Capilia™ TB-Neo

WHO endorses "lateral flow immunochromatographic assay" for identification of *M.tuberculosis* complex.

- Rapid test for identification of *M.tuberculosis* complex
  Detecting MPB64 protein, specifically produced by *M.tuberculosis* complex
- Extremely high specificity to *M.tuberculosis* complex
  Equivalent accuracy to the nucleic-acid probe assay
- Fast test results with one-step operation
  Reading time is 15 min. No special equipment required

**Need Culture**

Both liquid medium and solid medium can be used as sample
For solid medium, Capilia™ TB-Neo Extraction Buffer (sold separately) is required
Rapid test for identification of *M. tuberculosis* complex

**Capilia™ TB-Neo**

**Capilia™ TB-Neo Diagnosis Flow**

- **AFB Culture Incubation** → **AFB Positive** → **Capilia™ TB-Neo** → **Non-tuberculous mycobacteria**
- **Capilia™ TB-Neo** → **M. tuberculosis complex** → **Positive**

**Test Procedure**

**Sample preparation**

- **Using a liquid medium for AFB (e.g. Middle Brook 7H9 broth)**
  - Incubate at 37°C for 1 to 3 weeks until the liquid medium becomes cloudy due to the growth of bacteria. In the event that MGIT is used, incubate until a positive interpretation is possible. In both cases, it is necessary to confirm the presence of AFB by acid-fast staining. Stir the liquid medium in the incubator and use the medium as a sample.

- **Using a solid medium for AFB (e.g. Ogawa medium)**
  - Incubate at 37°C for 2 to 4 weeks until the growth of bacterial colonies is confirmed on the solid medium, and then confirm the presence of AFB by acid-fast staining.
  - (1) Dispense 0.2 mL of the extraction buffer (sold separately) into the tube.
  - (2) Pick 1 μL of bacteria (equivalent to a 1mm-diameter platinum micro-loop) from the bacterial colony that has grown on the solid medium.
  - (3) Suspend the collected bacteria in the buffer solution in the tube.
  - (4) Close the tube with a stopper and fully suspend with a mixer. Then, use the bacterial suspension as a sample.

**Sample application**

- Dispense 80-100 μL sample into the sample placement area at the test plate.

**Reading result**

- **15min**
- **C** (Positive)
- **T** (Negative)

**Reference Data**

1. **Sensitivity**

<table>
<thead>
<tr>
<th>Result</th>
<th>Clinical isolate of <em>M. tuberculosis</em> complex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>497</td>
</tr>
<tr>
<td>Negative</td>
<td>3^NNN</td>
</tr>
<tr>
<td>Total</td>
<td>500</td>
</tr>
</tbody>
</table>

Sensitivity: 99.4%

^NNN: 3 *M. tuberculosis* complex isolates that tested negative by Capilia™ TB-Neo
1. *M. tuberculosis* possesses a 65-bp deletion in the rps24 gene
2. *M. tuberculosis* possesses a 3,659-bp deletion from rv1977 to rv1981c, a region including the entire rps24 gene
3. *M. bovis* BCG Connaught lacked Rv02 including the mpt64 gene

2. **Specificity**

<table>
<thead>
<tr>
<th>Clinical isolate of NTM</th>
<th>Number of strain</th>
<th>Number of negative result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>M. abscessus</em></td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><em>M. avium complex</em></td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td><em>M. chelonae</em></td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><em>M. fortuitum</em></td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td><em>M. gastri</em></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><em>M. gordonae</em></td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td><em>M. intracellular</em></td>
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<td>1</td>
</tr>
<tr>
<td><em>M. kansasii</em></td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td><em>M. marinum</em></td>
<td>1</td>
<td>1</td>
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<tr>
<td><em>M. nonchromogenicum</em></td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><em>M. peregrinum</em></td>
<td>2</td>
<td>2</td>
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<tr>
<td><em>M. scrofulaceum</em></td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><em>M. szulgai</em></td>
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<td>1</td>
</tr>
<tr>
<td><em>M. xenopi</em></td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Total: 90

Specificity: 100%


**Product Summary**

- **CatB0870 (100 Tests)**
  - Kit content: Test Plate × 100

- **CatB0871 (10 Tests)**
  - Kit content: Test Plate × 10

- Sold Separately: CatB0877: Capilia™ TB-Neo Extraction Buffer (20mL/Bottle)

- Validity: 27 months
- Storage: Store at 2-30°C
- Reading time: 15 minutes

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[Logo and contact information]