METHOD: LATEX- IMMUNOTURBIDIMETRIC ASSAY; ENDPOINT

SEKURE™ TPLA AND RPR REAGENTS

The SEKURE TPLA (treponemal) and RPR (non- treponemal) reagents are fully automated, quantitative latex immunoturbidimetric methods that are used as an aid in the diagnosis of Syphilis.

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.

FEATURES:

- ✔ Fully automated methodologies
- ✔ TPLA and RPR run on the same platform allowing for reflex testing
- ✔ Fast results (10 minute assay)
- ✔ Good correlation with traditional methods (TPHA/ RPR Card test)
- ✔ Definitive quantitative result

BENEFITS:

- ✔ Accurate, precise and consistent results
- ✔ Flexible workflow and faster turnaround time
- ✔ Convenient and efficient
- ✔ Reliability and confidence in results
- ✔ 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

SEKISUI DIAGNOSTICS

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NOT AVAILABLE IN USA OR CANADA

PERFORMANCE CHARACTERISTICS

	TPLA	RPR
PRECISION	Within-Run: < 2.7% Total Precision: < 4.5%	Within-Run: < 3.8% Total Precision: < 5.1%
METHOD COMPARISON	Slope: 1.06 Intercept: 10.5 T.U. Correlation Coefficient: 0.828	Slope: 1.01 Intercept: 0.35 R.U. Correlation Coefficient: 0.909
LINEARITY	5 T.U. TO 250 T.U.	0.2 TO 8.0 R.U.
NO SIGNIFICANT INTERFERENCES UP TO LEVELS INDICATED	Hemoglobin: 490 mg/dL (76.0 µmol/L) Conjugated Bilirubin: 18.5 mg/dL (316.4 µmol/L) Unconjugated Bilirubin: 18.5 mg/dL (316.4 µmol/L) Lipemia: 0.25% (intralipid) Rheumatoid factor: 500 IU/mL A high dose hook effect was not observed at analyte concentrations up to 362 T.U. No false positives were found in samples from collagenosis patients, pregnant women and dialysis patients.	Hemoglobin: 488 mg/dL (75.7 µmol/L) Conjugated Bilirubin: 21 mg/dL (359.1 µmol/L) Unconjugated Bilirubin: 19.7 mg/dL (336.9 µmol/L) Lipemia: 1.0% (intralipid) Rheumatoid factor: 450 IU/mL A high dose hook effect was not observed at analyte concentrations up to 100.5 R.U.
REFERENCE RANGE	A measurement of 10 T.U. or higher indicates that the sample is antibody positive.	A measurement of 1 R.U. or higher indicates that the sample is antibody positive.
CLINICAL SENSITIVITY	100% [1,3,4]	99.5% [1,5]
CLINICAL SPECIFICITY	99.6% [2,3,4]	99.5% [6]

(1) Osato K et al. Clinical 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.

NOTES:

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