Vaccination

MMR:

- The vaccine is a mixture of three live attenuated viruses, administered via injection
- The shot is generally administered to children around the age of one year, with a second dose before starting school (age 4/5). The first dose produces good immunity to measles (95–98%), mumps (97%), and rubella (95%). The second dose is intended to produce immunity in the 2-5% of persons who fail to develop immunity after the first dose
- In the United States, the vaccine was licensed in 1971 and the second dose was introduced in 1989[1]. It is widely used around the world; since introduction of its earliest versions in the 1970s, over 500 million doses have been used in over 60 countries

VZV:

- Routine vaccination against varicella zoster virus is performed in the United States, and the incidence of chickenpox has been reduced from 4 million cases per year in the pre-vaccine era to approximately 400,000 cases per year as of 2005.
- In Europe most countries do not currently vaccinate against varicella, though the vaccine is gaining wider acceptance.
- Australia, Canada, and other countries have now adopted recommendations for routine immunization of children and susceptible adults.

MMRV:

- The MMRV vaccine, a combined measles, mumps, rubella and varicella vaccine, has been proposed as a replacement for the MMR vaccine to simplify administration of the vaccines[2].

DiaSorin MMRV Assays

DiaSorin has developed a **fully automated MMRV panel** based on assays with unique characteristics to assure superior performance and simple result interpretation:

- Clinically relevant results - calibrated to the WHO International Standards
- Short total assay time for fast result delivery
- Selective use of antigens (recombinant or natural proteins) to achieve optimal performance
- Each individual assay has been designed to better fit the diagnostic algorithm when the assays need to be used in combination
- Low sample volume requirement compared to classical serology methods
- Quantitive measurement to follow the course of antibody titres

DiaSorin

The Diagnostic Specialist

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LIAISON®

MMRV PANEL

Full automation for Measles, Mumps, Rubella and Varicella-zoster antibody detection

M0870004257 12304 0411

Measles IgG Mumps IgG Rubella IgG VZV IgG

LIAISON® MMRV PANEL

MMRV

A complete panel of flexible and reliable assays for fully automated detection of Measles, Mumps, Rubella and Varicella-zoster antibodies

MMRV Clinical Background

MEASLES:

- Measles is a highly contagious virus, transmitted in droplets through coughing and sneezing
- Measles encephalitis occurs in 1 per 1,000 cases of natural measles, frequently resulting in permanent brain damage[4]
- Approximately 5% of children with measles will develop pneumonia, and 1 to 3 of every 1,000 children who get measles in the United States dies from the disease[4]

MUMPS:

- Mumps virus is spread from person to person by secretions sneezed or coughed from the nose or throat
- Complications can include inflamed testicles (20% to 50% of post-pubertal males infected), brain involvement including aseptic meningitis (15% of cases), and inflammation of the pancreas and ovaries[5]
- Permanent deafness occurs in 1 out of 2,000 cases[5]

RUBELLA:

- Rubella virus is transmitted through mucus droplets in the environment
- Rubella in pregnancy can lead to congenital rubella syndrome (CRS) in the fetus. This is characterized by deafness, mental retardation, and heart defects
- Up to 85% of expectant mothers infected in the first trimester are at risk of miscarriage or a baby with CRS

VARICELLA-ZOSTER:

- The virus is spread through direct contact with fluid from the rash blisters
- Chickenpox can cause pneumonia (23 in 10,000 cases), and is a risk factor for developing severe invasive group A streptococcal disease
- Complications of varicella include bacterial infections (up to 5% of cases), decreased platelets, arthritis, hepatitis, and brain inflammation (1 in 10,000 cases)
- If contracted in early pregnancy, VZV can cause abnormalities in 2% of cases

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1 Banatvala JE, Brown DW (2004). Rubella. Lancet 363 (9415): 1127–37.

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3 Klein NP, Yih WK, Marin M et al. (2008). Update: recommendations from the Advisory Committee on Immunization Practices (ACIP) regarding administration of combination MMRV vaccine. MMWR Morb Mortal Wkly Rep 57 (10): 258–60

4 Centers for Disease Control and Prevention. Program in brief: Measles Mortality Reduction and Regional Global Measles Elimination.

5 Committee on Infectious Diseases, American Academy of Pediatrics. Report of the Committee on Infectious Diseases. In: Red Book. 2003:439-443.

LIAISON® Analyzer

EASE OF USE

- Full automation
- No complicated pre-dilution steps
- Stored master curve
- Calibrators included
- Ready-to-use reagent cartridge
- Auto reflex testing
- Barcode identification

MAXIMUM FLEXIBILITY

- Random access, Batch mode, STAT function
- Up to 144 samples on board
- Up to 15 assays on board
- All common primary tubes accepted
- Continuous reloading
- Controlled reagent cooling and incubation conditions

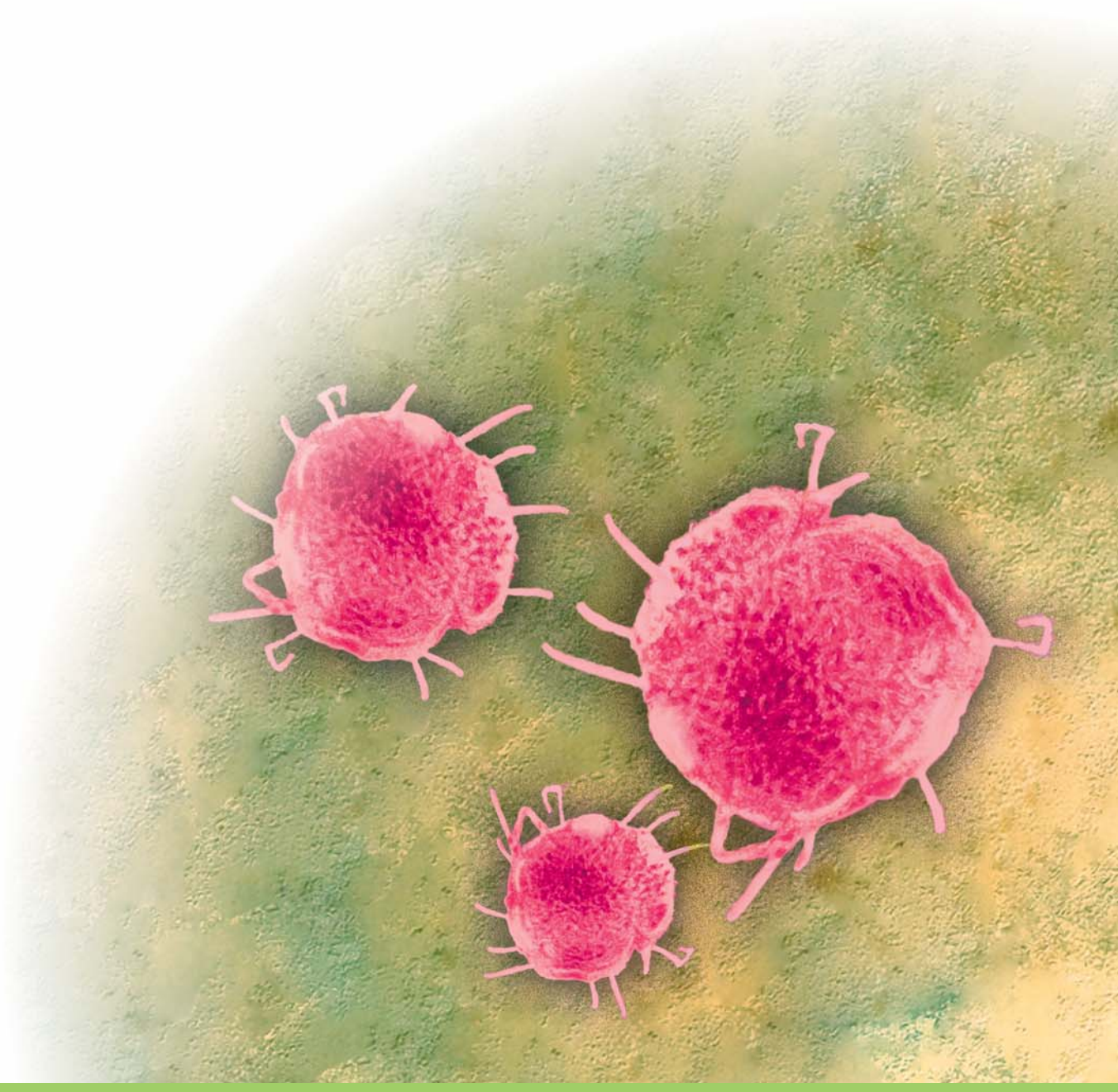
QUICK TESTS PROCESSING

- Throughput up to 180 results/hour
- Long walk-away time
- Short time to first results
- Short hands-on time

Infectious Disease

LIAISON® Measles IgG

The fully automated solution for quantitative antibody detection



DiaSorin

The Diagnostic Specialist

Infectious Disease LIAISON® Measles IgG

KEY ASSAY FEATURES

Number of tests	100
Method	Indirect Quantitative
Assay range	5 – 300 AU / mL
Solid Phase	Recombinant nucleoprotein expressed in baculovirus
Conjugate	MoAb to human IgG conjugated to isoluminol derivative
Label	ABEI
Sample	10µL serum or plasma

Throughput	90 results / hour
Time to first result	35 minutes
Integral on board stability	8 weeks
Calibrators availability	On board – positive and negative
Calibration stability	4 weeks
Controls availability	Positive and negative (60 tests per control kit – code 318811)
Controls stability once opened	8 weeks

Performance Characteristics

- **Reference to WHO Standard:** Cut-off value equates to 175 mIU/mL (WHO Third International Standard for Anti-Measles, NIBSC code: 97/648)
- **Cross-reactions:** Zero cross reactions observed with a panel consisting of antibodies to hCMV, EBV, rubella virus, parvovirus B19, mumps, Toxoplasma, HSV, VZV, HAV, ANA
- **Repeatability Coefficient of Variation:** 4.3-7.5 %
- **Reproducibility Coefficient of Variation:** Site 1: 10.0 - 14.5 %
  Site 2: 5.0 – 11.2 %

Diagnostic performance was assessed by testing 529 unselected specimens collected from a European laboratory routine (300 unselected individuals, 50 children ages 0-8 years, 117 subjects with serology suggestive of susceptibility to infection, 62 patients with serology suggestive of acute infection) against a commercially available reference EIA.

- **Diagnostic specificity:** 97.4% (189/194) (95% confidence interval: 94.1-99.2%)
- **Diagnostic sensitivity:** 94.7% (306/323) (95% confidence interval: 91.7-96.9%)

Ordering Information

LIAISON® Measles IgG (Code 318810)	LIAISON® Control Measles IgG (Code 318811)

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Infectious Disease

LIAISON® Rubella IgG

The fully automated solution for quantitative antibody detection

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Infectious Disease

LIAISON® Rubella IgG

KEY ASSAY FEATURES

Number of tests	100
Method	Indirect Quantitative
Assay range	0 – 350 IU / mL
Solid Phase	Inactivated rubella viral particle (HPV 77 strain)
Conjugate	MoAb to human IgG conjugated to isoluminol derivative
Tracer	ABEI
Sample	20µL serum or plasma

Throughput	90 results / hour
Time to first result	35 minutes
Integral on board stability	8 weeks
Calibrators availability	On board – positive and negative
Calibration stability	4 weeks
Controls availability	Positive and negative (60 tests per control kit – code 310721)
Controls stability once opened	8 weeks

Performance Characteristics

- **Reference to WHO Standard:** Calibrated against 1st NIBSC International Standard RUBI-1-94 (1997)
- Cross-reactions: Zero cross reactions observed with a panel consisting of antibodies to hCMV, HSV, HHV6, EBV, VZV, parvovirus B19, ANA, rheumatoid factor
- **Repeatability Coefficient of Variation:** 5.4 - 14.1 %
- **Reproducibility Coefficient of Variation (inter-site):** 6.4 – 11.5 %

Diagnostic performance was assessed by testing 632 specimens from different selected populations (subjects never infected by rubella virus, subjects affected by autoimmune diseases, patients affected by various infectious diseases with similar symptomatology, subjects with past rubella infection or vaccine recipients, patients affected by acute rubella infection or re-infection, subjects with long-lasting rubella virus IgM) against several commercially available EIA methods.

- **Diagnostic specificity:** 100.0 % (122/122) (95% confidence interval: 97.0-100.0%)
- **Diagnostic sensitivity:** 100.0 % (500/500) (95% confidence interval: 99.3-100.0%)

Ordering Information

LIAISON® Rubella IgG (Code 310720)	LIAISON® Control Rubella IgG (Code 310721)

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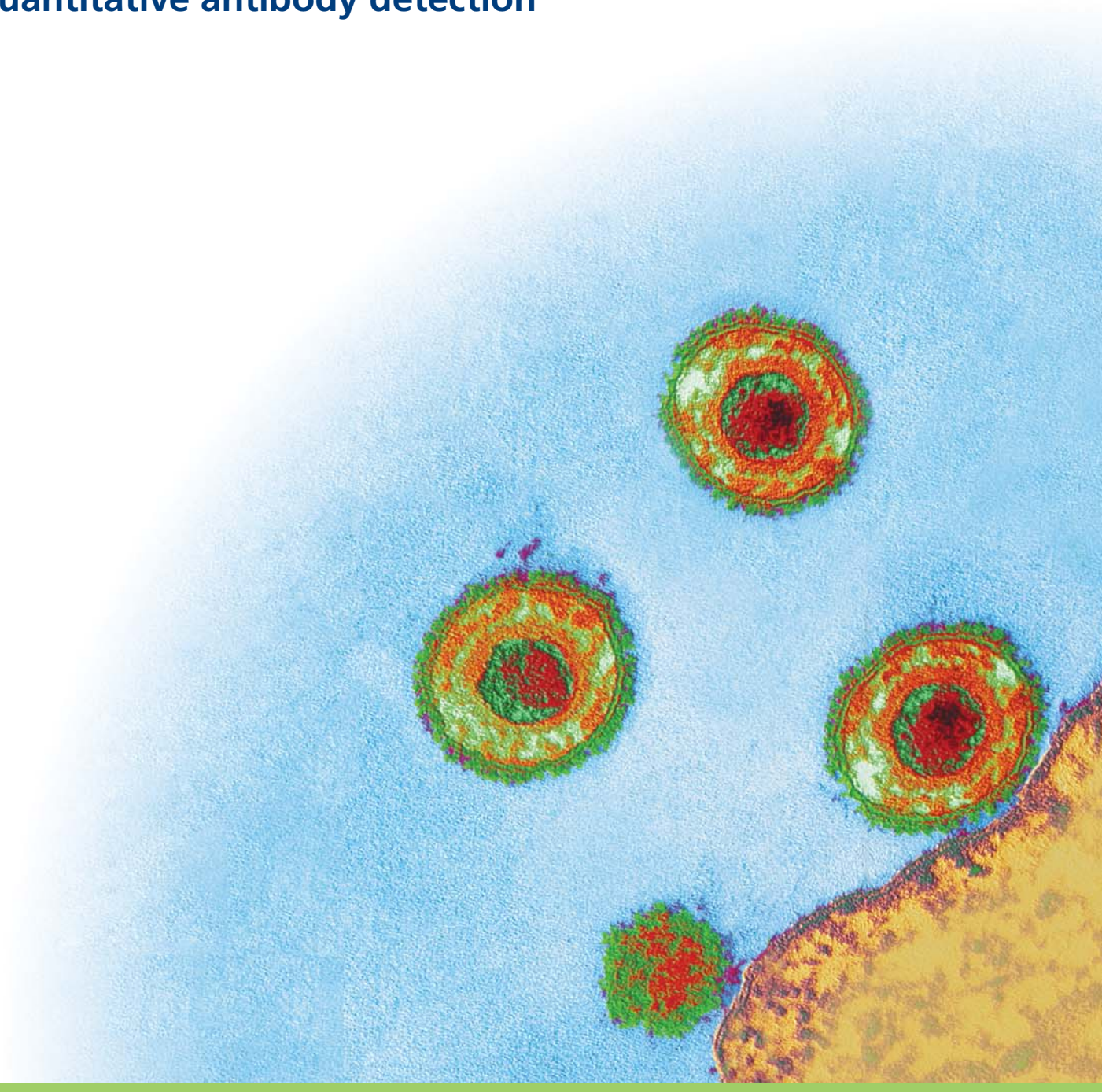
Infectious Disease

LIAISON® VZV IgG

The fully automated solution for quantitative antibody detection



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The Diagnostic Specialist

Infectious Disease

LIAISON® VZV IgG

KEY ASSAY FEATURES

Number of tests	50
Method	Indirect Quantitative
Assay range	10 – 4000 mIU / mL
Solid Phase	Partially purified extract of infected cell cultures (ROD strain)
Conjugate	MoAb to human IgG conjugated to isoluminol derivative
Label	ABEI
Sample	20µL serum or plasma

Throughput	90 results / hour
Time to first result	35 minutes
Integral on board stability	4 weeks
Calibrators availability	On board – positive and negative
Calibration stability	2 weeks
Controls availability	Positive and negative (60 tests per control kit – code 318811)
Controls stability once opened	4 weeks

Performance Characteristics

- **Reference to WHO Standard:** Calibrated against WHO International Preparation W1044
- **Cross-reactions:** Zero cross reactions observed with a panel consisting of antibodies to EBV EBNA, EBV VCA, hCMV, rubella, HSV 1/2, Toxoplasma, Borrelia, ANA
- **Repeatability Coefficient of Variation:** 5.4 - 14.1 %
- **Reproducibility Coefficient of Variation (inter-site):** 6.0 – 8.6 %

Diagnostic performance was assessed by testing 393 unselected specimens (pregnant women, blood donors, transplant recipients) against three CE-marked reference methods.

- **Diagnostic specificity:** 97.1 % (68/70) (95% confidence interval: 90.1-99.7%)
- **Diagnostic sensitivity:** 100.0 % (319/319) (95% confidence interval: 98.9-100.0%)

Ordering Information

LIAISON® VZV IgG (Code 310850)	LIAISON® Control VZV IgG (Code 310851)

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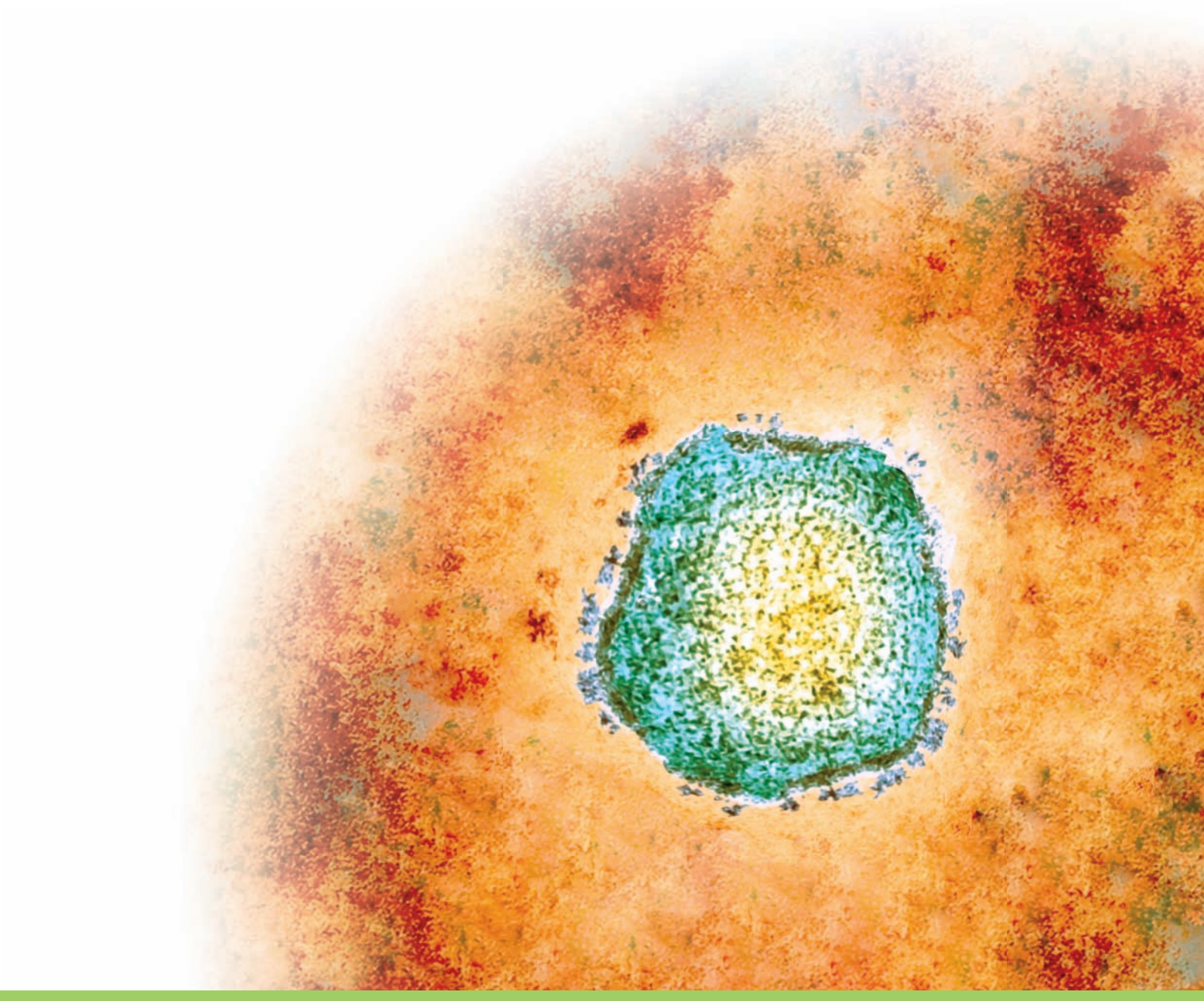
Infectious Disease

LIAISON® Mumps IgG

The fully automated solution for quantitative antibody detection



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The Diagnostic Specialist

Infectious Disease

LIAISON® Mumps IgG

KEY ASSAY FEATURES

Number of tests	100
Method	Indirect Quantitative
Assay range	5 – 300 AU / mL
Solid Phase	Recombinant nucleoprotein expressed in *P. pastoris*
Conjugate	MoAb to human IgG conjugated to isoluminol derivative
Label	ABEI
Sample	10µL serum or plasma

Throughput	90 results / hour
Time to first result	35 minutes
Integral on board stability	8 weeks
Calibrators availability	On board – positive and negative
Calibration stability	4 weeks
Controls availability	Positive and negative (60 tests per control kit – code 318811)
Controls stability once opened	8 weeks

Performance Characteristics

- **Cross-reactions:** Zero cross reactions observed with a panel consisting of antibodies to hCMV, EBV, rubella virus, parvovirus B19, measles, Toxoplasma, HSV, VZV, HAV, Treponema, ANA
- **Repeatability Coefficient of Variation:** 3.9 - 7.2 %
- **Reproducibility Coefficient of Variation (inter-site):** 10.7 – 14.5 %

Diagnostic performance was assessed by testing 519 unselected specimens collected from a European laboratory routine (300 unselected individuals, 50 children ages 0-8 years, 130 subjects with serology suggestive of susceptibility to infection, 39 patients with serology suggestive of acute infection) against a commercially available reference EIA.

- **Diagnostic specificity:** 98.2% (164/167) (95% confidence interval: 94.8-99.6%)
- **Diagnostic sensitivity:** 98.5% (330/335) (95% confidence interval: 96.5-99.5%)

Ordering Information

LIAISON® Mumps IgG (Code 318840)	LIAISON® Control Mumps IgG (Code 318841)

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