Infinity™
Calcium Arsenazo Liquid Stable Reagent

PRODUCT SUMMARY

<table>
<thead>
<tr>
<th>Stability</th>
<th>Until Expiry at 2-8°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear Range</td>
<td>1.50 - 3.75 mmol/L (6.0 - 15.0 mg/dL)</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>Serum</td>
</tr>
<tr>
<td>Method</td>
<td>Endpoint</td>
</tr>
<tr>
<td>Reagent Preparation</td>
<td>Supplied ready to use.</td>
</tr>
</tbody>
</table>

SYMBOLS IN PRODUCT LABELLING

Prior to use:
When stored at 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

Once the Reagent is Opened:
When stored capped at 2-8°C, the reagent is stable until expiry.

Indications of Reagent Deterioration:
- Calcium Reagent should be a bluish-purple solution.
- Turbidity:
- Reagent Absorbance > 0.80 AU (650 nm, 1 cm light path); and/or
- Failure to obtain control values within the assigned range.

SPECIMEN COLLECTION AND HANDLING

Collection:
- Specimen collection and storage tubes must be free of calcium.
- Normal and abnormal assayed control material.
- Analyser specific consumables, eg: sample cups.
- If required, pipettes for accurately dispensing measured volumes.
- Calibrator or a suitable aqueous Calcium standard.

ASSAY PROCEDURE

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

SYSTEM PARAMETERS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>37°C</td>
</tr>
<tr>
<td>Primary Wavelength</td>
<td>600 - 660 nm</td>
</tr>
<tr>
<td>Secondary Wavelength</td>
<td>700 nm</td>
</tr>
<tr>
<td>Assay Type</td>
<td>Endpoint</td>
</tr>
<tr>
<td>Direction</td>
<td>Increase</td>
</tr>
<tr>
<td>Sample: Reagent Ratio</td>
<td>1:60 – 1:70</td>
</tr>
<tr>
<td>Sample Vol</td>
<td>5 µL (5 µL)</td>
</tr>
<tr>
<td>Reagent Vol</td>
<td>300 µL (350 µL)</td>
</tr>
<tr>
<td>Incubation Time</td>
<td>60 seconds</td>
</tr>
<tr>
<td>Reagent Blank Limits</td>
<td>Low 0.00 AU</td>
</tr>
<tr>
<td>Linearity (650 nm, 1 cm light path)</td>
<td>1.00 – 3.75 mmol/L</td>
</tr>
<tr>
<td>Analytical Sensitivity (650 nm, 1 cm light path)</td>
<td>0.190 µA per mmol/L</td>
</tr>
</tbody>
</table>

CALCULATIONS

Results are calculated, usually automatically by the instrument, as follows:

\[ \text{Calcium} = \frac{\text{Absorbance of Unknown}}{\text{Absorbance of Calibrator}} \times \text{Calibrator Value} \]

Example:
- Absorbance of Calibrator = 0.61
- Absorbance of Unknown = 0.54
- Value of Calibrator = 3.20 mmol/L (12.8 mg/dL)

INTENDED USE

This reagent is intended for the in vitro quantitative determination of calcium in human serum.

CLINICAL SIGNIFICANCE

Calcium fulfills a variety of roles in human physiology. In bone, it combines with phosphorus to form hydroxyapatite crystals, giving strength to the bone structure and providing a constant reservoir of calcium for the rest of the body. It is also important in blood coagulation, muscle contraction, and membrane permeability. Low serum calcium values (hypocalcemia) can be seen in cases of osteomalacia, hypomagnesemia, vitamin D deficiency, hypoparathyroidism, sarcoidosis, thyrotoxicosis, multiple myeloma, and polycythemia vera.1 Low serum calcium levels can be seen in cases of osteomalacia, hypomagnesemia, vitamin D deficiency, hypoparathyroidism, sarcoidosis, thyrotoxicosis, multiple myeloma, and polycythemia vera.1

METHODOLOGY 2,3

A large array of methods is available for the determination of calcium. These include oxalate precipitation, EDTA chelation, flame photometry, atomic absorption, and specific dye binding. Arsenazo III reacts with calcium to form a bluish-purple colored complex. The amount of color formed is measured by an increase in absorbance of the reaction mixture at 600 - 660 nm.

REAGENT COMPOSITION

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenazo III</td>
<td>0.136 mmol/L</td>
</tr>
<tr>
<td>Sodium azide</td>
<td>0.05%</td>
</tr>
<tr>
<td>Buffer</td>
<td></td>
</tr>
<tr>
<td>Surfactant</td>
<td></td>
</tr>
</tbody>
</table>

Hazard Symbol: Exclamation Mark
Signal Word: Warning
Hazard Statements
H317 May cause an allergic skin reaction

Precautionary Statements - Prevention
Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves

Precautionary Statements - Response
Specific treatment (see supplemental first aid instructions on this label)
Skin
IF ON SKIN: Wash with plenty of soap and water
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant
Hazards not otherwise classified (HNOC)
Not applicable
Unknown Toxicity
0.36% of the mixture consists of ingredient(s) of unknown toxicity
Other information
Repeated or prolonged skin contact may cause allergic reactions with susceptible persons
Refer to the product Safety Data Sheet for additional information.

REAGENT PREPARATION
Reagent is ready to use as supplied. Mix the reagent well before using.

STABILITY AND STORAGE

When stored capped at 2-8°C, the reagent is stable until the expiration date stated on the bottle and kit box label.

For in vitro diagnostic use
Batch code/Lot number
Catalogue number
Consult instructions for use
Manufactured by

CAUTION. CONSULT INSTRUCTIONS FOR USE.
3. Studies to determine the level of interference from haemoglobin, bilirubin
2. It is recommended that gloves are worn when performing this procedure,
1. It is recommended that disposable plastic labware be used for this procedure.

LIMITATIONS
• If results are still out of control, contact Technical Services or your local distributor.

QUALITY CONTROL
To ensure adequate quality control, normal and abnormal control with assayed values should be run as unknown samples:-
• At least every eight hours or as established by the laboratory.
• When a new bottle of reagent is used.
• After preventative maintenance is performed or a critical component is replaced.
Control results falling above the upper limit or below the lower limit of the established ranges indicate the assay may be out of control.

The following corrective actions are recommended in such situations:-
• Repeat the same controls.
• If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
• If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
• If results are still out of control, perform a calibration with fresh reagent, then repeat the test.
• If results are still out of control, contact Technical Services or your local distributor.

• The lot number of reagent changes.
• Preventive maintenance is performed or a critical component is replaced.

EXPECTED VALUES
Adult 2.15 - 2.55 mmol/L (8.6 - 10.2 mg/dL)

The quoted values should serve as a guide only. It is recommended that each laboratory verify this range or derive a reference interval for the population it serves.8

PERFORMANCE DATA
The following data was obtained using a well maintained automated clinical chemistry analyser. Users should establish product performance on their specific analyser.

PRECISION
Within-run reproducibility was obtained by assaying 3 levels of control sera 20 times.

WITHIN-RUN

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean</th>
<th>STD. DEV</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>1.35</td>
<td>0.005</td>
<td>0.37</td>
</tr>
<tr>
<td>Level 2</td>
<td>2.35</td>
<td>0.008</td>
<td>0.32</td>
</tr>
<tr>
<td>Level 3</td>
<td>3.38</td>
<td>0.010</td>
<td>0.30</td>
</tr>
</tbody>
</table>

Run-to-run reproducibility was obtained by assaying 3 levels of control sera for 10 runs.

RUN-TO-RUN

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean</th>
<th>STD. DEV</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>1.35</td>
<td>0.10</td>
<td>0.74</td>
</tr>
<tr>
<td>Level 2</td>
<td>2.38</td>
<td>0.015</td>
<td>0.63</td>
</tr>
<tr>
<td>Level 3</td>
<td>3.38</td>
<td>0.023</td>
<td>0.67</td>
</tr>
</tbody>
</table>

METHOD COMPARISON
Comparison studies were carried out using another commercially available method as a reference. Serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained:-

Number of samples 153
Range of results 1.78 – 3.40 mmol/L (7.1 – 13.6 mg/dL)
Slope 0.927
Intercept 0.222
Correlation Coefficient 0.996

LINEARITY
When run as recommended, the assay is linear between 1.50 and 3.75 mmol/L (6.0 and 15 mg/dL).

ANALYTICAL SENSITIVITY
When run as recommended, the sensitivity of the assay is 0.190 A/A per mmol/L or 0.047 A/A per mg/dL (1cm light path, 650 nm).

REFERENCES

© 2012 Thermo Fisher Scientific Inc. All rights reserved. ©Hitachi is a registered trademark of Nissei Sangyo Co. Ltd., Japan. ILab 600 is a registered trademark of Instrumentation Laboratory Company, Lexington, MA 02421. All other trademarks are the property of Thermo Fisher Scientific Inc and its subsidiaries.