



SERION ELISA *classic* neonatal

SERION ELISA *classic* Cytomegalovirus IgM, Rubella Virus IgM and Toxoplasma gondii IgM tests are qualitative and quantitative immunoassays, which are evaluated for the detection of human IgM antibodies directed against Cytomegalovirus, Rubella Virus and *Toxoplasma gondii* in neonatal blood samples. A newborn screening can be performed with the regular dried neonatal heel blood spots (DBS) on filter papers with a diameter of 1/8 inch (3.2 mm).



Diagnostic Relevance

Due to their size, maternal IgM antibodies are not normally able to cross the placenta into the foetal blood stream. Consequently, the detection of pathogen specific IgM in a newborn is highly indicative of an intrauterine infection with that pathogen. Screening for IgM antibodies directed against these three significant pathogens can be of considerable assistance in identifying asymptomatic infections in newborns, particularly in regions that do not offer prophylactic pre-partal examinations and where the sero-negativity rate in women is high.

Cytomegalovirus

Cytomegalovirus causes the most frequent congenital and postnatal infections. If seroconversion occurs during pregnancy, virus transmission to the fetus occurs in 40 % of the cases. Up to 15 % of the affected infants suffering damage at birth. Late manifestations of disease such as long-term neurological damage or deafness can be observed in 10 to 15 % of infected children.

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Rubella Virus

During the first 8 to 11 weeks of pregnancy primary Rubella Virus infections lead to severe fetal malformations in 65 to 90 %. Infections between the 12th and 16th week of pregnancy cause malformations in approximately 10 %. There is only a minor risk of Rubella embryopathy after the 18th to 19th week of pregnancy.

Toxoplasma gondii

The transmission of *Toxoplasma gondii* via the transplacental route has been observed in all stages of pregnancy. In Germany, an incidence of 2 to 7 infected newborns per 1000 viable births is reported. Immediately after birth only 1 to 3 % of the infected newborns show clinical symptoms of toxoplasmosis. In contrast, up to 80 % of subclinically infected children suffer from late lesions and severe clinical manifestations.

Evaluation of SERION ELISA classic neonatal IgM

At the time of birth the content of IgM antibodies in newborn blood is significantly lower compared to adult samples. Therefore, a decrease of the borderline ranges of the SERION ELISA classic for neonatal diagnostics is necessary.

In addition to high sensitivity, immunoassays for neonatal diagnostics need high specificity, particularly with low borderline ranges. The high sensitivities in combination with high specificities of SERION ELISA classic tests allow the determination of threshold ranges for neonatal diagnostic as follows:

SERION ELISA classic	Threshold SERION ELISA neonatal (U/ml)	Threshold SERION ELISA classic (U/ml)
Cytomegalovirus IgM	2,5 - 3,8	10 - 15
Rubella Virus IgM	0,8 - 1,0	2,5 - 3,5
Toxoplasma gondii IgM	20 - 30	300 - 350

Specificity

The determination of the specificities of the SERION ELISA classic neonatal was assessed with DBS from more than 500 blood samples of anonymized newborns.

SERION ELISA classic	Specificity of SERION ELISA classic neonatal
Cytomegalovirus IgM	99,7 %
Rubella Virus IgM	99,5 %
Toxoplasma gondii IgM	99,8 %

Order Information

The following SERION ELISA classic are evaluated for neonatal screening on Dried Blood Spots (DBS).

SERION ELISA classic Cytomegalovirus IgM
SERION ELISA classic Rubella Virus IgM
SERION ELISA classic Toxoplasma gondii IgM

Order Nr.: ESR 109 M
Order Nr.: ESR 129 M
Order Nr.: ESR 110 M

Please visit our website www.virion-serion.com for more information on our SERION ELISA classic products.

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