Interest in any of the products, request or order them at Bio-Connect Diagnostics.
**Assay Procedure**

**Serum or Plasma**

- Hold the sample applicator vertically and add 25 µl of serum or plasma to the Sample well.
- Wait till the wet sample front reaches the blue line.
- Add 3 drops of chase buffer to Buffer well and pull the tab until resistance is felt.
- Add 1 drop of chase buffer to Sample well.
- Read results at 15 minutes.

**Whole Blood**

- Hold the sample applicator vertically and add 35 µl of whole blood, followed by 1 drop of chase buffer to Sample well.
- Wait till the wet sample front reaches the blue line.
- Add 3 drops of chase buffer to Buffer well and pull the tab until resistance is felt.
- Add 1 drop of chase buffer to Sample well.
- Read results at 15 minutes.

**Interpretation of Results**

- **Blue Line**
  - Only visible line before performing assay
  - Serves to aid timing of adding the chase buffer at the buffer well

- **Control Line**
  - Check on proper sample additions, migration and buffer control
  - Contains protein which when binds with the dye conjugated with anti-human IgG in the chase buffer, produces a visible pink color
  - Appearance of a pink control line indicates the correct functioning of the rapid test hence confirming the validity of the assay

- **2 Test Lines**
  - 2 test lines impregnated with multiple antigens to maximize the sensitivity of the test
  - Appearance of any one or both lines together with the control line indicates a positive result

**References:**


**Serological Test of Choice for TB Infections:**

- Rapid non-instrument based complementary serological test in TB diagnosis
- Performance matches smear and culture with sensitivity ranges from 64-81%
- High specificity of 80-100%
- Detect additional 36-48% bacteriology negative but confirmed TB patients
- Higher detection rate when used with either smear or culture compared to using smear with culture

**Excellent Performance comparable to Gold Standard (Smear/Culture)**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smear/Culture</td>
<td>68% (n = 340)</td>
<td>84% (n = 409)</td>
</tr>
</tbody>
</table>

- Easy to use – 3 step assay procedure, no set-up or equipment required
- Simple – addition of whole blood/serum/plasma and buffer only
- Convenient – fast result at the point of care
- Reliable – built-in procedure control
- Easy to interpret – visual reading of results
- Fast – results in 15 minutes

**Note:**

1 = Sample well  2 = Buffer well  C = Control line area  T = Test lines area

**Abbreviations:**

- ASSURE®
- TB: Tuberculosis
TB Infection: Serious Public Health Threat

TB infection remains to be one of the most serious threats to millions of people. In 2003 alone, WHO reported an estimate of 8.8 million new cases, among which only 3.9 million were smear positive. Out of the 15.4 million prevalent cases, 1.7 million patients died in 2003. WHO pointed out in 2002 that inadequate case detection has become the primary impediment to disease control. The priority needs for TB diagnostics are tools that improve case detection.

ASSURE® TB Rapid Test is a simple, fast and convenient premium quality serological test which can detect both pulmonary and extra-pulmonary TB infections.

ASSURE® TB Rapid Test is the test of choice when tests are used in combination for TB diagnosis

ASSURE® TB + Smear performed comparably to Culture + Smear

ASSURE® TB is a much easier, simpler & more convenient test

ASSURE® TB gives results at the point of care in 15 minutes

ASSURE® TB + Culture increased detection rate versus Culture + Smear

ASSURE® TB + Culture is the preferred combination for higher detection rate

ASSURE® TB is a simpler and faster test, gives results at the point of care

The combination can potentially reduce drop-out in patient follow-up

When ASSURE® TB is used either with Smear or Culture method, detection rate is significantly improved

ASSURE® TB is the test of choice in the multi-test diagnosis of TB infections

Graph 1*: High Specificity

High specificity of 84% to 90% in both Non-TB patients and normal healthy subjects

Graph 2*: High Sensitivity

Study Population: Confirmed TB Patients

<table>
<thead>
<tr>
<th>Smear / Culture Bacteriology</th>
<th>ASSURE® TB RT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>238/331</td>
<td>344/409</td>
<td>583</td>
</tr>
<tr>
<td>264/446</td>
<td>340/464</td>
<td>686</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TASER® TB RT</th>
<th>No. of Positive Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients</td>
<td></td>
</tr>
<tr>
<td>70%</td>
<td>344/409</td>
</tr>
<tr>
<td>156/174</td>
<td>340/464</td>
</tr>
<tr>
<td>150/174</td>
<td>340/464</td>
</tr>
<tr>
<td>90%</td>
<td>340/464</td>
</tr>
</tbody>
</table>

$\text{Sensitivity of ASSURE® TB Rapid Test is comparable to that of Smear/Culture in confirmed TB patients: (56% vs. 50%)}$

$\text{ASSURE® TB Rapid Test detects additional 43% bacteriology negative but confirmed TB patients}$

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$\text{ASSURE® TB Rapid Test detects additional 43% bacteriology negative but confirmed TB patients}$

* Data derived from clinical studies done at National University Hospital, Singapore