

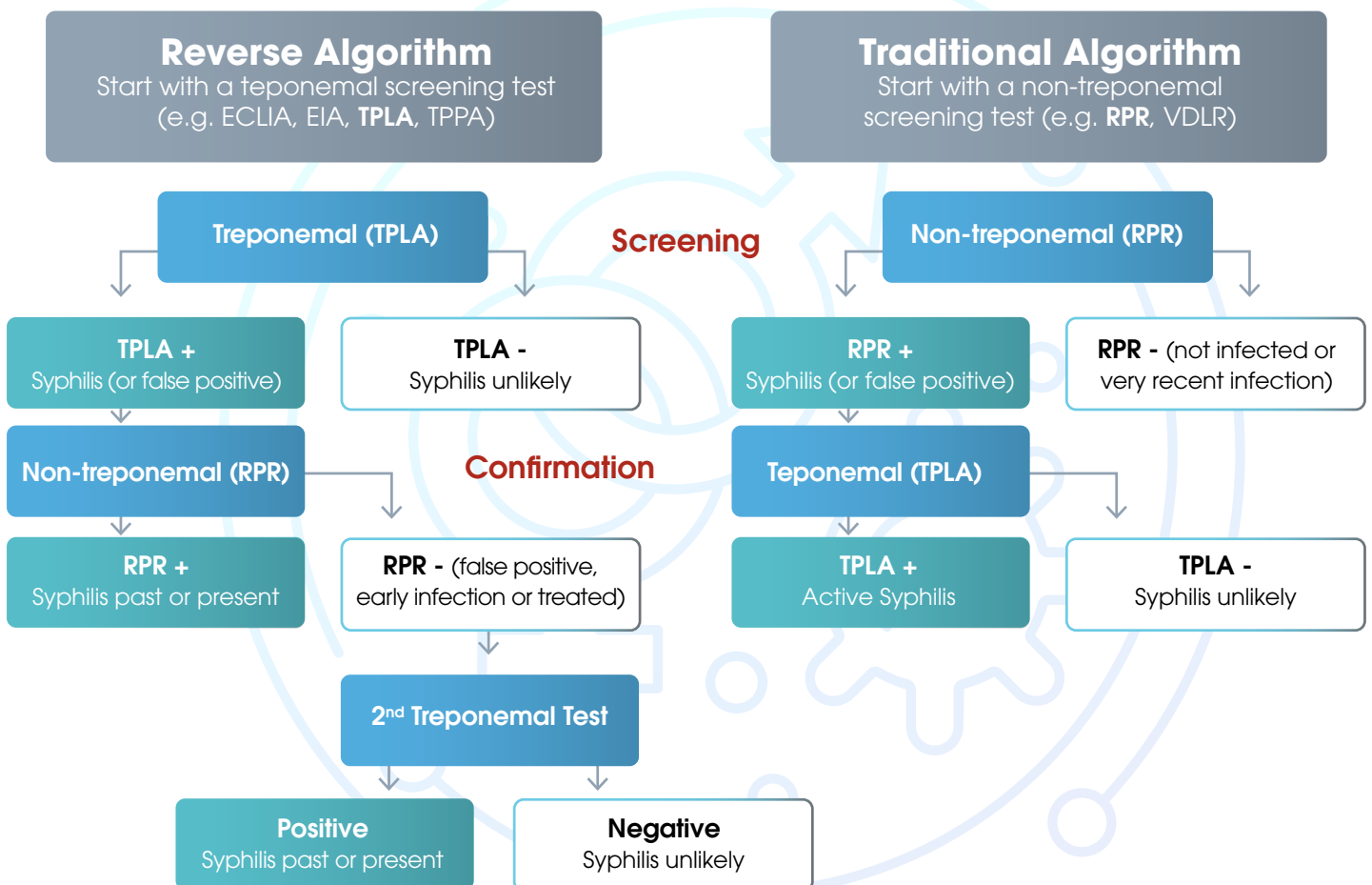
Fully Automated, Quantitative Syphilis Testing

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

SEKURE® RPR AND TPLA ASSAYS FOR AUTOMATED SCREENING & CONFIRMATION

- Fully automated latex agglutination assay. Quantitative results in 10 min: Perfect for screening
- Fit into various testing algorithms: For screening or confirmation
- Open system reagents for use on various instruments: To complement your existing test panel

SEKURE® RPR AND TPLA TESTING IN DIFFERENT SYPHILIS TESTING ALGORITHMS



ECLIA: Electrochemiluminescence immunoassay; EIA: Enzyme immunoassay; RPR: Rapid plasmin reagin; TPLA: Treponema pallidum latex agglutination; TPPA: Treponema pallidum particle agglutination; VDRL: Venereal Disease Research Laboratory-Test

Modified from Binder et al. 2016.

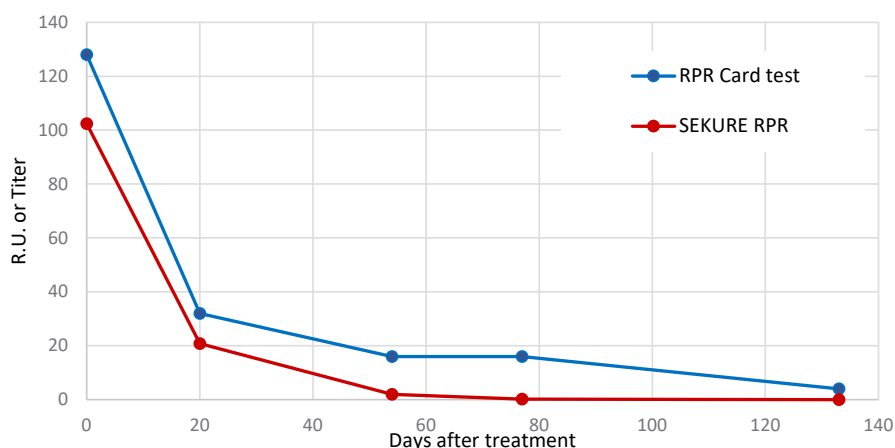


SEKURE® RPR (non-treponemal) and TPLA (treponemal) Fully automated & quantitative testing

QUANTITATIVE & AUTOMATED RPR TESTING FOR THERAPY MONITORING

- The SEKURE® RPR test can detect small changes in titre, giving a finer reflection of therapeutic effects compared to the RPR card test
- SEKURE® RPR may reflect therapeutic effects earlier than the RPR test card

Patient 105 (Primary Syphilis)



Modified from Osato et al. 2002.

RELIABILITY AND CONFIDENCE IN RESULTS

- Methods correlate with traditional methods (TPHA and RPR Card test)
- The SEKURE® RPR test is a quantitative test standardized to the WHO International Standard for Syphilitic Human serum⁴

PERFORMANCE CHARACTERISTICS OF SEKURE RPR AND TPLA ^{3,4,5}

	RPR	TPLA
WITHIN-RUN PRECISION (SK 500)	≤3.5% ³	≤3.2% ³
TOTAL PRECISION (Hitachi® 7180/9000)	≤5.1% ⁴	≤5.2% ⁵
METHOD COMPARISON <i>The performance of this method on a Hitachi® analyzer was compared to a commercially available TPHA or RPR card method.</i>	Slope: 1.01 Intercept: 0.35 R.U. Correlation Coefficient: 0.909	Slope: 1.06 Intercept: 10.3 T.U. Correlation Coefficient: 0.828
CLINICAL SENSITIVITY (Hitachi®)	99.5% ⁴	100% ⁵
CLINICAL SPECIFICITY (Hitachi®)	99.5% ⁴	99.6% ⁵

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

Fully automated & quantitative testing

COMPARISON: AUTOMATED VS. MANUAL SYPHILIS TESTING

SEKURE RPR vs. other non-treponemal assays

ASSAY	SEKURE RPR	RPR CARD TEST	VDRL
Testing type	Automated	Manual	Manual
Preparation	Ready for use	Requires preanalytical step	Requires preanalytical step
Turn around time	10 min	> 10 min	> 10 min
Throughput	*480 tests/hr Depends on System	Depends on individual skill	Depends on individual skill
Interpretation of results	Quantitative	Qualitative or semi-quantitative	Qualitative or semi-quantitative
Report type	Automated	Manual	Manual
Human error	Greatly reduced	Higher risk	Higher risk
Risk of infection	Reduced	Higher risk	Higher risk

SEKURE TPLA vs. other treponemal assays

ASSAY	SEKURE TPLA	TPHA	TPPA	CMIA	EIA (ELISA)
Testing type	Automated	Manual		Automated	Semi-automated
Preparation	Ready for use	Requires preanalytical step		Ready for use	Requires preanalytical step
Turn around time	10 min	> 30 min		~30 min	> 60 min
Throughput	*480 tests/hr Depends on System	Depends on individual skill		~ 200 tests/hr	n.a.
Interpretation of results	Quantitative	Qualitative or semi-quantitative		Qualitative	Qualitative or semi-quantitative
Report type	Automated	Manual		Automated	Manual or automated
Human error	Greatly reduced	Higher risk		Greatly reduced	Higher risk
Risk of infection	Reduced	Higher risk		Reduced	Higher risk

* Typical moderate throughput clinical chemistry analyser

CMIA: Chemiluminescent microparticle immunoassay; TPHA: Treponema pallidum hemagglutination

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

Fully automated & quantitative testing

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

To learn more about our clinical chemistry products scan the QR code or go to [Clinical Chemistry - SEKISUI Diagnostics](#)



REFERENCES:

1. Binder et al. Syphilis testing algorithms: A review. World Journal of Immunology 2016; 6(1): 1-8.
2. 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.
3. Data on file at Sekisui Diagnostics
4. RPR package Insert
5. TPLA package insert

Not available in the US or Canada

INTERNATIONAL

SEKISUI Diagnostics (UK) Limited
Liphook Way, Allington
Maidstone, Kent, ME16 0LQ, UK
Phone: +44 1622 607800
Fax: +44 1622 607801
Email: info@sekisui-dx.com

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sekisuidiagnostics.com