The Tuberculosis Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma specimens.

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30°C) for 2 years, or frozen at -20°C for up to 2 years. The test cassette is stable for 1 year after opening the foil pouch. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

**PERFORMANCE CHARACTERISTICS**

Clinical Sensitivity, Specificity and Accuracy

The Tuberculosis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested with specimens from children below 15 years, who have been administered BCG vaccine. No cross-reactivity was observed, indicating that the performance of the Tuberculosis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested using negative, low positive, middle positive, and high positive specimens. The specimens were correctly identified >99% of the time.

**Interfering Substances**

The Tuberculosis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from viral hemolytic and ischemic specimens, as well as serum specimens containing high bilirubin levels. Results indicate that no interference was observed in specimens containing up to 500 mg/dL hemoglobin; up to 30 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

### Bibliography