



Syphilis Rapid Test (DTS563)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Intended Use	The Syphilis Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in serum or plasma to aid in the diagnosis of syphilis.
Storage	The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE.
Sensitivity	The Syphilis Ultra Test Device (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPHA syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Ultra Test Device (Serum/Plasma) is greater than 99.5%.
Specificity	The Syphilis Ultra Test Device (Serum/Plasma) uses an antigen that is highly specific for TP antibodies in serum or plasma. The results show that the relative specificity of the Syphilis Ultra Test Device (Serum/Plasma) is 99.3%.