

# 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

### Two modes

- Automated Qualitative screening
- Titer for therapeutic monitoring 1:2048 Dilution

### 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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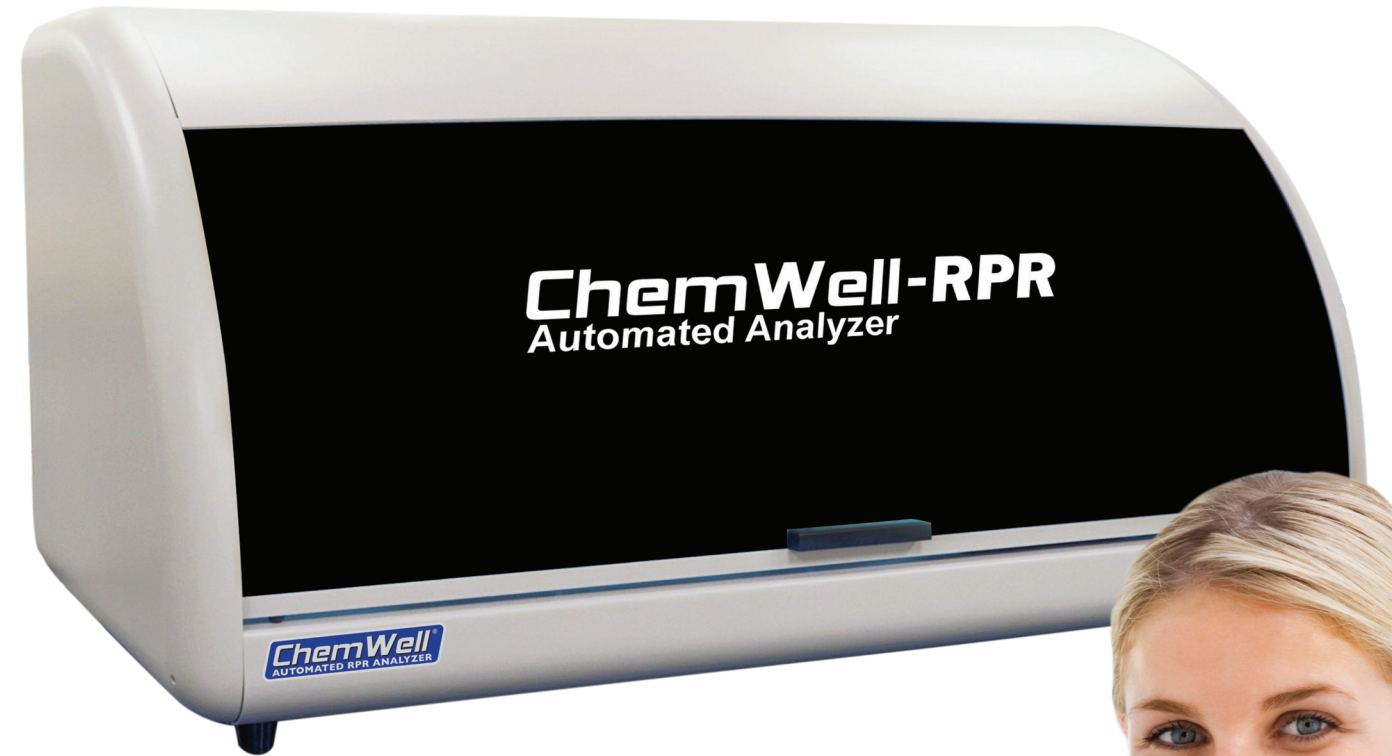
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# ChemWell®-RPR

Automated Analyzer



## Automated Nontreponemal Syphilis Testing

- **Reliable**
- **Accurate Results**
- **192 Test Per hour**
- **Titer Up To 1:2048 Dilution**



International market only



315801G



# ChemWell®-RPR Automated Analyzer

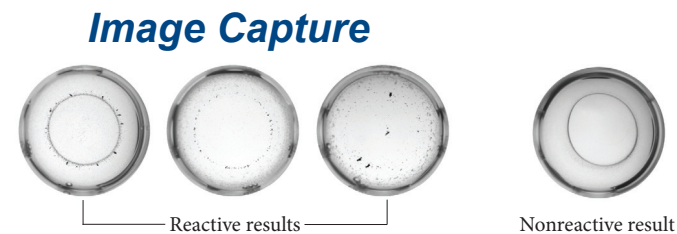
Introducing the next evolution in syphilis testing which complies with the USA CDC recommended traditional algorithm for Nontreponemal syphilis screening<sup>1</sup>. Laboratorians can now automate Nontreponemal testing and drive significant operational efficiencies while minimizing false-positive results.

Made in the USA, ChemWell-RPR is a fully automated syphilis analyzer. Laboratories will benefit from substantial labor savings and removing all subjectivity from 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 intervention. High resolution images are interpreted by a proven algorithm and retained for later reference. A second test can be run on positive samples to determine titers.



## 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: Later the 5 discordant samples were tested with a treponemal and another nontreponemal test 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 past exposures that are no longer active
- Lower total healthcare costs
- Two modes: Qualitative screening and Titer for therapeutic monitoring

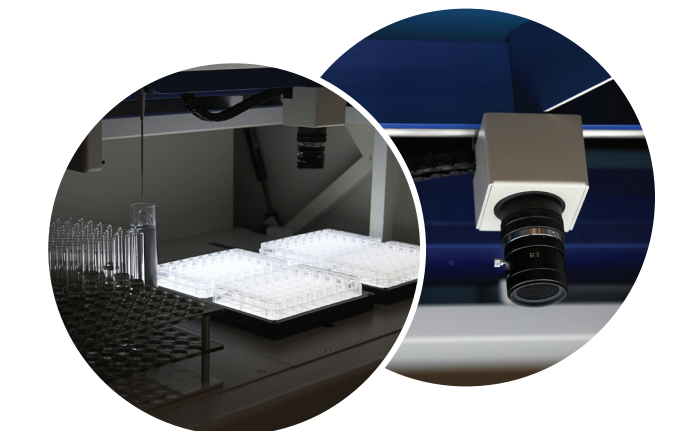
## The Nontreponemal Advantage

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				
	CW RPR	BD RPR	NT EIA	Treponema	PK TP	Serodia	Trinity Biotech	
				Syphilis	Syphilis	TPPA Syp	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