

# Congenital Syphilis Diagnosis

## **SYPHILIS VIRCLIA<sup>®</sup> IgM MONOTEST**

Indirect chemiluminescent immunoassay (CLIA) to detect IgM antibodies against *Treponema pallidum* in human serum/plasma.



Cat. No. VCM032

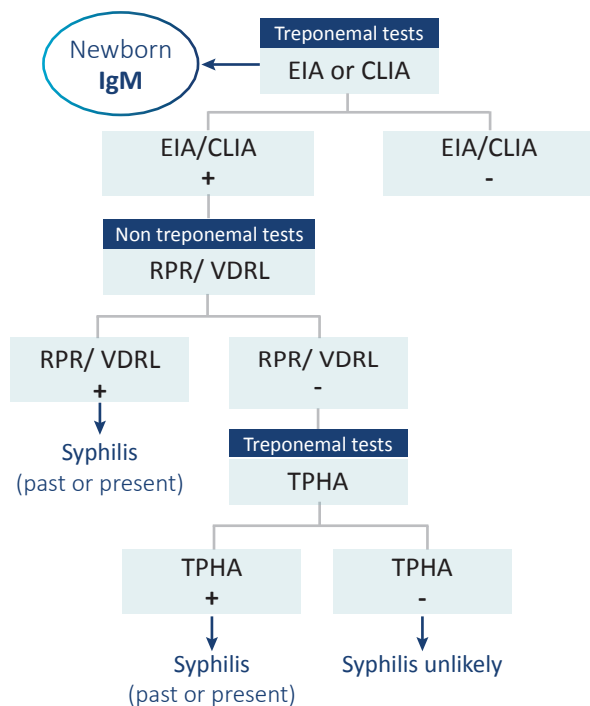
## **PRODUCT FEATURES**

- Monotest format with ready-to-use reagents
- Objective method with extraordinary sensitivity and accuracy in the results
- IgM detection is particularly interesting for the diagnosis of congenital syphilis (CS) in newborns
- Potentially useful for diagnosis of early syphilis in adults
- It can be used as a confirmatory assay for non treponemal tests
- Highly convenient solution to urgent samples
- Simple and automated protocol that provides results within 1 hour
- Sample dispensed from primary tube
- Serum diluent contains sorbent to remove rheumatoid factor and human IgG interference

Syphilis is a systemic human disease caused by *Treponema pallidum* and can be classified as acquired (mostly transmitted by sexual contact) or congenital (transplacental transmission). Serological testing is the method most often used, as the bacterium cannot be cultured.

Syphilis serological tests are divided into nontreponemal and treponemal tests, and neither is sufficient alone for diagnosis. Nontreponemal tests, such as RPR or VDRL, were recommended for many years for screening, followed by confirmation using a treponemal tests. However, the recent availability of new automatable EIA/CLIA tests, has reduced the time and labor required for syphilis testing and laboratories have started preferring this reverse sequence.

## Syphilis serologic screening algorithm Reverse sequence



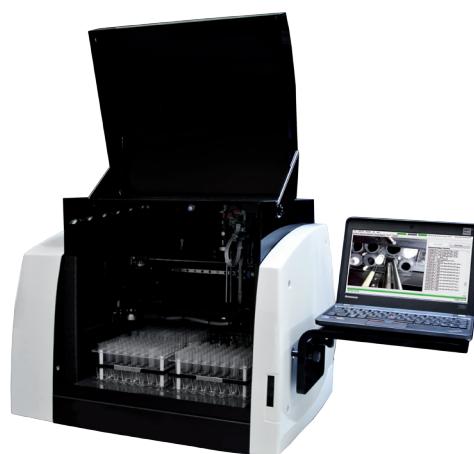
**Congenital syphilis (CS)** can occur when a mother is inadequately treated or not treated at all for an active *Treponema pallidum* infection and can cause miscarriage, low newborn weight, premature birth or perinatal mortality.

The diagnosis of CS can be difficult, as maternal nontreponemal and treponemal IgG antibodies can be transferred through the placenta to the fetus, complicating the interpretation of reactive serological tests for syphilis in neonates. Furthermore, half of all infants are asymptomatic at birth, and signs in symptomatic infants may be subtle and non specific.

**The detection of specific IgM in the newborn has proven to be a very reliable serological method** because maternal IgM does not cross the placenta and the fetus is capable of mounting an immune response by 24 weeks of gestation.

### Why EIA/CLIA is preferred as screening?

- Automated techniques (high throughput)
- Objective results
- High sensitivity and specificity
- Low cost, especially in high volume settings
- Less lab occupational hazard (pipetting)
- No false negatives due to prozone reaction



### Ordering information for EIA/CLIA products

Technique	Cat. No.	Description	Pack size
CLIA	VCM085	SYPHILIS VIRCLIA® IgG MONOTEST	24 tests
CLIA	VCM086	SYPHILIS VIRCLIA® IgG+IgM MONOTEST	24 tests
<b>CLIA</b>	<b>VCM032</b>	<b>SYPHILIS VIRCLIA® IgM MONOTEST</b>	<b>24 tests</b>
EIA	G1060	SYPHILIS ELISA IgG	96 tests
EIA	T1060	SYPHILIS ELISA IgG+IgM	96 tests