StepOne® Comprehensive Biochemical Profile

<table>
<thead>
<tr>
<th>Test Code</th>
<th>B0200</th>
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<tbody>
<tr>
<td>Test Summary</td>
<td>The StepOne® Comprehensive Biochemical Profile is a newborn screening test that can detect more than 50 disorders in newborns from just a few drops of blood.</td>
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<tr>
<td>Turn-Around-Time (TAT)*</td>
<td>3 - 5 days</td>
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<tr>
<td>Acceptable Sample Types</td>
<td>Dried Blood Spots</td>
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<td>Acceptable Billing Types</td>
<td>Self (patient) Payment, Institutional Billing</td>
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Indications for Testing

This test may be appropriate for individuals with a clinical suspicion of an inherited metabolic disorder.

Test Description

A comprehensive biochemical profile is performed to identify the presence of more than 50 inherited disorders, the full core and secondary panel recommended by the American College of Medical Genetics. This includes conditions that may not be included in state-mandated programs.

Condition Description

StepOne Comprehensive Biochemical Profile includes fatty acid oxidation disorders, organic acid disorders, amino acid disorders, and other conditions recommended by the American College of Medical Genetics. Please refer to the Condition List sheet below for the complete list of conditions.

Test Methods and Limitations

The StepOne Comprehensive Biochemical Profile is performed by tandem mass spectrometry and other technologies.

Detailed Sample Requirements

Dried Blood Spots

Collection Container(s):

Dried blood spot card

Collection:

Follow kit instructions. Briefly, allow blood to saturate card until indicated areas are filled and blood has soaked through card. Air dry card at ambient temperature for at least 3 hours.

- **NBS**: Please contact PKIG to request the StepOne® kit.
- **Gene Sequencing**: Please contact PKIG to request the DBS collection kit.
- **For pre-punched DBS**: The required minimum 6 punches with 3.2 mm or 4 punches 4.75 mm.

**Sample Condition:** Follow the instructions provided with the collection set. Store the dried blood at ambient temperature for up to two days. If the specimen cannot be sent as soon as it is dry, the filter paper should be placed in a sealable plastic bag and stored in a refrigerator (≤ 8°C).
or preferably in a freezer.
Shipping: Follow kit instructions. Double bag and ship overnight at ambient temperature.