

Infectious Disease

Cytomegalovirus IgG, IgM, IgG Avidity II

Total automation for accurate staging
of infection during pregnancy



DiaSorin

The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

Confidence in Your Results

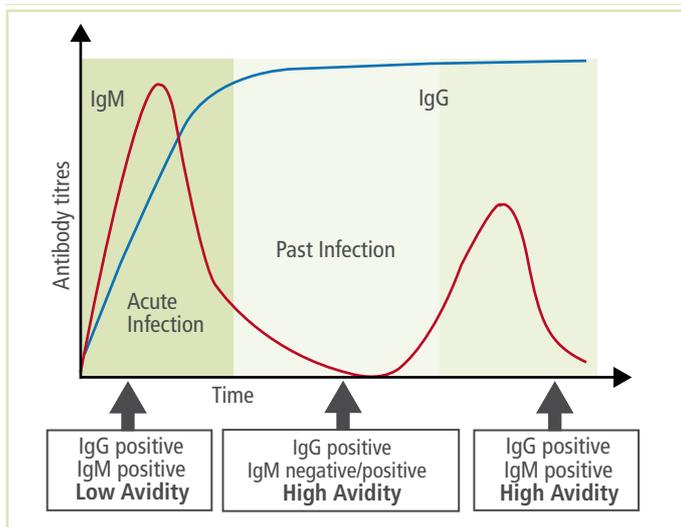
LIAISON®

Cytomegalovirus IgG, IgM, IgG Avidity II

Acute infection or reactivation? LIAISON® CMV assay panel is the solution

Human Cytomegalovirus (hCMV) is the most common cause of viral intrauterine infection. Fetal damage is mostly due to maternal primary infection. Intrauterine transmission of CMV is significantly reduced in immunoprotected mothers compared to primary infections contracted during pregnancy (< 2% vs 40-50%, respectively). As infections are either asymptomatic or accompanied by symptoms which are non-specific for CMV, laboratory techniques are the sole means of diagnosing acute infections. However, the establishment of primary infection as opposed to reactivation, chronic infection, IgM persistency or polyclonal stimulation may be difficult on the basis of current classical CMV IgM and IgG detection.

DiaSorin LIAISON® serology line has been developed to solve diagnostic ambiguities. Sensitive and quantitative CMV IgM, with highly specific and quantitative CMV IgG, both complemented by CMV avidity determination in a fully automated LIAISON® assay environment, will allow the laboratory to report clear and unequivocal results. Positive IgM and low-avidity IgG are suggestive of primary infection, whereas high-avidity IgG indicates IgM presence due to persistency or reactivation. In addition, to avoid misinterpretation of positive, yet low IgM responses in primary infection, the IgM test will point to the need of IgG avidity determination to overrule primary infection.



IgG	IgM	Avidity	Diagnosis
Negative	Negative		No infection
Positive	Positive	Low	Possible Acute infection
Positive	Positive	High	Reactivation/ Past infection
Positive	Negative		Past infection

Main Features of LIAISON® CMV assays

- Number of tests: 100 (IgG avidity: 25 tests)
- Solid phase: CMV immunodominant antigens (pp28, pp150, pp52)
- Label: Isoluminol derivative
- Method: CLIA
- Quantitative IgG and IgM Assays
- Sample type: Serum/Plasma

Ordering information

LIAISON® CMV IgG II (code 310745)
LIAISON® CMV IgM II (code 310755)
LIAISON® CMV IgG Avidity II (code 310765)

Flexibility enables quick and accurate results

- High throughput
- Reagent stability on board: 2/8 weeks
- Two-point recalibration, stable for 4 weeks
- Sample volume: 20-30 µL

LIAISON® Control CMV IgG II (code 310746)
LIAISON® Control CMV IgM II (code 310756)
LIAISON® Control CMV IgG Avidity II (code 310766)

AVAILABLE ON **LIAISON®** SYSTEMS

Product availability subject to required regulatory approval.



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Infectious Disease

Toxoplasma gondii IgG, IgM, IgG Avidity

Total automation for accurate staging
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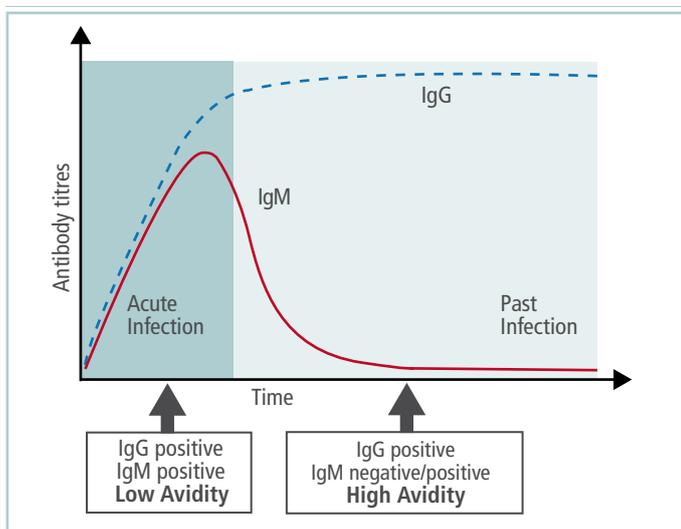
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Toxoplasma gondii IgG, IgM, IgG Avidity

Dating the infection? LIAISON® Toxoplasma assay panel is the solution

Toxoplasma infection can cause severe damage in cases of congenitally acquired infection. The diagnosis of primary infection in pregnant women and the timing of infection are of particular importance. Serology is the only method to determine if the mother has been infected by Toxoplasma gondii. Early diagnosis of primary infection requires a highly sensitive and quantitative assay for IgG and IgM antibodies, to discriminate between chronic and recent infections. The presence of Toxoplasma-specific IgM in serum is an indicator of recent infection, but often IgM persists and may be detected

for years after the occurrence of the infection. Measurement of IgG avidity may improve the accuracy of the serological diagnosis dating the infection more precisely. A high Avidity Index excludes recent Toxoplasma infection within the last four months. Therefore a high IgG Avidity Index during the first trimester excludes acute infection during pregnancy for many women who, only on the basis of a positive specific IgG and IgM result, would have been identified as having a recent infection.



IgG	IgM	Avidity	Diagnosis
Negative	Negative		No infection
Positive	Positive	Low	Possible Acute infection
Positive	Positive	High	Past infection
Positive	Negative		Past infection

Main Features of LIAISON® Toxoplasma gondii assays

- Number of tests: 100 (IgG avidity: 25 tests)
- Solid phase: Toxoplasma immunodominant antigens (p30, p22, GRA6, GRA7, ROP2, SAG1)
- Label: Isoluminol derivative
- Method: CLIA
- Quantitative IgG and IgM Assays
- Sample type: Serum/Plasma

Ordering information

LIAISON® Toxo IgG II (code 310780)
LIAISON® Toxo IgM (code 310710)
LIAISON® XL Toxo IgG Avidity (code 310795)

Flexibility enables quick and accurate results

- High throughput
- Referenced to WHO 2nd International Standard (1980)
- Reagent stability on board: 4/8 weeks
- Two-point recalibration, stable for 2/4 weeks
- Sample volume: 20-30 µL

LIAISON® Control Toxo IgG II (code 310781)
LIAISON® Control Toxo IgM (code 310711)
LIAISON® XL Control Toxo IgG Avidity (code 310796)

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Product availability subject to required regulatory approval.

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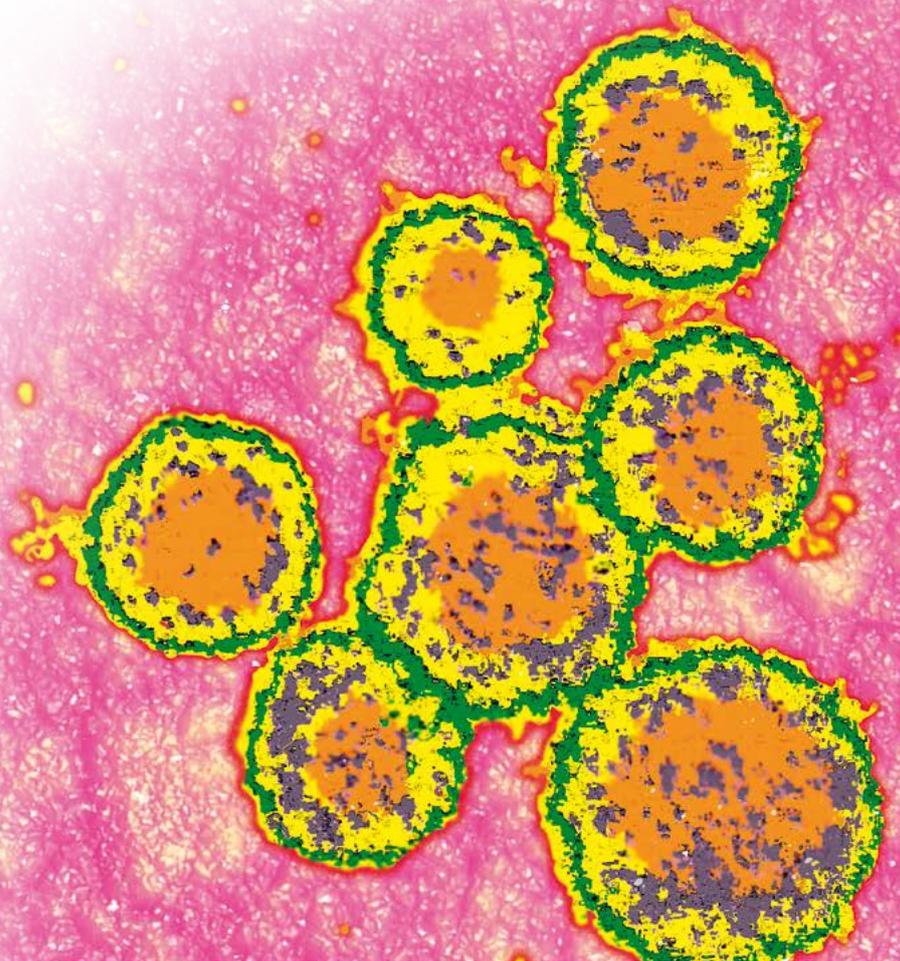
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M0870004275/A 04/14

Infectious Disease

Rubella Virus IgG, IgM

Total automation
for accurate differential diagnosis



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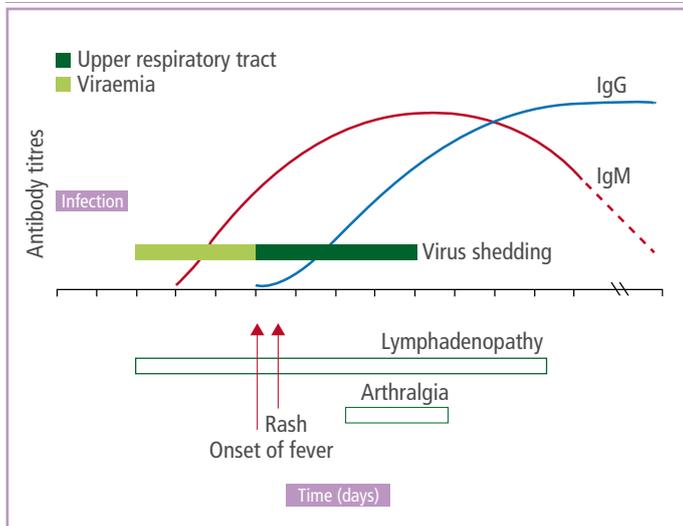
LIAISON®

Rubella virus IgG, IgM

Accurate differential diagnosis? LIAISON® Rubella assay panel is the solution

Rubella infection, acquired in the first trimester of pregnancy, is associated with a very high risk of Congenital Rubella Syndrome (CRS). Fetal damage is mostly due to maternal primary infection. Although incidence of CRS is significantly reduced because of successful vaccination programs especially in developed countries, rubella continues to occur because rubella vaccination coverage is not sufficient throughout the world. As infections are either asymptomatic or accompanied by symptoms which are non-specific for rubella, laboratory techniques are the sole means of diagnosing acute infections. DiaSorin LIAISON® serology line has been developed to

help identify women who are susceptible to rubella during pregnancy and for whom vaccination is advised in the immediate postpartum period and to prevent congenital rubella syndrome. LIAISON® Rubella IgG II is a sensitive assay able to detect low IgG antibody titers present in vaccinated population reducing the number of samples to be confirmed. LIAISON® Rubella IgM is a sensitive and quantitative assay for early identification of infection in at risk pregnant women. In conjunction with highly specific LIAISON® Rubella IgG II test, Rubella IgM test will allow the laboratory to report clear and unequivocal results.



IgG	IgM	Diagnosis
Negative	Negative	No infection
Positive	Negative	Past infection
Positive	Positive	Acute infection / Past infection (long lasting IgM)

Main Features of LIAISON® Rubella assays

- Number of tests: 100
- Solid phase: Rubella viral particle (HPV 77 strain)
- Label: Isoluminol derivative
- Method: CLIA
- Quantitative assays
- Sample type: Serum/Plasma
- High throughput

Ordering information

LIAISON® Rubella IgG II (code 317260)
LIAISON® Rubella IgM (code 310730)

Flexibility enables quick and accurate results

- Referenc to WHO Standard: 1st NIBSC International Standard RUBI-1-94 (1997)
- Reagent stability on board: 12 weeks (IgG); 8 weeks (IgM)
- Two-point recalibration, stable for 8 weeks (IgG), 4 weeks (IgM)
- Sample volume: 20 µL
- Calibrators included in the reagent cartridge
- All reagents ready to use

LIAISON® Control Rubella IgG II (code 317261)
LIAISON® Control Rubella IgM (code 310731)

AVAILABLE ON **LIAISON®** SYSTEMS

Product availability subject to required regulatory approval.

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Herpes Simplex Virus

HSV-1/2 IgG, HSV-2 IgG,
HSV-1 IgG, HSV-1/2 IgM

Total automation
for accurate differential diagnosis

Confidence in Your Results

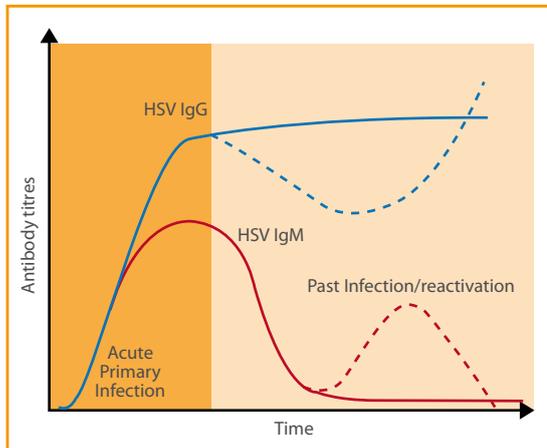
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Herpes Simplex Virus Antibodies

Accurate differential diagnosis? LIAISON® HSV assay panel is the solution

Genital herpes simplex virus (HSV) infection in pregnant women is associated with risk of viral transmission to the infant at delivery. The identification of risk pregnancies is necessary to avoid life-threatening consequences in newborns. Herpes simplex virus type 2 (HSV-2) is the main cause of genital herpes. HSV-2 reactivation or primary infection during pregnancy is common, but the risk of associated neonatal HSV-2 infection is 10 times greater for women with primary infection in the last trimester of pregnancy. Since most individuals infected with HSV-2 are asymptomatic, the serological evaluation of HSV-2 infection can reduce viral transmission. However, serological diagnosis of HSV-2 infection has been difficult, since discrimination between HSV-1 and HSV-2 specific antibodies

in serum is complicated by the shared antigenicity of the two viruses and consequently by their considerable cross-reactivity. DiaSorin LIAISON® serology line has been developed to solve such diagnostic ambiguities. The determination of type-specific antibodies to glycoprotein G2 allows the laboratory to establish a specific diagnosis of HSV-2 infection in a fully automated LIAISON® environment. LIAISON® HSV-1 IgG assay, based on recombinant gG1 antigen, allows accurate and type-specific detection of IgG antibodies to herpes simplex virus type 1. A highly specific and sensitive screening tool for determination of IgG antibodies to HSV-1 and HSV-2 as well as a complementary test for detection of Immunoglobulin M have been developed to complete the line.



HSV-1/2 IgG	HSV-2 IgG	Diagnosis	HSV-1 IgG	HSV-2 IgG	Diagnosis
-	-	Not exposed	-	-	Not exposed
+	-	HSV-1 infection	+	-	HSV-1 infection
-	+	HSV-2 infection or HSV-1 and HSV-2 associated infections	-	+	HSV-2 infection
+	+	HSV-1 and HSV-2 associated infections	+	+	HSV-1 and HSV-2 associated infections

IgM HSV antibodies may occur in both primary and recurrent infections.

Main Features of LIAISON® HSV assays

- Number of tests: 100
- Solid phase: Recombinant antigens
- Label: Isoluminol derivative
- Method: CLIA
- Qualitative assays
- Sample type: Serum/Plasma

Flexibility enables quick and accurate results

- High throughput
- Reagent stability on board: 4/8 weeks
- Two-point recalibration, stable for 4 weeks
- Sample volume: 20-40 µL

Ordering information

LIAISON® HSV-1/2 IgG (code 310800)
 LIAISON® HSV-2 IgG (code 310810)
 LIAISON® HSV-1 Type Specific IgG (code 310830)
 LIAISON® HSV-1/2 IgM (code 310820)

LIAISON® Control HSV-1/2 IgG (code 310801)
 LIAISON® Control HSV-2 IgG (code 310811)
 LIAISON® Control HSV-1 IgG (code 310831)
 LIAISON® Control HSV-1/2 IgM (code 310821)

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Infectious Disease

LIAISON[®] Biotrin Parvovirus B19 IgG, IgM

Biotrin quality. Total automation

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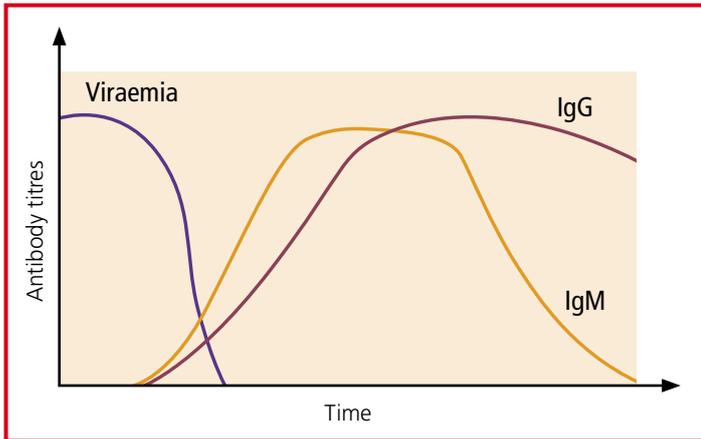
LIAISON®

LIAISON® Biotrin Parvovirus B19 IgG, IgM

The unique technological advantages of the LIAISON® systems and the superior quality of the Biotrin Parvovirus B19 ELISA

Parvovirus B19 is an erythrovirus that has been associated to a growing number of clinical presentations, the two most important being Fifth Disease in children and fetal complications during pregnancy. Observed in outbreaks, parvovirus B19 is highly contagious and presents children, especially in the age group 4-11 with fever, muscle pains, arthralgia and a characteristic facial rash. In pregnancy, infection of the fetus during the first 28 weeks of term, can lead to cardiac failure, spontaneous abortion, or fetal hydrops. It is estimated that every year, in a population such as that of the European Union, there are more than 1.2 million pregnant women who are at risk of infection. Screening for IgG antibodies to parvovirus B19 allows the pregnant woman to know whether she is immune to infection. In parallel, the detection of IgM antibodies will alert the clinician to a current parvovirus B19 infection.

DiaSorin has collaborated with Biotrin International (Dublin, Ireland) to transfer the very successful Biotrin ELISA parvovirus B19 antibody detection technology to its LIAISON® fully automated platform. Due to exclusive antigen expression system in baculovirus, and unique assay features such as the direct IgM capture system, Biotrin has been the reference assay and market leader in parvovirus B19 diagnostics for over 10 years. Laboratories and clinicians can now benefit from all the features of the Biotrin EIA kits, but with the added technological advantages of full automation on the LIAISON® instrument. Consequently, it is important to identify the Parvovirus B19 antibody status in individuals who may be at risk of infection.



IgG	IgM	Diagnostic
Negative	Negative	No infection
Positive	Negative	Past infection
Negative	Positive	Acute infection
Positive	Positive	Acute infection

Main Features of LIAISON® Parvovirus B19 assays

- Number of tests: 50
- Solid phase: Recombinant VP2 (expressed in baculovirus)
- Label: Isoluminol derivative
- Method: CLIA
- Qualitative assays
- Sample type: Serum/Plasma

Flexibility enables quick and accurate results

- High throughput
- Two-point recalibration stable for 2 weeks
- Quantitative determinations of IgG
- Direct IgM capture assay
- Sample volume: 20 uL

Ordering Information

LIAISON® Biotrin Parvovirus B19 IgG (code 310700)
LIAISON® Biotrin Parvovirus B19 IgM (code 310710)

LIAISON® Biotrin Control Parvovirus B19 IgG (code 310701)
LIAISON® Biotrin Control Parvovirus B19 IgM (code 310711)

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