the 2

11.4 Performance Characteristics

14.4 Specificity

14.5 High Dose Hook-Effect

Since the assay is sequential in design, high levels of Ferritin do not show the hook effect. Samples with concentrations over 10,000ng/ml demonstrated extremely high levels of light intensity.

11.0 Q.C. PARAMETERS

Approximate reference ranges for normal males and female adults were established with 0mIU/ml serum calibrator and using the 2

11.3 Expected Ranges of Values

It is important to keep in mind that establishment of a reference range of values which can be expected to be found by a given method for a population of "normal"-persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analyst. The method with a population indigenous to the area in which the laboratory is located.

14.0 Performance Characteristics

14.1 Precision

The within and between assay precision of this method were

Table 3 Between Assay Precision (Values in ng/ml)

Table 3

<table>
<thead>
<tr>
<th>Sample</th>
<th>X</th>
<th>a</th>
<th>C.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>10</td>
<td>52.4</td>
<td>2.3</td>
</tr>
<tr>
<td>Level 2</td>
<td>20</td>
<td>112.9</td>
<td>9.4</td>
</tr>
<tr>
<td>Level 3</td>
<td>30</td>
<td>193.6</td>
<td>21.2</td>
</tr>
</tbody>
</table>

* As measured in ten experiments in duplicate.

14.2 Sensitivity

The sensitivity (detection limit) was ascertained by determining the lowest serum calibrator and using the 2

6. Accurate and precise pipetting, as well as following the exact sequence to eliminate any time-deviation during reaction.

11.1 Accuracy

The sensitivity (detection limit) was ascertained by determining the lowest serum calibrator and using the 2

8. Accurate and precise pipetting, as well as following the exact sequence to eliminate any time-deviation during reaction.

10. The data presented in Example 1 and Figure 1 is for illustration purposes only and should not be used in lieu of a dose response curve prepared with each assay. In addition, the RLUs of the calorimeter have been normalized to 100,000 RLUs for the F calibrator for each unknown specimen.

11.2 Interpretation

9. The sensitivity (detection limit) was ascertained by determining the lowest serum calibrator and using the 2

11.4 Performance Characteristics

14.4 Specificity

The cross-reactivity of the Ferritin AccuLITE® CLIA test system to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between doses of interfering substance to dose of ferritin needed to produce the same light intensity.

14.5 High Dose Hook-Effect

Since the assay is sequential in design, high levels of Ferritin do not show the hook effect. Samples with concentrations over 10,000ng/ml demonstrated extremely high levels of light intensity.

11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria must be met:

1. The Dose Response Curve should be within established parameters.

2. Four out of six quality control pools should be within the established ranges.

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.

13.0 Expected Ranges of Values

12.0 Risk Analysis

The MSDS form for this product is available on request from Monobind Inc.

5. If test kits are altered, such as by mixing parts of different kits, the reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

3. Highly lipemic, hemolyzed or grossly contaminated specimens were not used.

2. Plot the RLUs for each serum reference versus the

3. The reagents for the test system have been formulated to prevent erroneous results. Heterophilic antibodies often cause these

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor dose response curve.