Status iFOBT

Rapid Immunassay for the Qualitative Detection of Immunochemical Fecal Occult Blood
(Human Hemoglobin in Human Fecal Specimens)

- CLIA Waived
- Superior sensitivity and specificity
- Human hemoglobin specific reduces false positives
- Easy one-step test procedure
- Specimen can be collected in office or at home
- Patient friendly and easy-to-follow instructions
- Non-invasive collection method
- Only one test device needed
- No dietary or drug restrictions for iFOBT

Learn more online at: www.statusifobt.com

CPT CODE
82274QW
G0328QW
(Medicare Annual Screen)
Sample Collection

1. Deposit the fecal sample on collection paper or in a clean container.

   NOTE: Do not allow collection paper or feces to come into contact with toilet water or urine. The sample should not be tested if it becomes wet or contaminated. If this happens, place a clean tissue on the collection paper, then collect new feces sample for testing.

2. Unscrew the sampler from the collection tube with the fecal sample still on collection paper, randomly insert the grooved end of the sampler into the fecal sample in at least 6 different sites. Ensure the grooved end of the sampler is completely covered with fecal sample.

3. Insert the sampler into the collection tube and firmly tighten it. Do not reopen.

4. Shake the tube vigorously to mix the sample and the collection tube.

   NOTE: The extracted fecal sample may be stored at room temperature for up to 10 days.

Sample Application

1. Shake the collection tube vigorously for 20-30 seconds to ensure the sample is well mixed with the buffer. Some small amount of sample may not dissolve; this is normal.

2. Remove test device from its foil pouch by tearing at the notch.

3. Tap the collection tube on a hard surface to dislodge any trapped air in top of cap.

4. Unscrew tip cap on the collection tube. Holding the tube vertically above the sample well of the Status iFOBT device, squeeze the tube gently to dispense three (3) drops into the sample well.

5. Read the result in 5-10 minutes. Important: DO NOT READ RESULTS AFTER 10 MINUTES.

Interpretation of Results

Two Lines

Positive (+)

Any visible T line

is positive

C Line only

Negative (-)

No C Line

Invalid

Repeat with new sample and device

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th># OF TESTS</th>
<th>ITEM #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status iFOBT</td>
<td>30</td>
<td>38030-DTM</td>
</tr>
<tr>
<td>Status iFOBT Sample Collection Tubes (refill)</td>
<td>50</td>
<td>38050-T</td>
</tr>
<tr>
<td>Status iFOBT Mailing Envelopes (refill)</td>
<td>50</td>
<td>38050-M</td>
</tr>
<tr>
<td>Status iFOBT Test Devices (refill)</td>
<td>50</td>
<td>38050-D</td>
</tr>
<tr>
<td>Status iFOBT Control Set - POS &amp; NEG</td>
<td>2 x 0.5ml</td>
<td>200020</td>
</tr>
</tbody>
</table>

For more information or to place an order, contact:

A PBM Group Company
85 Orchard Road • Skillman • New Jersey • 08558
800.526.2125 • 732.246.3366 • Fax: 732.246.0570 • www.lifesignmed.com