Acid Phosphatase
Reagent Set

Intended Use
For the quantitative determination of acid phosphatase in serum using the Tokyo Boeki Medisys Inc. Biolis 24i analyzer.

Clinical Significance
Large elevations of prostatic acid phosphatase are found in cases of metastasized prostatic cancer. Since acid phosphatase is also produced in other tissues, the prostatic isoenzyme must be distinguished from the non-prostatic for accurate diagnosis. Elevated levels of non-prostatic acid phosphatase have been observed in patients with Paget's disease, hyperparathyroidism with skeletal involvement, and in cancers which have invaded the bones. 7

Method History
Phosphate compounds proposed throughout the years as substrates for measuring acid phosphatase activity included Phenylphosphate, α-Glycerophosphate, ρ-Nitrophenylphosphate and Thymolphthalein Phosphate. Most of the above substrates were either insensitive to the small increases in prostatic acid phosphatase activity, or were too sensitive to non-prostatic acid phosphatase in the serum. Roy et al. proposed a method using Sodium Thymolphthalein Monophosphate as a specific substrate for prostatic Acid Phosphatase in 1971. A modification by Ewen and Spitzer in 1976 improved the sensitivity of the Roy method. Even though the modified procedure has found wide acceptance, it suffers from being a long and tedious procedure as well as not being totally specific for the prostatic acid phosphatase; also measuring erythrocyte and platelet acid phosphatase. 

Interferences
A number of drugs and substances affect Acid Phosphatase activity. Young, and/or cause turbidity. Do not use plasma. Some anticoagulants inhibit acid phosphatase activity and/or cause turbidity.

Materials Provided
1. Acid Phosphatase Reagent.
2. L-Tartrate Reagent.
3. Acetate Buffer.

Materials Required but not Provided
1. Analyzer.
3. Chemistry Calibrator, catalog number C7506-50
4. Chemistry Control, catalog number C7592-100

Test Parameters

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item Name</th>
<th>Acid Phosphatase</th>
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Reagent Storage
1. Unopened vials are stable until stated expiration date on vial label when stored refrigerated (2-8°C).
2. The reconstituted acid phosphatase reagent is stable for 24 hours at room temperature (22-28°C) and for 14 days when stored refrigerated (2-8°C).
3. The reconstituted L-Tartrate Reagent is stable refrigerated (2-8°C), until expiration date on vial label. If crystallization occurs, warm at moderate temperatures (40-50°C) until dissolved.
4. Acetate Buffer solution is stable refrigerated (2-8°C) until the expiration date listed on the vial label.

Reagent Deterioration
The reagent should not be used if:
1. The reconstituted acid phosphatase reagent, without serum added, has an absorbance greater than 0.300 when measured at 405 nm against water.
2. The L-Tartrate Reagent is precipitated. Apply heat (40-50°C) to re-dissolve reagent.

Precautions
This reagent is for in vitro diagnostic use only.

Specimen Collection and Storage
1. Use only clear, unhemolized serum.
2. Serum must be separated from clot within two hours after collection.
3. Acid Phosphatase activity is extremely labile at room temperature. Stabilization of the enzyme can only be achieved by acidifying with Acetate buffer provided. Add 20ul (0.02ml) of buffer per 1.0ml of serum. Mix. Treated serum samples will remain stable for 7 days when kept refrigerated at 2-8°C. 8
4. Do not use plasma. Some anticoagulants inhibit acid phosphatase activity and/or cause turbidity.

Corr. Slope Inter
Y=[1.000]X+[0.000]
CV%

Calibration

| Type | Factor | O Level Point |  |
|------|--------|---------------|
| 1150 | 3.000  |                |  |
Acid Phosphatase
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Expected Values
Total Acid Phosphatase: 0.9u/L at 30°C; 2.5-11.7u/L at 37°C
Prostatic Acid Phosphatase: 0.3u/L at 30°C, 0.2-3.5u/L at 37°C
Values were taken from literature. It is strongly recommended that each laboratory establish its own normal range.

Performance
1. Linearity: 40u/L
2. Comparison: A study was performed between the Biolis 24i and a similar analyzer and method, resulting in the following:

<table>
<thead>
<tr>
<th>Method</th>
<th>Acid Phosphatase</th>
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<tbody>
<tr>
<td>N</td>
<td>50</td>
</tr>
<tr>
<td>Mean Acid Phos (u/L)</td>
<td>4.92</td>
</tr>
<tr>
<td>Range (u/L)</td>
<td>0.0-41.2</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>8.67</td>
</tr>
<tr>
<td>Regression Analysis</td>
<td>y = 1.003x + 1.13</td>
</tr>
<tr>
<td>Correlation Coefficient</td>
<td>0.9927</td>
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</table>

3. Precision: Precision studies were performed using the Biolis 24i analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.

<table>
<thead>
<tr>
<th>Sample</th>
<th>LOW</th>
<th>MID</th>
<th>HIGH</th>
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<tbody>
<tr>
<td>Mean</td>
<td>9.70</td>
<td>17.47</td>
<td>24.42</td>
</tr>
<tr>
<td>SD</td>
<td>0.17</td>
<td>0.22</td>
<td>0.34</td>
</tr>
<tr>
<td>CV(%)</td>
<td>1.8%</td>
<td>1.3%</td>
<td>1.4%</td>
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4. Sensitivity: 2SD limit of detection (95% Conf) = 0 u/L

References

Manufactured by Pointe Scientific, Inc.
5449 Research Drive, Canton, MI 48188

European Authorized Representative:
Obelis s.a.
Boulevard Général Wahis 53
1030 Brussels, BELGIUM
Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net

REF 15-A7503-100

Manufactured by Pointe Scientific, Inc.
5449 Research Drive Canton, MI 48188

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