ARCHITECT Toxo IgM

REF 6C20-25
REF 6C20-35

en
Toxo IgM
6C20
G47818R04
B6C200

Read Highlighted Changes: Revised July 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 Toxo IgM

INTENDED USE

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

SUMMARY AND EXPLANATION OF THE TEST

Toxoplasma gondii is an obligate intracellular protozoan parasite that infects most species of warm-blooded animals, including humans.[1] Toxoplasmosis is primarily acquired by ingestion of undercooked, infected meat; via oocysts from fecally contaminated hands, food and water; and maternally through transplacental transmission.[2] In addition, transmission associated with organ transplantation and during blood transfusion has been reported, although the risk of transmission through blood transfusion is extremely low.[3]

Acquired infection with *Toxoplasma gondii* in healthy individuals is commonly asymptomatic, however 10-20% of patients with acute infection may develop lymphadenopathy.[4]

Severe infections can occur in AIDS patients and adults immunocompromised by cancer chemotherapy or transplant recipients receiving immunosuppressive treatment. These infections can be fatal. Toxoplasmic encephalitis is the most common presentation and is the most frequent cause of focal central nervous system lesions in AIDS patients.[5]

Primary infection during pregnancy can result in transplacental transmission of the parasite resulting in congenital infection. The risk of congenital infection is lowest (10-25%) if acute maternal infection occurs during the first trimester and highest (60-90%) if it occurs during the third trimester.[2]

Severity of congenital infection is greatest when maternal infection is acquired early during pregnancy. Common outcomes of congenital toxoplasmosis include chorioretinitis, intracranial calcifications, and hydrocephalus. The majority of infants infected later in pregnancy are asymptomatic at birth, with sequelae occurring later in life.

Early treatment after prenatal diagnosis of *Toxoplasma gondii* infection has been shown to reduce the frequency and severity of congenital toxoplasmosis.[6] Serological tests can be used to identify seronegative women, who then should be monitored during pregnancy.

The presence of IgG antibodies to *Toxoplasma gondii* indicates that infection has occurred but does not distinguish between recent and past infection. IgM antibodies are detected in individuals with a recently acquired infection, but antibodies may persist for up to 18 months post-infection.[2]

To differentiate between a recently acquired and a past infection, IgM and IgG positive specimens should be tested for IgG avidity. A high avidity index for IgG antibodies is a strong indication that an infection took place more than 4 months ago. Low avidity results cannot be used to diagnose an acute toxoplasmosis.

Toxo IgG	Toxo IgM	Toxo IgG Avidity	May indicate…/ Testing recommendation
nonreactive	nonreactive	N/A	no infection
nonreactive	reactive	N/A	obtain new sample 2-3 weeks after initial sample and test for Toxo IgG and Toxo IgM
reactive	nonreactive	high avidity	past infection. Strong indication that an infection took place more than 4 months ago
reactive	reactive	low avidity	obtain new sample 3 weeks after initial sample and test for Toxo IgG and Toxo IgM
reactive	reactive	high avidity	past infection. Strong indication that an infection took place more than 4 months ago

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Toxo IgM assay is a two-step immunoassay for the qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. In the first step, pre-diluted sample and anti-human IgM mouse monoclonal antibody coated paramagnetic microparticles are combined. Together with IgM antibodies of other specificities, anti-Toxo specific IgM present in the sample is bound by the anti-human IgM mouse monoclonal antibody coated microparticles, forming an antibody-antibody complex.
2. After washing, a conjugate complex consisting of an acridinium-labeled anti-Toxo p30 antigen mouse monoclonal F(ab')2 fragment and native *Toxoplasma gondii* lysate, containing the p30 antigen, is added to create a reaction mixture in the second step. This conjugate complex is bound by anti-Toxo specific IgM that has been captured by the anti-human IgM mouse monoclonal antibody coated microparticles in the first step, forming an antibody-antibody-conjugate complex.
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-Toxo IgM in the sample and the RLUs detected by the ARCHITECT iSystem optics.

The presence or absence of anti-Toxo 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 reaction is greater than or equal to the cutoff signal, the specimen is considered reactive for anti-Toxo IgM.

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

REAGENTS

Kit Contents

ARCHITECT Toxo IgM 6C20

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

REF	6C20-25	6C20-35
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

MICROPARTICLES Anti-human IgM (mouse, monoclonal) antibody coated microparticles in TRIS buffer with protein stabilizers and detergent. Minimum concentration: 0.08% solids. Preservatives: antimicrobial agents.

CONJUGATE Conjugate complex consisting of acridinium-labeled anti-Toxoplasma p30 antigen (mouse, monoclonal) antibody and native *Toxoplasma gondii* lysate in phosphate buffer with protein stabilizers and detergent. Minimum concentration: 25 µg/mL. Preservative: sodium azide.

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.[7-10]

The following warnings and precautions apply to: CONJUGATE	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
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.

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.

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 Toxo 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.

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.

Alternate Result Units

Edit assay parameter "Result concentration units" to select an alternate unit.

Conversion formula:

Index value ÷ 0.60 = S/CO.

Default result unit	Conversion divisor	Alternate result unit
Index	0.60	S/CO

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 heparin
	Lithium heparin

- Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum and plasma.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- Sodium citrate tubes cannot be used with the ARCHITECT Toxo IgM assay.
- 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, 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. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not 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/plasma	15-30°C	≤ 3 days
	2-8°C	≤ 14 days
	-20°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 15-30°C or 2-8°C storage time and store frozen at -20°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 on dry ice.
- Do not exceed the storage time limitations listed above.

PROCEDURE

Materials Provided

6C20 ARCHITECT Toxo IgM Reagent Kit

Materials Required but not Provided

- ARCHITECT Toxo IgM Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 6C20-01 ARCHITECT Toxo IgM Calibrator
- 6C20-10 ARCHITECT Toxo 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, discard the cap and place a septum on the bottle. For instructions on 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: 70 µL

    Sample volume for each additional test from same sample cup: 20 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 150 µL

    Sample volume for each additional test from same sample cup: 20 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 Toxo 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 Calibrator 1: 6 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 Toxo IgM assay.

Calibration

- Test Calibrator 1 in replicates of three. Calibrator 1 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 Toxo 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 Toxo 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 Toxo 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 Toxo 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 Toxo IgM assay is Index. Sample results may also be reported as sample to cutoff (S/CO). Index value divided by 0.60 equals S/CO value.

Interpretation of Results

Initial Results

Specimens with results	Interpretation	Retest Procedure
< 0.50 Index (< 0.83 S/CO)	Nonreactive for IgM antibodies to *Toxoplasma gondii*	--
0.50 ≤ x < 0.60 Index (0.83 ≤ x < 1.00 S/CO)	Grayzone	It is recommended to take a second sample within a reasonable period of time (e.g. two weeks) and repeat ARCHITECT Toxo IgM testing.
≥ 0.60 Index (≥ 1.00 S/CO)	Reactive for IgM antibodies to *Toxoplasma gondii*	--

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 Toxo 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 (Toxo IgG, Toxo IgG Avidity), clinical impressions, etc.
- 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.[11]
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as ARCHITECT Toxo IgM that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.[12, 13]
- Specimens from patients with high levels of IgM, e.g. from patients with multiple myeloma, may show depressed values when tested with µ-capture format assays.
- Human plasma collected in sodium citrate tubes cannot be used with this assay, since the ARCHITECT Toxo IgM results may be affected by this tube type.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Toxo IgM assay is designed to have a total** precision of ≤ 10% CV for a positive specimen in the range of 0.60 – 2.40 Index. The study was performed at one internal and one external evaluation site each using one instrument. Precision was assessed on a panel consisting of three different control lots and one human plasma specimen.

Panel members were tested in replicates of four across three reagent lots and one calibrator lot at the external site and three calibrator lots at the internal site, on one instrument at each site. Each combination of panel members and reagent lots was tested in four runs across several days. Data from this study are summarized in the following table*.

			Within Run		Total**	
Member	**N**	**Mean Index**	**SD**	**%CV**	**SD**	**%CV**
Negative Control	288	0.03	0.01	16.79	0.01	17.13
Positive Control	**288**	**1.52**	**0.04**	**2.80**	**0.05**	**3.02**
Human Plasma Specimen	**96**	**1.42**	**0.05**	**3.26**	**0.05**	**3.72**

* 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 assay is designed to show a seroconversion sensitivity comparable to a commercially available diagnostic kit. A total of 122 bleeds from 39 different individuals seroconverting during acute toxoplasmosis infection were tested. Data from seven representative seroconverting individuals are shown in the following table*.

Sample ID	Months after last negative bleed	ARCHITECT Toxo IgM [Index]	Commercially available diagnostic kit [Index]	Isaga (Toxo-M) [Index]	Sabin-Feldman Dye Test [IU/mL]	HS Agglutination Test [IU/mL]
Grayzone		*0.50 - 0.59*	*0.500 - 0.599*	*6-8*	*N/A*	*1*
Reactive cutoff		**0.60**	**0.600**	**9**	**2**	**2**
30944001	0.0	0.05	0.061	0	< 2	< 1
30944002	1.2	*0.56*	0.351	4	**5**	*1*
30944003	2.1	**0.89**	*0.588*	**10**	**800**	**64**
30944004	2.2	**0.77**	*0.542*	**10**	**800**	**64**
30944005	4.3	0.38	0.193	1	**1600**	**200**
30944016	0.0	0.04	0.099	0	< 2	< 1
30944017	1.4	**1.16**	**1.038**	**11**	**20**	**2**
30944018	1.6	**1.04**	**0.897**	**10**	**20**	**4**
30944019	4.1	*0.52*	0.380	**9**	**10**	**8**
30944033	0.0	0.04	0.218	0	< 2	< 1
30944034	2.6	**1.99**	**2.026**	**12**	**400**	**64**
30944035	7.5	0.05	0.057	0	**800**	**100**
30944073	0.0	0.04	0.078	0	< 2	< 1
30944074	0.9	**1.32**	**1.125**	**12**	**5**	*1*
30944075	1.4	**2.35**	**1.733**	**12**	**200**	**16**
30944076	3.8	**1.12**	**0.877**	**12**	**100**	**8**
30944086	0.0	0.30	0.437	*7*	**2**	< 1
30944087	0.5	**10.39**	**7.974**	**12**	**40**	**8**
30944088	1.3	**9.23**	**6.464**	**12**	**400**	**128**
30944089	2.3	**8.53**	**5.398**	**12**	**400**	**50**
30944090	0.0	0.05	0.081	0	< 2	< 1
30944091	1.2	**5.95**	**4.195**	**12**	**20**	**2**
30944092	1.5	**5.72**	**3.679**	**12**	**200**	**16**
30944093	4.7	**2.66**	**1.700**	**12**	**400**	**50**
30944118	0.0	0.05	0.113	0	< 2	< 1
30944119	1.0	**5.76**	**3.784**	**12**	**2**	*1*
30944120	1.8	**6.56**	**3.536**	**12**	**200**	**64**
30944121	2.5	**3.88**	**1.910**	**12**	**1600**	**100**

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

Resolved Relative Specificity

The ARCHITECT Toxo IgM assay is designed to have a resolved relative specificity comparable to a commercially available diagnostic kit. A study was performed at one internal and one external evaluation site. From the 2772*** specimens evaluated to assess resolved relative specificity 36 specimens were concordant reactive and additional three were confirmed positive after discordant resolution and therefore excluded from the specificity calculation.

*** **NOTE:** Specimens that could not be resolved or showed grayzone result interpretation on any assay being compared or used for discordant resolution were not included in the evaluation of resolved relative specificity.

Data from this study are summarized in the following table*.

Resolved Relative Specificity

	ARCHITECT Toxo IgM		Commercially available diagnostic kit	
Sample Type	Observed	Lower 95% Confidence Limit	Observed	Lower 95% Confidence Limit
Pregnant Women	99.95% (1987/1988)	99.72%	99.95% (1987/1988)	99.72%
Diagnostic / Hospital Patients	100% (451/451)	99.19%	100% (451/451)	99.19%
Blood Donors (Serum)	100% (154/154)	97.63%	100% (154/154)	97.63%
Blood Donors (Plasma)	98.57% (138/140)	94.93%	100% (140/140)	97.40%
Total	99.89% (2730/2733)	99.68%	99.96% (2732/2733)	99.80%

* 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 (12 g/dL), red blood cells (0.4% v/v), or hemoglobin (500 mg/dL).

Other Potential Interferants

Additional studies were performed to evaluate other potential interfering disease states on the ARCHITECT Toxo IgM assay. Sample categories were tested both unspiked and spiked with anti-Toxo IgM positive plasma.

A total of 167 unspiked specimens and a total of 165 spiked anti-Toxo IgM reactive specimens were tested from the following categories: Anti-nuclear antibodies (ANA), anti-dsDNA antibodies, Rheumatoid Factor, Herpes Simplex Virus 1 (anti-HSV-1 positive), Herpes Simplex Virus 2 (anti-HSV-2 positive), Epstein-Barr Virus (anti-EBV positive), Measles, Parvovirus B19 (anti-B19 virus positive), Varicella Zoster Virus (anti-VZV positive), Rubella Virus (anti-Rubella positive), Cytomegalovirus (anti-CMV positive), Hyperpolyclonal IgG, Hyperpolyclonal IgM, Monoclonal IgG, Monoclonal IgM, Human anti-mouse antibodies (HAMA), Influenza vaccine recipients, and Syphilis.

ARCHITECT Toxo IgM showed expected qualitative results in all categories with the exception of the categories summarized in the following table*.

		ARCHITECT Toxo IgM		
Category	N tested	Nonreactive	Reactive	Grayzone
Anti-nuclear Antibodies (ANA) Unspiked	10	8	1	1
Hyperpolyclonal IgM Spiked Reactive	10	1	8	1
Monoclonal IgM Spiked Reactive	5	4	0	1

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

After discordant resolution the unspiked ANA specimen tested reactive on ARCHITECT Toxo IgM could not be resolved. Specimens from patients with high levels of IgM, e.g. from patients with multiple myeloma, may show depressed values when tested with µ-capture format assays. Refer to the **LIMITATIONS OF THE PROCEDURE** section of this package insert.

BIBLIOGRAPHY

1. Willis MS, Southern P, Latimer MJ. Toxoplasma infection. Making the best use of laboratory tests. *Infect Med* 2002; 19: 522-532.
2. Jones JL et al. Congenital Toxoplasmosis: A Review. *CME Review Article* Vol. 56, Number 5 2001; 296-305.
3. Shulman IA. Parasitic infections and their impact on blood donor selection and testing. *Arch Pathol Lab Med.* 1994; 118: 366-370.
4. Montoya J.G. Laboratory Diagnosis of Toxoplasma gondii Infection and Toxoplasmosis. *Journal of Infectious Diseases* 2002; 185 (Suppl 1) 73-82.
5. Israelski DM, Remington JS. Toxoplasmosis in the non-AIDS immunocompromised host. *Curr Clin Top Infect Dis* 1993; 13: 322-356.
6. Wong SY and Remington. Toxoplasmosis in Pregnancy. *Clinical Infectious Diseases* 1994; 18:853-862.
7. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
8. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
9. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
10. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline–Third Edition.* CLSI Document M29-A3. Wayne, PA: CLSI; 2005.
11. Boscato LM, Stuart MC. Heterophilic antibodies: a problem for all immunoassays. *Clin Chem* 1988;34(1):27-33.
12. Primus FJ, Kelley EA, Hansen HJ, et al. "Sandwich"-type immunoassay of carcinoembryonic antigen in patients receiving murine monoclonal antibodies for diagnosis and therapy. *Clin Chem* 1988;34(2):261-264.
13. Schroff RW, Foon KA, Beatty SM, et al. Human anti-murine immunoglobulin responses in patients receiving monoclonal antibody therapy. *Cancer Res* 1985;45(2):879-885.

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
CONJUGATE	Conjugate
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL NO.	Control Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF GERMANY	Product of Germany
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
WASH BUFFER	Wash Buffer

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

CE
0123

Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

Revised July 2019.

Abbott