BIOBOON BIOTECH LLC

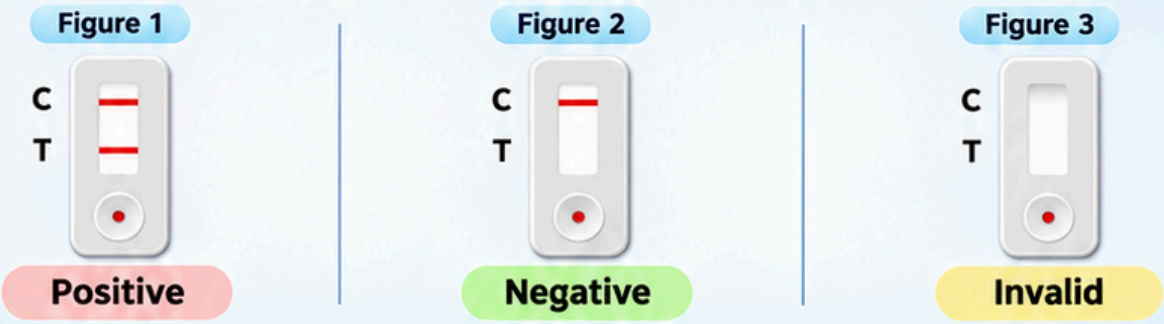
TSH Rapid Test Kit

(Serum / Plasma / Whole Blood)

- Rapid qualitative detection of TSH hormone.
- For in vitro diagnostic use.
- Use with serum, plasma or whole blood specimen.



INTERPRETATION OF RESULTS



DIRECTIONS FOR USE

Allow the test device, specimen to equilibrate at room temperature (15–30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen:** Hold the dropper vertically and transfer 1 drop (25 µL) drops of serum or plasma and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drop (25 µL) drops of whole blood and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer.
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL (1 drops) of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer.
4. **Note:** Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

- **Positive:** The control line (C) and test line (T) lines are visible on the test device. This is positive for TSH hormone.
- **Negative:** The control line is the only visible line on the test device. No TSH hormone were detected.
- **Invalid:** The control line fails to appear.

SENSITIVITY AND SPECIFICITY

SENSITIVITY : >98% (95% CI: 94.4%–99.8%)

SPECIFICITY : >98% (95% CI: 96.7%–99.6%)

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