3.0 PRINCIPLE
erythroid proliferation and iron demand but as sTfR is not an
various hemoglobinopathies. Serum sTfR also reflects the rate of
has also been shown to be superior to routine tests for predicting
coeliac disease. Subclinical iron deficiency in early pregnancy is
application.7 A recent study indicated that the sTfR/ferritin ratio
sTfR and the sTfR/ferritin ratio also appear to have other useful
12 As well as helping identify iron deficiency, sTfR is useful for
monocytes and iron deficiency in early pregnancy is strongly
adequate iron deficiency in early pregnancy is strongly
bacterial vaginosis, and therefore sTfR
expression of the membrane- associated TfR and increases with
proliferative capacity, which can be monitored with sTfR.2,3
normal values.3,4 In anemia of chronic renal failure, the early
increased cellular iron needs and cellular proliferation.4 Furthermore,
children. Serum ferritin is increased in malnutrition, iron deficiency
increased levels of sTfR are only seen in children with iron deficiency
sTfR and the sTfR/ferritin ratio also appear to have other useful
and iron deficiency screening tests.
the same sequence to eliminate any time-deviation during reaction.
6. Plate readers measure vertically. Do not touch the bottom of
the wells.
7. Failure to remove adhering solution adequately in the aspiration or
calculation wash step(s) may result in poor
replication and spurious results.
8. Use components from the same lot. No intermixing of reagents
from different batches.
9. Accurate and precise pipetting, as well as following the exact
time and temperature requirements prescribed are essential.
Any deviation from Monobind’s IFU may yield inaccurate
results.
10. All applicable national standards, regulations and laws,
including, but not limited to, good laboratory procedures, must
be strictly followed to ensure compliance and proper device usage.
11. It is important to calibrate all the equipment e.g. Pipettes,
Readers, Washers and/or the automated instruments used with
this device, and to perform routine preventative
maintenance.
12. Risk Analysis- as required by CE Mark IV Directive 98/79/EC -
for this and other devices, made by Monobind, can be
requested via email from Monobind@monobind.com.
12.2 Interpretation
1. Measurements and interpretation of results must be performed by
a skilled individual or trained professional.
2. Laboratory results alone are only one aspect for determining
patient care and should not be the sole basis for therapy,
particularly if the results conflict with other determinants.
3. The reagents for the test system have been formulated to
eliminate maximal interference; however, potential interaction
between rare serum specimens and test reagents can cause
erroneous results. Heterophilic antibodies often cause these
interactions and have been known to be problems for all kinds of
immunoassays (Boscatio LM, Stuart MC. ‘Heterophilic
1988:3427-33). For diagnostic purposes, the results from this
assay should be in combination with clinical examination,
patient history and all other clinical findings.
4. For valid test results, adequate controls and other parameters
must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits,
the calibrators fall within 10% of the assigned concentrations.
6. If test kits are altered, such as by mixing parts of different kits,
the calibrators fall within 10% of the assigned concentrations.
7. If computer controlled data reduction is used to interpret the
results of the test, it is imperative that the predicted values for
the calibrators fall within 10% of the assigned concentrations.
13.0 EXPECTED RANGES OF VALUES
In agreement with established reference intervals for a “normal”
adult population, the expected ranges for the sTfR AccuLite®
CLIA Test System are detailed in Table 1.

<table>
<thead>
<tr>
<th>Substrate</th>
<th>Cross Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Dimeric Transferrin</td>
<td>ND</td>
</tr>
<tr>
<td>Human Apotransferrin</td>
<td>ND</td>
</tr>
<tr>
<td>Human Heart Ferritin</td>
<td>ND</td>
</tr>
<tr>
<td>Human Liver Ferritin</td>
<td>ND</td>
</tr>
<tr>
<td>Human Spleen Ferritin</td>
<td>ND</td>
</tr>
<tr>
<td>Tranluein</td>
<td>ND</td>
</tr>
<tr>
<td>Human Serum Albumin</td>
<td>ND</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>ND</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>ND</td>
</tr>
</tbody>
</table>

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precision of the sTfR AccuLite®
CLIA Test System were determined by analyses on three different
levels of pool control sera. The number, mean standard,
deviation and coefficient of variation for each of these control sera
are presented in Table 2 and Table 3.

<table>
<thead>
<tr>
<th>Size</th>
<th>N(A)</th>
<th>N(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A)</td>
<td>0.5 ml set</td>
<td>1 ml set</td>
</tr>
<tr>
<td>B)</td>
<td>1 (12ml)</td>
<td>2 (12ml)</td>
</tr>
<tr>
<td>C)</td>
<td>1 (12ml)</td>
<td>2 (12ml)</td>
</tr>
<tr>
<td>D)</td>
<td>1 plate</td>
<td>2 plates</td>
</tr>
<tr>
<td>E)</td>
<td>1 (20ml)</td>
<td>1 (20ml)</td>
</tr>
<tr>
<td>F)</td>
<td>1 (7ml)</td>
<td>2 (7ml)</td>
</tr>
<tr>
<td>G)</td>
<td>1 (7ml)</td>
<td>2 (7ml)</td>
</tr>
</tbody>
</table>

15.0 REFERENCES


Revision: 1 Date: 2013-10-02 Product Code: 8675-300