



For use
in the
U.S. only

Atellica Solution

TORCH and Syphilis Assays

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TORCH is an acronym for a group of infectious agents that include **T**oxoplasma, **R**ubella, **C**ytomegalovirus (CMV), and **H**erpes. When acquired during pregnancy these agents can cause significant birth defects and fetal death. Recognizing maternal disease and monitoring the patient when diagnosed is critical for clinicians and patients. The portfolio of TORCH and specialty assays on the Atellica® IM Analyzer is designed with the latest technological advances that enable laboratories to deliver the high-quality test results which aid in diagnosis and treatment of important infectious diseases.



Immunoassay

CMV IgG

CMV IgM*

Herpes-1 IgG

Herpes-2 IgG

Rubella IgG

Rubella IgM

Syphilis

Toxoplasma IgG

Toxoplasma IgM

- Delivers fast results so clinicians can counsel their patients on preventing infection, address fetal outcomes if infected, and offer optimal care.
- Reduces hands-on labor and improve workflow efficiency and turnaround time with fully automated tests.
- Increases lab efficiency by consolidating a broad menu of infectious disease assays on one platform.

The Atellica® Solution provides a broad and expanding menu to help your lab drive better clinical and business outcomes. The Atellica IM Analyzer utilizes proven advanced Acridinium Ester (AE) technology, with over 50 patents granted or pending.

*Under development. Not commercially available. Future availability cannot be guaranteed. Product availability may vary by country.

Assay Characteristics

Assay	Sample Type	Sample Volume (µL)	Time to First Result (min)	Cutoff (Index)	Analytical Measuring Range	Reagent Onboard Stability (days)	Lot Calibration Interval (days)
CMV IgG	Serum, Plasma: Dipotassium EDTA, lithium heparin	20	40	Non-Reactive: <1.00 Reactive: ≥1.00	N/A	60	Lot: 77 Pack: 60
Herpes-1 IgG	Serum, Plasma: EDTA, lithium heparin	20	39	Non-Reactive: <1.00 Reactive: ≥1.00	N/A	57	Lot: 90 Pack: 28
Herpes-2 IgG	Serum, Plasma: EDTA, lithium heparin	20	39	Non-Reactive: <1.00 Reactive: ≥1.00	N/A	90	Lot: 90 Pack: 28
Rubella IgG	Serum, Plasma: EDTA, Heparin	10	19	Non-Reactive: <5.0 IU/mL Reactive: ≥10.0 IU/mL Equivocal: ≥5.0 IU/mL and <10.0 IU/mL	0.2–500.0 IU/mL	23	Lot: 53 Pack: 14
Rubella IgM	Serum, Plasma; EDTA, Heparin	20	40	Non-Reactive: <0.80 Reactive: ≥1.00 Equivocal: ≥0.8 and <1.00	0.00–15.00 Index	56	Lot: 91 Pack: 28
Syphilis	Serum, Plasma: EDTA, lithium heparin, sodium heparin, and citrate	100	29	Non-Reactive: <0.90 Reactive: ≥1.10 Equivocal: ≥0.90 and <1.10	N/A	60	Lot: 37 Pack: 21
Toxoplasma IgG	Serum, Plasma: EDTA, Heparin	10	28	Non-Reactive: <6.4 IU/mL Reactive: ≥10.0 IU/mL Equivocal: ≥6.4 IU/mL and <10.0 IU/mL	0.5–700.0 IU/mL	28	Lot: 56 Pack: 14
Toxoplasma IgM	Serum, Plasma: EDTA, Heparin	10	39	Non-Reactive: <0.90 Reactive: ≥1.00 Equivocal: ≥0.90 and <1.00	0.10–40.00 Index	19	Lot: 21 Pack: 14

Table of Method Comparisons

Assay	Comparator Assay—ADVIA Centaur® XP	
	Positive % Agreement	Negative % Agreement
CMV IgG	99.5%	99.4%
Herpes-1 IgG	100%	96%
Herpes-2 IgG	97.9%	100%
Rubella IgG	100%	100%
Rubella IgM	98.6%	100%
Syphilis	100%	100%
Toxoplasma IgG	100%	100%
Toxoplasma IgM	100%	100%

Ordering Information

	SMN No.	Tests per Kit	Contents
CMV IgG			
Atellica IM CMV IgG	11202208	100	1 Atellica IM CMVG ReadyPack® primary reagent pack 1 Atellica IM CMVG ReadyPack ancillary reagent pack 1 vial Atellica IM CMVG CAL low calibrator 1 vial Atellica IM CMVG CAL high calibrator
Atellica IM CMV IgG QC	11202209		2 vials negative quality control (Control 1) 2 vials positive quality control (Control 2)
Herpes-1 IgG			
Atellica IM Herpes-1 IgG	10733031	100	1 Atellica IM HSV1 ReadyPack primary reagent pack 1 vial Atellica IM HSV1 CAL low calibrator 1 vial Atellica IM HSV1 CAL high calibrator
Atellica IM Herpes-1 IgG QC	10733032		1 vial negative control, Level 1 1 vial positive control, Level 2
Herpes-2 IgG			
Atellica IM Herpes-2 IgG	10733033	100	1 Atellica IM HSV2 ReadyPack primary reagent pack 1 vial Atellica IM HSV2 CAL low calibrator 1 vial Atellica IM HSV2 CAL high calibrator
Atellica IM Herpes-2 IgG QC	10733034		1 vial negative control, Level 1 1 vial positive control, Level 2
Rubella IgG			
Atellica IM Rub G	10995670	100	1 Atellica IM Rub G ReadyPack primary reagent pack 1 vial Atellica IM Rub G CAL low calibrator 1 vial Atellica IM Rub G CAL high calibrator
Atellica IM Rub G QC	10995671		2 vials negative QC 2 vials positive quality control, low level 2 vials positive quality control, high level
Rubella IgM			
Atellica IM Rub M	10995668	50	1 Atellica IM Rub M ReadyPack primary reagent pack 1 vial Atellica IM Rub M CAL low calibrator 1 vial Atellica IM Rub M CAL high calibrator
Atellica IM Rub M QC	10995669		2 vials negative quality control 2 vials positive quality control
Syphilis			
Atellica IM SYPH	10995675	200	1 Atellica IM SYPH ReadyPack primary reagent pack 1 Atellica IM SYPH ReadyPack ancillary reagent pack 2 vials Atellica IM Syph CAL low calibrator 2 vials Atellica IM Syph CAL high calibrator
Atellica IM SYPH QC	10995676		2 vials negative quality control 2 vials positive quality control
Toxoplasma IgG			
Atellica IM Toxo G	10995699	100	1 Atellica IM Toxo G ReadyPack primary reagent pack 1 vial Atellica IM Toxo G CAL low calibrator 1 vial Atellica IM Toxo G CAL high calibrator
Atellica IM Toxo G QC	10995700		2 vials negative quality control 2 vials positive quality control
Toxoplasma IgM			
Atellica IM Toxo M	10995701	50	1 Atellica IM Toxo M ReadyPack primary reagent pack 1 vial Atellica IM Toxo M CAL low calibrator 1 vial Atellica IM Toxo M CAL high calibrator
Atellica IM Toxo M QC	10995702		2 vials negative quality control 2 vials positive quality control

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Siemens Healthineers Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
siemens-healthineers.com

USA

Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005, USA
siemens-healthineers.us