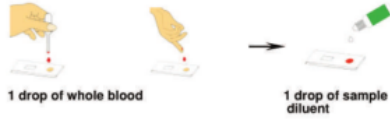


**Step 4: For whole blood test**  
Apply 1 drop of whole blood (about 40-50 µL) into the sample well.  
Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.



**For serum or plasma test**  
Fill the pipette dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.

Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.



1 drop of specimen 1 drop of sample diluent 15 minutes

**Step 5:** Set up timer.

**Step 6:** Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

**Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.**

**QUALITY CONTROL**

Using individual NADAL TB IgG/IgM Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

**Negative Control**

Only the C band shows color development, the two T bands (T1 and T2) show no color development.



**Positive Control**

The C band and two T bands (T1 and T2) show color development.



The appearance of any burgundy color in the T bands, regardless of intensity, must be considered as presence of the band.

**INTERPRETATION OF ASSAY RESULT**

**1. NEGATIVE RESULT:** If only the C band is present, the absence of any burgundy color in the both T bands (T1 and T2) indicates that no anti-M.TB antibodies are detected. The result is negative.



**2. POSITIVE RESULT:**  
2.1 In addition to the presence of C band, if only T1 band is developed, indicates for the presence of IgM anti- M.TB. The result is positive.



**2.2** In addition to the presence of C band, if only T2 band is developed, the test indicates for the presence of IgG anti- M.TB. The result is positive.



**2.3** In addition to the presence of C band, both T1 and T2 bands are developed, indicates for the presence of IgG and IgM anti- M.TB. The result is also positive.



**Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.**

**3. INVALID:** If no C band is developed, the assay is invalid regardless of any burgundy color in the T bands as indicated below. Repeat the assay with a new device.



**PERFORMANCE CHARACTERISTICS**

**1. Clinical Performance For IgM Test**

A total of 200 specimens from non-TB patients and 35 specimens from patients under anti TB treatment were tested by the NADAL TB IgG/IgM Combo Rapid Test and a commercial TB IgM ELISA kit. Comparison for all subjects is showed in the following table.

IgM ELISA Test	NADAL TB IgG/IgM Combo Rapid Test		Total
	Positive	Negative	
Positive	30	5	35
Negative	7	193	200
<b>Total</b>	<b>37</b>	<b>198</b>	<b>235</b>

Relative Sensitivity: 85.7%, Relative Specificity: 96.5%, Overall Agreement: 94.9%

**2. Clinical Performance For IgG Test**

A total of 200 specimens from the non-TB patients and 35 specimens from the patients under anti TB treatment were tested by the NADAL TB IgG/IgM Combo Rapid Test and a commercial TB IgG ELISA kit. Comparison for all subjects is showed in the following table.

IgG ELISA Test	NADAL TB IgG/IgM Combo Rapid Test		Total
	Positive	Negative	
Positive	31	4	35
Negative	7	193	200
<b>Total</b>	<b>38</b>	<b>197</b>	<b>235</b>

Relative Sensitivity: 88.6%, Relative Specificity: 96.5%, Overall Agreement: 95.3%

**LIMITATIONS OF TEST**

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of antibodies to M.TB in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The NADAL TB IgG/IgM Rapid Test is limited to the qualitative detection of IgG and IgM anti-M.TB in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.