ARCHITECT CMV IgM

REF 6C16-25
REF 6C16-30

en
CMV IgM
6C16
G53004R05
B6C160

Read Highlighted Changes: Revised May 2019.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

ARCHITECT CMV IgM

INTENDED USE

The ARCHITECT CMV IgM assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibodies to Cytomegalovirus in human serum and plasma.

SUMMARY AND EXPLANATION OF THE TEST

Infections with Cytomegalovirus (CMV), a member of the herpesvirus family, are common in man and are usually mild and asymptomatic. However in pregnant women,[1] newborns,[2] and immunocompromised individuals[3, 4] CMV infections may pose a significant medical risk.

CMV infection remains difficult to diagnose on symptoms alone since a high percentage of infections remain without symptoms. *In utero* infection may result in sequelae of varying degree including mental retardation, chorioretinitis, hearing loss and neurological problems. Since the risk of *in utero* virus transmission and CMV related damage of the fetus is strongly increased during primary infection, reliable recognition of primary CMV infections is of high importance for pregnant women.[5-7] Reinfection with exogenous virus or reactivation of latent virus may lead to the presence of anti-CMV IgM in absence of a primary CMV infection. Although presence of anti-CMV IgG reduces the likelihood of CMV related complications, it does not assure complete protection from disease.

CMV acquisition in infants can occur transplacentally following maternal infection, during birth by contact with the virus excreted from the cervix[8] or following birth through the ingestion of infected maternal breast milk. Both seronegative individuals and infants may acquire CMV through infected blood products[3] or contact with an infected individual. Children beyond the neonatal period are susceptible to infection and subsequent transmission of CMV when in day care.

If primary infection needs to be excluded, CMV IgG reactive samples should be tested for CMV IgM and CMV IgG Avidity. A positive CMV IgM result in connection with low avidity result is a strong indicator of a primary CMV infection within the last 4 months.

CMV IgG	CMV IgM	CMV IgG Avidity	Indication for...
nonreactive	nonreactive	N/A	no infection
reactive	nonreactive	high avidity	past infection; low risk for *in utero* transmission
reactive	reactive	low avidity	primary infection; high risk for *in utero* transmission
reactive	reactive	high avidity	non-primary infection; low risk for *in utero* transmission

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT CMV IgM assay is a two-step immunoassay for the qualitative detection of IgM antibodies in human serum and plasma with flexible assay protocols, referred to as Chemiflex.[9]

1. Sample, assay diluent, and coated paramagnetic microparticles are combined. The anti-CMV IgM present in the sample binds to the CMV virus lysate (strain AD169) and recombinant CMV antigen coated microparticles.
2. After washing, anti-human IgM acridinium-labeled conjugate is added to create a reaction mixture
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of anti-CMV IgM in the sample and the RLUs detected by the ARCHITECT iSystem optics.

The presence or absence of anti-CMV IgM in the specimen is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an active calibration.

If the chemiluminescent signal in the specimen is greater than or equal to the cutoff signal, the sample is considered reactive for anti-CMV IgM.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT CMV IgM 6C16

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	6C16-25	6C16-30
Σ	100	500
MICROPARTICLES	1 x 6.6 mL	1 x 27.0 mL
CONJUGATE	1 x 5.9 mL	1 x 26.3 mL
ASSAY DILUENT	1 x 10.0 mL	1 x 50.9 mL

MICROPARTICLES CMV virus lysate (strain AD169) and recombinant CMV antigen coated microparticles in TRIS buffered saline. Minimum concentration: 0.08% solids. Preservatives: ProClin 300 and antimicrobial agents.

CONJUGATE Murine acridinium-labeled anti-human IgM in MES buffer. Minimum concentration: 48 ng/mL. Preservatives: ProClin 300 and antimicrobial agents.

ASSAY DILUENT CMV IgM assay diluent containing TRIS buffer and goat anti-human IgG. Preservatives: sodium azide and ProClin 950.

Other Reagents

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product contains human-sourced and/or potentially infectious components. Refer to the **REAGENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[10-13]

The following warnings and precautions apply to: MICROPARTICLES / CONJUGATE	
WARNING:	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: ASSAY DILUENT	
WARNING:	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between kits.**
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
  - To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  - Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
- When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgM will result in a neutralized conjugate.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8˚C	Until expiration date	May be used immediately after removal from 2-8˚C storage. Store in upright position.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8˚C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

It is recommended that the assay be calibrated every 30 days.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The ARCHITECT CMV IgM assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

500 test kit size can only be run with the following assay file version:

CMV IgM version 6 (541_006) or higher

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Verified specimen types to be used with this assay:

Specimen Types	Collection Tubes
Human serum	Serum
	Serum separator tubes
Human plasma	Plasma separator tubes (lithium heparin)
	Potassium EDTA
	Sodium citrate
	Lithium heparin
	Sodium heparin

- Other specimen collection tube types have not been tested with this assay.
- Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum or plasma.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed (> 500 mg/dL hemoglobin)
  - obvious microbial contamination
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
- All samples (Calibrator 1, controls, and patient specimens) should be tested within 3 hours of being placed on board the ARCHITECT iSystem.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at ≥ 10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if
  - they contain fibrin, red blood cells, or other particulate matter,
  - they require repeat testing, or
  - they were frozen and thawed.

  Transfer clarified specimen to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Storage

Specimen Type	Storage Temperature	Maximum Storage Time
Serum or plasma	2-8°C	≤ 14 days
	- 10°C or colder	

Specimens may be stored on or off the clot, red blood cells, or separator gel.

Remove serum or plasma from the clot, red blood cells, or separator gel if stored longer than the maximum 2-8°C storage time.

Specimens may be stored for up to 14 days refrigerated at 2-8°C prior to being tested. If testing will be delayed more than 14 days, store frozen (-10°C or colder).

No qualitative performance differences were observed between experimental controls and nonreactive or reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

Specimen Shipping

- Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- It is recommended that specimens be removed from the clot, red blood cells, or separator gel.
- Ship on wet ice or dry ice.
- Do not exceed the storage time limitations listed above.

PROCEDURE

Materials Provided

6C16 ARCHITECT CMV IgM Reagent Kit

Materials Required but not Provided

- ARCHITECT CMV IgM Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 6C16-01 ARCHITECT CMV IgM Calibrator
- 6C16-10 ARCHITECT CMV IgM Controls
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions about placing septums on bottles, refer to the **Reagent Handling** section of this package insert.
- Load the reagent kit on the ARCHITECT iSystem.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Minimum sample cup volume is calculated by the system and printed on the Orderlist report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

  Maximum number of replicates sampled from the same sample cup: 10
  - Priority:

    Sample volume for first test: 75 µL

    Sample volume for each additional test from same sample cup: 25 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 150 µL

    Sample volume for each additional test from same sample cup: 25 µL
  - > 3 hours on board: Additional sample volume required. For information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare ARCHITECT CMV IgM Calibrator and Controls.
  - Mix calibrator(s) and controls by gentle inversion before use.
  - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: 4 drops

    for each control: 4 drops
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Specimen Dilution Procedures

Specimens cannot be diluted for the ARCHITECT CMV IgM assay.

Calibration

- Test Calibrator 1 in replicates of three. The calibrator should be priority loaded.

  A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
- Once an ARCHITECT CMV IgM calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used or
  - Controls are out of range.
- It is recommended that the assay be calibrated every 30 days.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

The recommended control requirement for the ARCHITECT CMV IgM assay is that a single sample of each control level be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

The ARCHITECT CMV IgM Control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and samples must be retested. Recalibration may be indicated.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

The ARCHITECT CMV IgM assay belongs to method group 5 (except functional sensitivity).

RESULTS

Calculation

The ARCHITECT iSystem calculates the Calibrator 1 mean chemiluminescent signal from three Calibrator 1 replicates and stores the result. Results are reported by dividing sample result by the stored Calibrator 1 result.

The default result unit for the ARCHITECT CMV IgM assay is Index. Sample results may also be reported as sample to cutoff (S/CO). The values for Index and S/CO are equivalent.

Interpretation of Results

- Specimens with concentration values < 0.85 Index are considered nonreactive for IgM antibodies to CMV and indicate the absence of acute infection.
- Specimens with concentration values ≥ 1.00 Index are considered reactive for IgM antibodies to CMV and indicate acute infection. Such individuals are potentially at risk of transmitting CMV infection.
- **NOTE:** It is recommended to confirm the clinical relevance of results ≥ 0.85 Index by testing the sample for CMV IgG Avidity. If the results continue to be unclear, consider taking a second sample within an appropriate period of time (e.g. 2 weeks) and repeating testing.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- If the ARCHITECT CMV IgM results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with other data; e.g., results of other tests (CMV IgG, CMV IgG Avidity), clinical impressions, etc.
- IgM rheumatoid factor (RF) in combination with CMV specific IgG can lead to false reactive results in IgM detecting assays. The ARCHITECT CMV IgM Assay Diluent minimizes RF interference, however, in rare cases interference caused by high concentrations of RFs and CMV specific IgG cannot be excluded.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.[14]
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested with assay kits (such as ARCHITECT CMV IgM) that employ mouse monoclonal antibodies.[15, 16]

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT CMV IgM assay is designed to have a precision of ≤ 10% total** CV for the Positive Control.

A study was performed with the ARCHITECT CMV IgM assay based on guidance from the Clinical and Laboratory Standards Institute. Calibrator 1 and controls were tested with 3 reagent lots at the internal site and with 2 reagent lots at 1 external evaluation site. Each sample was tested on a total of 2 instruments in replicates of 5 at 2 separate times per day for 5 days. Data from this study are summarized in the following table.*

			Within Run		Total**	
Sample	**N**	**Mean RLU**	**RLU SD**	**RLU %CV**	**RLU SD**	**RLU %CV**
Calibrator 1	500	2853	108.7	3.8	108.7	3.8

			Within Run		Total**	
Sample	**N**	**Mean Index**	**Index SD**	**Index %CV**	**Index SD**	**Index %CV**
NC	1500	0.14	0.010	6.885	0.010	6.885
PC	1500	2.54	0.083	3.265	0.085	3.328

* Representative data; results in individual laboratories may vary from these data.

** Total is an accumulation of within run, between run and between day.

Seroconversion Sensitivity

The ARCHITECT CMV IgM assay is designed to show a comparable seroconversion sensitivity to a commercially available diagnostic kit. Three commercially available seroconversion panels were obtained and tested. The following table shows data from these seroconversion panels.*

Panel	Day after 1st draw	ARCHITECT CMV IgM (Index) Cutoff: 1.00 Index	Commercially available diagnostic kit (Index) Cutoff: 0.500 Index
PTC901 (Boston Biomedica, Inc.)	0	0.15 (nonreactive)	0.171 (negative)
	2	0.12 (nonreactive)	0.145 (negative)
	7	0.13 (nonreactive)	0.138 (negative)
	10	0.13 (nonreactive)	0.133 (negative)
	17	**3.09 (reactive)**	0.187 (negative)
	24	**5.29 (reactive)**	**1.655 (positive)**
	32	**4.87 (reactive)**	**1.962 (positive)**
	51	**4.50 (reactive)**	**1.527 (positive)**
	67	**4.07 (reactive)**	**1.597 (positive)**
RP-003 (Profile Diagnostics)	1	**1.60 (reactive)**	0.205 (negative)
	4	**4.71 (reactive)**	**0.982 (positive)**
	8	**5.70 (reactive)**	**2.896 (positive)**
	51	**1.74 (reactive)**	**0.732 (positive)**
	55	**1.44 (reactive)**	**0.808 (positive)**
	59	**1.29 (reactive)**	**0.616 (positive)**
	65	**1.20 (reactive)**	**0.739 (positive)**
	67	**1.18 (reactive)**	**0.668 (positive)**
	72	**1.08 (reactive)**	**0.622 (positive)**
	74	**1.05 (reactive)**	**0.652 (positive)**
	79	**1.07 (reactive)**	**0.593 (positive)**
	84	**1.07 (reactive)**	**0.710 (positive)**
	88	**1.15 (reactive)**	**0.846 (positive)**
	95	**1.05 (reactive)**	**0.679 (positive)**
	99	**1.02 (reactive)**	**0.698 (positive)**
RP-019 (Profile Diagnostics)	1	0.26 (nonreactive)	0.188 (negative)
	5	0.24 (nonreactive)	0.121 (negative)
	8	0.25 (nonreactive)	0.143 (negative)
	12	0.27 (nonreactive)	0.148 (negative)
	15	0.24 (nonreactive)	0.123 (negative)
	21	0.35 (nonreactive)	0.294 (negative)
	26	0.41 (nonreactive)	0.214 (negative)
	29	0.99 (grayzone)	0.168 (negative)
	33	**4.22 (reactive)**	**0.670 (positive)**
	36	**6.30 (reactive)**	**1.433 (positive)**
	43	**7.05 (reactive)**	**2.925 (positive)**
	50	**6.06 (reactive)**	**2.094 (positive)**
	57	**5.30 (reactive)**	**1.909 (positive)**
	68	**4.11 (reactive)**	**1.389 (positive)**
	75	**3.68 (reactive)**	**1.160 (positive)**
	82	**2.98 (reactive)**	**0.933 (positive)**
	86	**3.19 (reactive)**	**1.099 (positive)**
	89	**2.87 (reactive)**	**0.830 (positive)**
	96	**2.66 (reactive)**	**0.864 (positive)**
	104	**2.50 (reactive)**	**0.691 (positive)**
	109	**2.24 (reactive)**	**0.647 (positive)**
	113	**2.43 (reactive)**	**0.805 (positive)**
	116	**2.66 (reactive)**	**0.886 (positive)**
	121	**2.12 (reactive)**	**0.635 (positive)**
	124	**2.18 (reactive)**	**0.670 (positive)**

* Representative data; results in individual laboratories may vary from these data.

Resolved Relative Specificity

The ARCHITECT CMV IgM assay is designed to have a resolved relative specificity equal to or greater than a commercially available diagnostic kit. From the 1085*** specimens evaluated 24 specimens were confirmed positive after discordant resolution.

***Note: Specimens that could not be resolved or showed grayzone result interpretation were not included in the evaluation of relative specificity.

Data for resolved relative specificity are summarized in the following table.*

	Resolved Relative Specificity			
	ARCHITECT CMV IgM		Commercially available diagnostic kit	
Sample Type	Observed	Lower 95% Confidence Limit	Observed	Lower 95% Confidence Limit
Blood Donors (Serum)	99.63% (268/269)	97.95%	98.88% (266/269)	96.78%
Blood Donors (Plasma)	100.00% (147/147)	97.52%	97.96% (144/147)	94.15%
Pregnant Women	99.30% (283/285)	97.49%	96.84% (276/285)	94.09%
Diagnostic/ Hospital Patients	99.44% (358/360)	98.01%	95.83% (345/360)	93.22%
Total	99.53% (1056/1061)	98.90%	97.17% (1031/1061)	95.99%

* Representative data; results in individual laboratories may vary from these data.

Interference

No interference was observed between experimental controls and nonreactive or reactive specimens tested with elevated levels of bilirubin (20 mg/dL), triglycerides (3000 mg/dL), protein (4.5 - 12 g/dL), red blood cells (0.4% v/v), or hemoglobin (500 mg/dL).

The interference of the ARCHITECT CMV IgM assay was further evaluated on 351 specimens positive for anti-nuclear antibody, systemic lupus erythematosus, rheumatoid factor, herpes simplex virus types 1 and 2, Epstein-Barr virus, measles, parvovirus B19, varicella zoster virus, hyperpolyclonal IgM, hyperpolyclonal IgG, human anti-mouse antibody, high titer CMV IgG, and influenza vaccine recipients. With these specimens, ARCHITECT CMV IgM and a commercially available diagnostic kit showed 95.44% agreement (335/351) (lower 95% confidence limit: 92.70%). Of the 16 discordant specimens 3 specimens were false reactive, 9 specimens true negative, and 4 specimens true positive by the ARCHITECT CMV IgM assay after discordant resolution.

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Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL NO.	Control Number
GTIN	Global Trade Item Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF IRELAND	Product of Ireland
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REF	List Number
REPLACEMENT CAPS	Replacement Caps
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
SN	Serial number
TRIGGER SOLUTION	Trigger Solution
WARNING: SENSITIZER	Warning: May cause an allergic reaction.
WASH BUFFER	Wash Buffer

The following US Patents are relevant to the ARCHITECT iSystem or its components. There are other such patents and patent applications in the United States and worldwide.

5 468 646	5 543 524	5 545 739
5 565 570	5 669 819	5 783 699

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