SEKURE®
TPLA (Treponemal)
RPR (Non-treponemal)
Assays

Efficient and Reliable Management of Syphilis Patient Care

SEKURE®

SEKURE® TPLA (treponemal) and RPR (non- treponemal) Assays

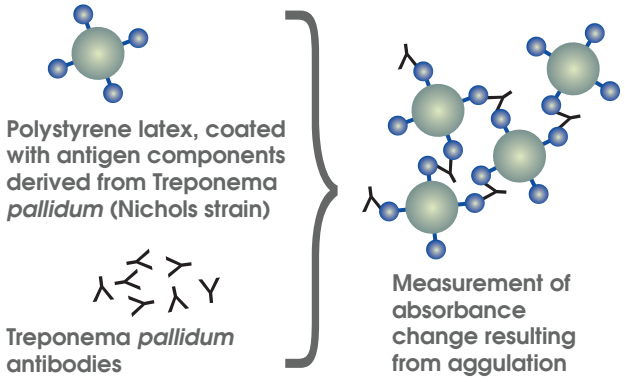
Syphilis is a curable, chronic infection caused by the spirochete bacterium *Treponema pallidum*. A reportable disease in many countries, syphilis diagnosis requires both screening and confirmatory testing, along with clinical signs and assessment. Various testing algorithms are used in different countries, and the SEKURE® assays can be helpful in managing the process flow through these algorithms.

The SEKURE® TPLA and RPR assays are both fully automated, making them ideal for screening purposes. They can be run on the same clinical chemistry platform, including the SK™ 500 Chemistry System (as well as other platforms), allowing for rapid reflex testing of multiple test samples. The RPR results are quantitative, providing a tool to aid physicians in treating syphilis and monitoring therapy.

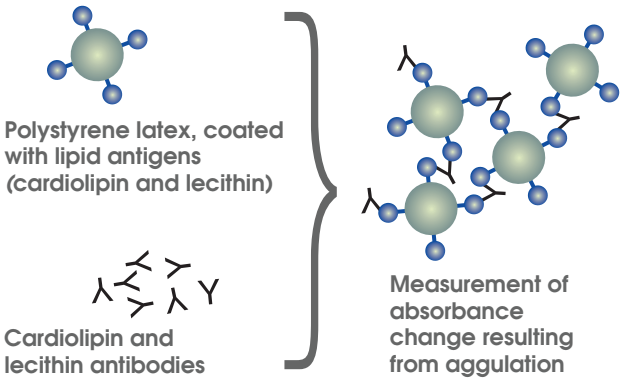
SK™ 500 CHEMISTRY

The SEKURE® TPLA (treponemal antibody) and RPR (non-treponemal lipid antibody) reagents are quantitative latex immunoturbidimetric methods.

The SEKURE® TPLA Reagent method utilizes polystyrene latex, coated with antigen components derived from Treponema pallidum (Nichols strain). It is intended for the determination of anti-Treponema pallidum antibodies in human serum or plasma.



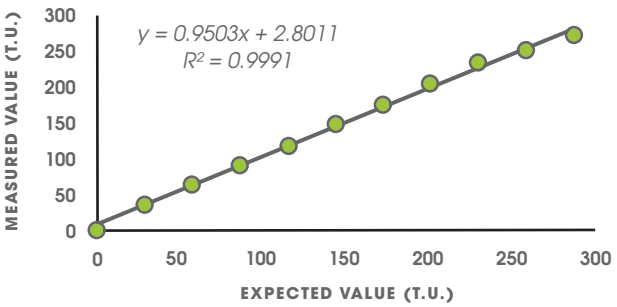
The SEKURE® RPR Reagent method utilizes polystyrene latex, coated with lipid antigens (cardiolipin and lecithin). It is intended for the determination of syphilitic anti-lipid antibodies in human serum or plasma.



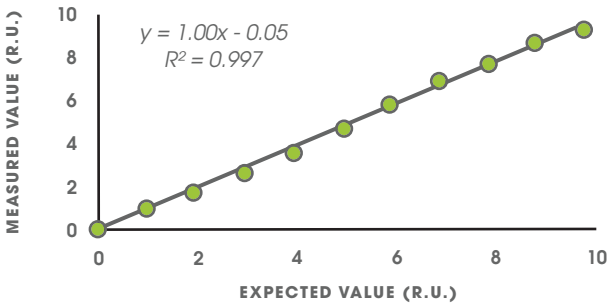
PERFORMANCE CHARACTERISTICS ON A SK™500 (UNLESS OTHERWISE STATED)

	TPLA	RPR
WITHIN-RUN PRECISION	≤3.2%	≤3.5%
TOTAL PRECISION (Hitachi® 9000/7180)	≤5.2%	≤5.1%
METHOD COMPARISON *The performance of this method (y) on a Hitachi® 917 analyzer was compared to a commercially available TPHA or RPR card method (x).*	Slope: 1.06 Intercept: 10.3 T.U. Correlation Coefficient: 0.828	Slope: 1.01 Intercept: 0.35 R.U. Correlation Coefficient: 0.909
NO SIGNIFICANT INTERFERENCES UP TO LEVELS INDICATED	Hemoglobin: 500 mg/dL (77.6 µmol/L) Conjugated Bilirubin: 20 mg/dL (342 µmol/L) Unconjugated Bilirubin: 20 mg/dL (342 µmol/L) Lipemia: 2% (intralipid) Rheumatoid factor: 500 IU/mL Chyle: 2000 FTU Ascorbic Acid: Up to 50 mg/dL (2,839 µmol/L) No false positives found in samples from collagenosis patients, pregnant women, and dialysis patients	Hemoglobin: 500 mg/dL (77.6 µmol/L) Conjugated Bilirubin: 21 mg/dL (359.1 µmol/L) Unconjugated Bilirubin: 20 mg/dL (342 µmol/L) Lipemia: 3% (intralipid) Rheumatoid factor: 500 IU/mL Chyle: 400 FTU Ascorbic Acid: Up to 50 mg/dL (2,839 µmol/L)
REFERENCE RANGE	10 T.U. or higher indicates sample is antibody positive	1 R.U. or higher indicates sample is antibody positive
CLINICAL SENSITIVITY (Hitachi®)	100% [1,3,4]	99.5% [1,5]
CLINICAL SPECIFICITY (Hitachi®)	99.6% [2,3,4]	99.5% [6]

LINEARITY (SK™500)



TPLA is linear from 3.3 to 288.3 T.U.



RPR is linear from 0.4 to 9.4 R.U.

SEKURE® TPLA and RPR Assays

Customer Benefits

Accuracy, precision and consistent results

- Methods are fully automated leading to more consistent, accurate and precise results

Flexible workflow and faster turnaround time

- The SEKURE® TPLA and RPR can be run on the same platform, allowing for reflex testing and improved laboratory workflow

Convenient and efficient

- Fast results (10 minute assay)

Reliability and confidence in results

- Methods correlate with traditional methods (TPHA/ RPR Card test)
- The SEKURE® RPR test is standardized to the WHO International Standard for Syphilitic Human Serum

Improved treatment monitoring

- The SEKURE® RPR can detect small changes in titre, giving a truer reflection of therapeutic effects compared to the RPR card test[1]

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER
SEKURE® TPLA REAGENT	R1 1 x 60 mL R2 1 x 10 mL	486647
SEKURE® TPLA CALIBRATOR SET	5 Levels x 2 mL	515132
SEKURE® TPLA CONTROL SET	Level A: 1 x 3 mL Level B: 1 x 3 mL	515149
SEKURE® RPR REAGENT	R1 1 x 60 mL R2 1 x 20 mL	486616
SEKURE® RPR CALIBRATOR SET	5 Levels x 1 mL	486623
SEKURE® RPR CONTROL SET	Positive 2 x 1 mL Negative 2 x 1 mL	486630

References

(1) Osato K et al. Clincal Evaluation of Latex Agglutination Test Kits for Detecting Anti-syphilitic Lipoidal Antibodies and Anti-treponemal Antibodies. Japanese Journal of Sexually Transmitted Diseases 2002; 13 (1):124–130.

(2) Shibazaki M et al. An Automated Measurement of Anti-Treponema Antibody Titer by MEDIACE TPLA, a Latex Agglutination Test using Hitachi 7170 Automatic Analyzer. The Journal of Clinical Laboratory Instruments and Reagents 1996; 19 (4):635–639.

(3) Osato K et al. Clinical Evaluation of Automated Latex Agglutination Test Kits (TPLA) for Syphilis Diagnosis. The Journal of Clinical Laboratory Instruments and Reagents 1991; 14 (4):739–743.

(4) Kataniwa Y et al. Clinical Evaluation of Latex Reagent Semedia TPLA for Diagnosis of Syphilis. The Journal of Clinical Laboratory Instruments and Reagents 1991; 14 (4):735–738.

(5) Kawai K et al. The possibility of assessing the stage of infection by using Mediace TPLA and RPR. The Journal of Clinical Laboratory Instruments and Reagents 2003; 26 (4): 301–304.

(6) Kinjo T et al. Laboratory -based evaluation of Latex Agglutination Turbidimetric Assay by Mediace RPR on P Module of Hitachi Auto analyzer 7600 to Quantitatively Determine Serum RPR Antibody. Japanese Journal of Clinical Laboratory Automation (JJCLA) 2005; 30 (3): 257–262.

Not available in the U.S. or Canada

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Because every result matters™

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