

ChemWell®-RPR

Automated Analyzer

Reagent

ChemWell-RPR 480 Test Kit

1 x 20 ml bottle of carbon antigen, 10 x 48 well microwell plates

ChemWell-RPR 4800 Test Kit

10 x 20 ml bottle of carbon antigen, 100 x 48 well microwell plates

ChemWell-RPR Titer Diluent

20 ml bottle

Quality Controls

ChemWell-RPR Control Set

2.5 ml each

Reactive / Weak Reactive / Nonreactive

ChemWell-RPR Control Set

5 ml each

Reactive / Weak Reactive / Nonreactive

Specifications

Recommended Environmental Conditions

- Operating Temperature: 18°C - 35°C
- Operating Humidity: Less than 85% recommended

Physical Specifications

- 36.25" W x 18.75" L x 21.5" H Approx. weight 77 lbs.
- 92.1 cm W x 47.6 cm L x 54.6 cm H Approx. weight 35 kg

Environmental Conditions

- Indoor Use
- Main Supply Voltage: Fluctuations not to exceed $\pm 10\%$ of nominal voltage
- Altitude: Up to 2000 m
- Temperature: 5°C to 40°C, may vary depending on reagent temperature requirements



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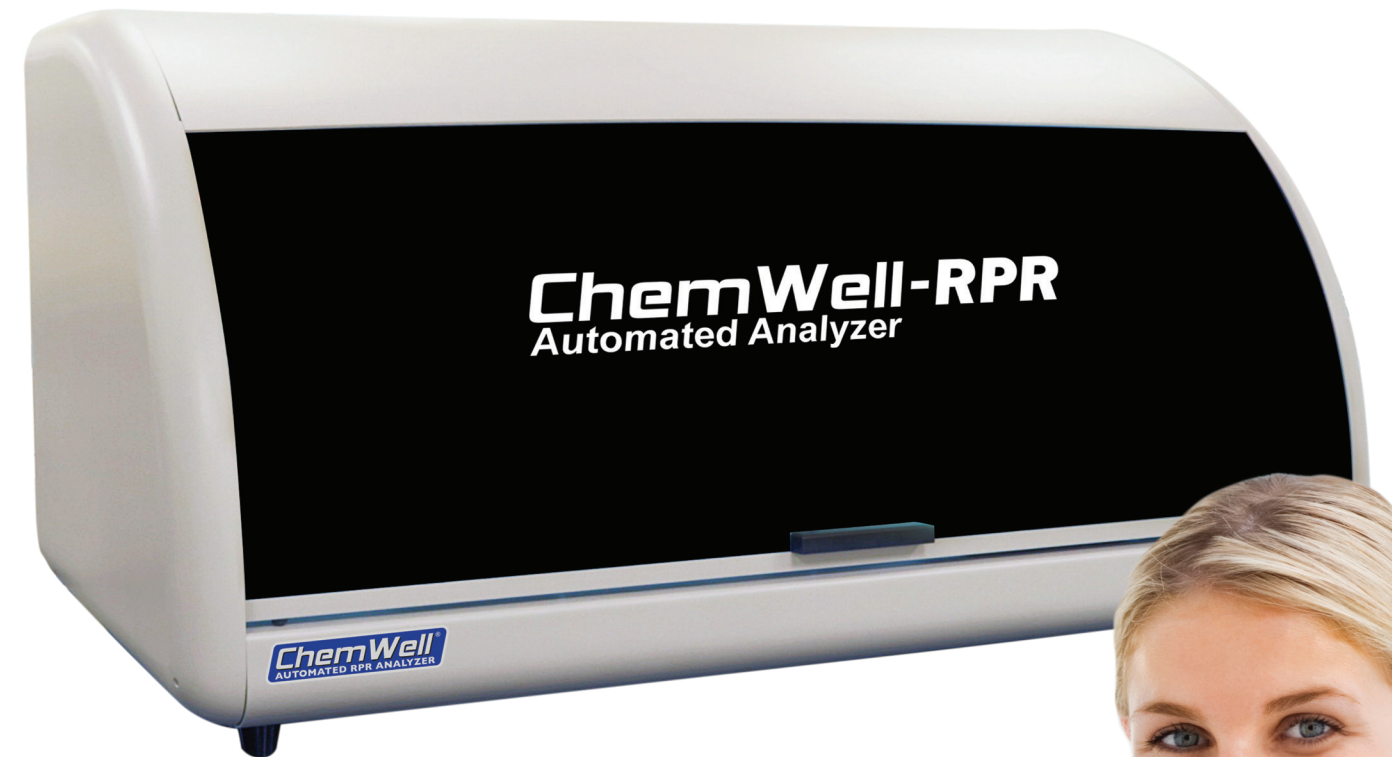
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315801 Rev D

ChemWell®-RPR

Automated Analyzer



Automated Nontreponemal Syphilis Testing

- **Reliable**
- **Accurate Results**
- **192 Test Per hour**



International market only



ChemWell®-RPR Automated Analyzer

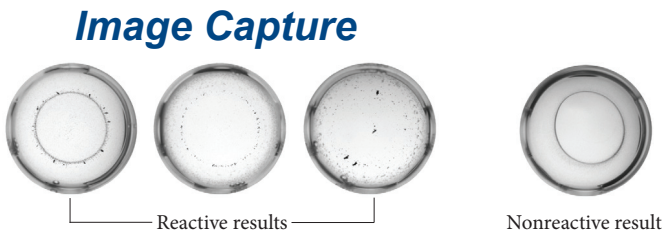
Introducing the next evolution in syphilis testing which complies with the USA CDC recommended traditional algorithm for Nontreponemal syphilis screening¹. Laboratorians can now automate Nontreponemal testing and drive significant operational efficiencies while minimizing false-positive results.

The USA made ChemWell-RPR is a fully automated syphilis analyzer. Laboratories will benefit from substantial labor savings and removing all subjectivity from the results interpretation.

1. MMWR, Vol. 60, #5, Feb. 11, 2001

How It Works

In place of manual RPR cards, this system uses 4 standard 48 well microplates to analyze 192 samples with no operator interaction. High resolution images are interpreted by a proven algorithm and retained for later reference. A second test can be run to determine titer.



Evaluation of the ChemWell-RPR Automated Syphilis Analyzer

A total of 5838 specimens were evaluated to determine reactivity. Of the 5838 - 1760 were reactive and 4072 specimens were nonreactive. A sensitivity >99.0% and a specificity >99.0% were determined.

ChemWell® RPR Analyzer Results			
Visual Results			
		Reactive	Nonreactive
	Reactive	1760	*5
	Nonreactive	1	4072

*Note: The 5 of 5 discordant results were tested with a treponemal and a nontreponemal tests and found to be nonreactive. The reactive samples ranged in reactivity from minimal 1:1 titers to 1:64 titers.

Operational Value

- Automated, walkaway system
- Throughput of 192 test per hour
- Eliminate subjectivity
- Reduced technical training
- Data Management (Analyze, Archive, Retrieve)
- Superior quality and service from a reliable and experienced provider

“The Most Significant Innovation to Syphilis Testing in the Last 30 Years”



Clinical Value

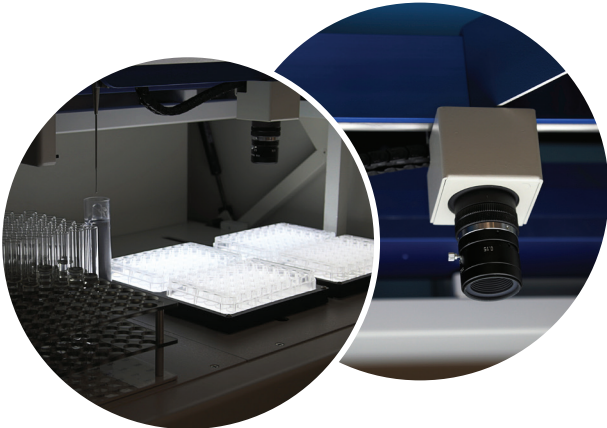
- Accurate and reproducible results
- Less over-treatment from positives due to post exposures that are no longer active
- Lower total healthcare costs

The Nontreponemal Advantage

Because of the demand for manual labor and due to the subjectivity in borderline samples, some laboratories preferred running Treponemal ELISA first in a reverse algorithm. With ChemWell-RPR there’s no need to compromise. Use the USA CDC recommended algorithm and save money since automated RPR cost much less than ELISA.

Day Since 1st Bleed	Non-treponemal Test			Treponemal Test				
				Treponema	PK TP	Serodia	Trinity Biotech	
	CW RPR	BD RPR	NT EIA	Syphilis	Syphilis	TPPA Syph	Syphilis IgG	Syphilis IgM
Day 0	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
Day 5	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
Day 10	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
Day 13	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
Day 31	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG
Day 45	POS	POS	POS	POS	POS	POS	IND	POS
Day 48	POS	POS	POS	POS	POS	POS	IND	POS
Day 52	POS	POS	POS	POS	POS	POS	IND	POS
Day 59	POS	POS	POS	POS	POS	POS	POS	POS
NEG= Negative, POS= Positive, IND= Indeterminate, Syphilis Seroconversion panel PSS901								

Courtesy of Centers for Disease Control and Prevention



- A 2015 study by the USA CDC determined that Nontreponemal tests can detect infection up to 14 days earlier than Treponemal test
- Treponemal test will be positive for IgG long after infection
- Preserve valuable blood resources with fewer false-positives in blood bank screening
- Only Nontreponemal test can be used to monitor therapy