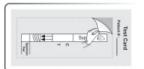
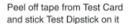
■ Test Procedure







Add 50 µL sample on specimen pad of Test Dipstick



Add 1 drop Reaction Buffer on specimen pad of Test Dipstick

Read the results after 10 minutes

Interpretation of Results

Note: Results should not be read beyond 30 minutes



One band at C



Two bands at T & C



Band only at T



No band

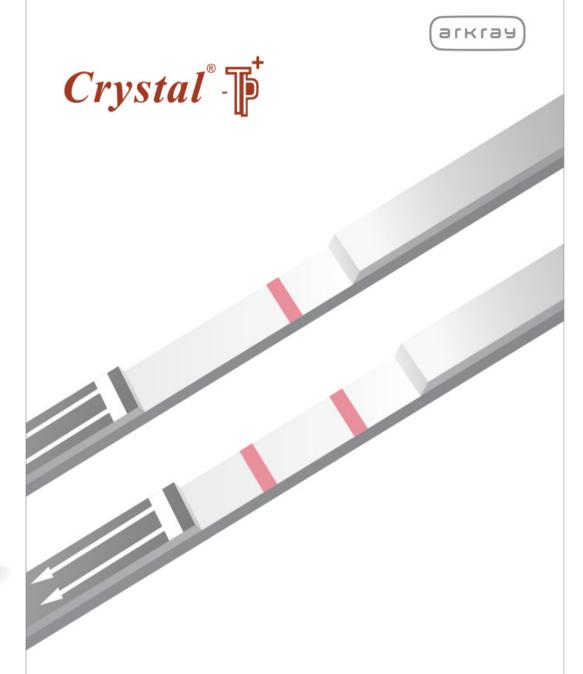
Ordering Information

Product	Code No.	Pack Size
Constal [®] T	54IC111-20	20 Tests
Crystal -	54IC111-60	100 Tests



THE MANUFACTURING SITE'S QMS IS CERTIFIED FOR ISO 13485:2003, ISO 9001:2008

arkray healthcare pvt. Ltd. Plot No. 336, 338, 340, Road No. 3, G.I.D.C., Sachin - 394 230, (Surat), INDIA. Telephone: 0261-239 7712 to 15, Facsimile: 0261-239 7719, Website: www.arkray.co.in Specifications may change without prior notice



Rapid visual immunochromatographic test for qualitative detection of IgM, IgG and IgA antibodies to *Treponema pallidum* in human serum or plasma or whole blood

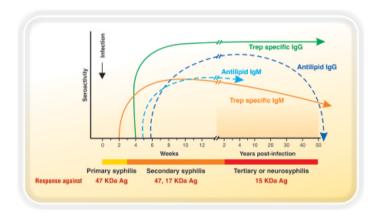
■ Fact File

Syphilis is distributed worldwide but is especially prevalent in developing countries. WHO estimates that **12 million** new cases of syphilis occurs every year.

Highest number of new cases are seen in Sub-Saharan Africa and Southeast Asia, followed by South America. The incidence is highest in sexually active people (20-29 years age group).

In developing countries like India, 3-15 % of women of child-bearing age have syphilis. About 30% of pregnant women with Syphilis gives birth to a dead baby and another 30% to a live baby with congenital syphilis, a condition with mortality of up to 50%.

Diagnosis



In recent years, tests detecting specific antibodies are widely used for Syphilis diagnosis as these tests are very specific to *T. pallidum* and are able to detect different stages of Syphilis infection.

Different Treponema specific serological tests available are TPHA, FTA-ABS, EIAs, Immunoblotting, Rapid ICTs, etc. TPHA is the most widely used traditional test but has variable sensitivity in detecting early stage of infection as well as it is time-consuming. Due to these shortcomings, the use of rapid ICTs is increasing in recent years as these tests are time saving, user-friendly and are highly sensitive and specific.

Salient Features



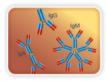
Non instrumental visual qualitative immunoassay with inbuilt control band to validate successful completion of assay procedure.



Simple, convenient and rapid assay procedure of 15 minutes, suitable for field use.



Assay protocol suitable with serum, plasma or whole blood with no sample predilution, imparts flexibility and convenience of usage.



Double antigen sandwich immunochromatographic assay, detects all (IgM, IgG and IgA) antibodies specific to *T. pallidum*, enhances the sensitivity of the test.



Available in individually packed Test Dipstick.

■ Performance*

Crystal has demonstrated sensitivity and specificity with in possible range as concluded in WHO report TDR/SDi/DE/03.1.

*Data on Arkray file