EXPLANATION OF THE TEST
The ulti med thyroid stimulating hormone (TSH) test is intended to measure thyroid stimulating hormone, also known as thyrotropin and thyrotrophic hormone, in whole blood, serum and plasma. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The TSH Test is a rapid immunochromatographic assay. The test sensitivity is 5 μIU/ml.

MATERIALS PROVIDED
- TSH test cassette with pipette in foil pouch (25 per kit box)
- Instructions (1 per kit box)

MATERIALS REQUIRED, BUT NOT PROVIDED
- Stop watch
- Alcohol pads
- Lancets

PRECAUTIONS
The TSH test kit must be stored at 4-30°C. The test device is sensitive to humidity and to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

PROCEDURE OF THE TEST
1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.  
   Note: Once the test cassette is removed from the pouch, it should be used as soon as possible.
2. Clean the second or third finger by rubbing it with an alcohol pad.
3. Collect blood from the patient’s finger. Massage near the puncture site to obtain blood flow.
4. Add 100 μl of blood (4 drops) into the Sample Well (S). Before adding the next drop, the previous one should be fully absorbed.
5. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
6. Interpret test results at 15 minutes. Do not interpret test results after more than 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, the interpretation time should be properly increased.

INTERPRETATION OF THE TEST
- A coloured line will appear in the section of the Result Window marked with “C” to show that the test is working properly. This is the Control Line.
- The section of the Result Window marked with “T” indicates the test results. If another coloured line appears in this section it is the Test Line.

**Positive Result:** The presence of two coloured lines (“T” and “C” lines) in the result window regardless of which line appears first indicates a positive result (Figure 1). **Note:** Generally, the higher the TSH level in the specimen, the darker the “T” line colour will be. When the TSH level is close to but still within the sensitivity limit of the test, the colour of the “T” line will be very faint.

**Negative Result:** The presence of only one purple coloured line (“C” line), in the Result Window indicates a negative result (Figure 2).

**Invalid Result:** If after performing the test no coloured line is visible in the Result Window or only one line at “T”, the result is considered invalid. Some causes of invalid results are not following the directions correctly or the tests beyond the expiration date (Figure 3 and 4).

**Note:** A positive result will not change once it has been established at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 20 minutes. When interpreting test results after 20 minutes, the sensitivity of the test will be higher than 5 μIU/ml. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.
LIMITATIONS OF THE TEST
Although the TSH Test is very accurate in detecting TSH, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARNINGS
- The same lancet needle should be used for one person only and must not be shared with another person, because the used needle is a biohazard.
- Decontaminate and dispose of all specimens, reaction kits, lancet needle and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
- Do not use the kit after the expiration date.
- Do not use if pouch is torn or damaged.
- For in vitro diagnostic use only.

REFERENCES