SUMMARY
Syphilis is a sexually transmitted disease caused by Treponema pallidum, a bacterium classified under the category of Spirochetes. After infection the host in response to the Treponema pallidum forms Treponemal antibodies. In addition to Treponemal antibodies the host also forms non-Treponemal antilipoidal antibodies in response to the lipoidal material released from the host cell during infection. This antibody is traditionally referred to as Reagin. Cardiolipin, a phospholipid derived from the beef heart reacts with antilipoidal antibodies and this antigenic property of cardiolipin is used in non-Treponemal tests such as VDRL, modified VDRL, USR tests and SYPHFINAL®. Non-Treponemal tests are of great value when used for screening and follow up of therapy.

REAGENT
SYPHFINAL® reagent is a ready to use, uniform suspension of polystyrene latex particles coated with cardiolipin, suspended in a suitable buffer of proprietary composition. Though SYPHFINAL® reagent, in performance, corresponds to the other USRs, it accords better readability to the test results, thereby giving better confidence in reporting results. As against the conventional VDRL tests the samples do not require heat inactivation.

Each batch of reagent undergoes rigorous quality control at various stages of its manufacture for its sensitivity, specificity and performance.

REAGENT STORAGE AND STABILITY
Store the reagent at 2-8°C. DO NOT FREEZE. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Avoid exposure to elevated temperatures, air and direct sunlight as the reagents are highly sensitive to denaturation, drying and microbial contamination.

PRINCIPLE
SYPHFINAL®, latex VDRL reagent is based on the principle of agglutination. The test specimen, serum or plasma is mixed with SYPHFINAL®, latex VDRL reagent and allowed to react for six minutes. If antilipoidal antibodies are present in the specimen, they will react with the latex reagent forming a visible agglutination. If antilipoidal antibodies are not present in the specimen then no agglutination is observed.

NOTE
1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagent contains 0.1% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. All reagents derived from human source are tested for HBsAg and anti-HIV antibodies and found to be nonreactive. However, handle the material as if infectious.
4. SYPHFINAL®, latex VDRL reagent should be gently but thoroughly mixed before testing to disperse the latex particles uniformly and improve test readability.
5. Performance of the reagents must be verified with positive and negative controls provided with the kit and it is recommended that controls be run with each test series.

SAMPLE COLLECTION AND STORAGE
No special preparation of the patient is required prior to the sample collection by approved techniques. Do not use hemolysed samples. Fresh samples or plasma should be used for testing. Samples not tested immediately may be stored at 2-8°C for up to 48 hours. Hazy samples should be centrifuged. Use clear supernatant for testing.

MATERIAL PROVIDED WITH THE KIT
Latex VDRL reagent, Positive control reactive with the reagent. Negative control non-reactive with the reagent, disposable slides with eight reaction circles, Disposable sample/control dispensing pipettes, Mixing sticks, Rubber teats.
ADDITIONAL MATERIAL REQUIRED
Stop watch, High intensity direct light source, isotonic saline, Pipettes, Test tubes.

TEST PROCEDURE
Bring all the reagents and samples to room temperature before testing.

Qualitative Method
1. Pipette one drop of test sample onto one of the reaction circles of the disposable slide using a sample dispensing pipette. The disposable slides and the sample dispensing pipettes are provided with the kit.
2. Repeat the procedure with positive and negative controls.
3. Add one drop of well-mixed SYPHFINAL® latex reagent to the test sample, positive control and negative control respectively. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick mix the test sample and SYPHFINAL® reagent thoroughly spreading uniformly over the entire reaction circle.
5. Immediately start a stopwatch. Rotate the slide gently and continuously, observing for agglutination macroscopically at six minutes.

Quantitative Method
1. Using isotonic saline prepare serial dilutions of the test sample eg.,1:2,1:4,1:8,1:16,1:32,1:64,1:128 and so on.
2. Perform the qualitative method test procedure using each dilution as a test specimen.
3. The titre is reported as the reciprocal of the highest dilution, which shows a positive test result.

INTERPRETATION OF TEST RESULTS

Qualitative Method
Agglutination is a positive test result and indicates the presence of antilipoidal antibodies in the test sample. No agglutination is a negative test result indicating the absence of detectable levels of antilipoidal antibodies in the test specimen.

Quantitative Method
The titre of antilipoidal antibodies is the highest dilution of the test sample giving a positive test result (i.e., Agglutination).

PERFORMANCE CHARACTERISTICS
25 known VDRL positive samples and 217 known negative samples were evaluated with SYPHFINAL® latex VDRL reagent in parallel with modified VDRL test and RPR tests by both qualitative and quantitative techniques. SYPHFINAL® was found to correlate 100% with modified VDRL test and the RPR tests by the qualitative technique. SYPHFINAL® was found to correlate 96% with modified VDRL and 100% with RPR tests by the quantitative technique.

REMARKS
1. Quantitative procedure must be performed to determine the response to treatment and detect reinfection.
2. False positive reactions occur not infrequently and have been attributed to a variety of acute and chronic conditions.
3. In the absence of supporting clinical, historical, and epidemiological evidence, reactive results must be confirmed with more specific Treponemal tests.
4. It is strongly recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
5. Dispose all used and contaminated materials as per Standard Biohazard Safety Guidelines.

WARRANTY
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY
3. Data on file: Tulip Diagnostics (P) Ltd.