VIDAS® TOXO IgM (TXM)

Rx only IVD

The VIDAS® TOXO IgM (TXM) assay is intended for use on the instruments of the VIDAS family (VITEK® ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-*Toxoplasma gondii* IgM antibodies in human serum, as an aid in the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infection. This assay must be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay. VIDAS TOXO IgM (TXM) assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.

SUMMARY AND EXPLANATION OF THE TEST

Toxoplasmosis is an infectious disease caused by *Toxoplasma gondii*, an intracellular protozoan.

Epidemiology:

Prevalence of acquired toxoplasmosis varies according to country:

. Africa	North	65 %
	Tropical	47 %
	South	20 %
. America	USA	38.7 % (12 to 41 % according to state)
	Brazil	50 to 82 % according to town
. Asia	Japan	24 %
	Iran	62 %
. Europe	France, Belgium)	
	Austria, Sweden)	50 to 85 % according
	Italy, Yugoslavia)	to town
	Germany	20 to 72 % according to town
	Switzerland	50 %
	Spain, Greece	40 %
	United Kingdom	20 %
	Egypt	18 %

For most patients, toxoplasmosis is asymptomatic or accompanied by mild clinical signs. Nevertheless, pregnant women must protect themselves against toxoplasmosis because of potential transmission of the disease to the fetus. Congenital toxoplasmosis is rare if infection occurs during the first three months of pregnancy but it can involve serious complications (e.g. miscarriage, hydrocephalus, brain calcification, convulsions, ocular lesions). After four months of pregnancy, the placental barrier efficiency is decreased, and chances of transmission to the fetus are greater. However, the consequences are less serious (e.g. epilepsy, encephalomyelitis, chorioretinitis, neonatal jaundice) (1).
Cystic forms remaining after the acute phase of toxoplasmosis (during reactivation in the immunosuppressed patient) can cause complications. Encephalitis, the most frequent manifestation, can be lethal in absence of treatment.

Isolating parasites in cell culture is time-consuming Serological methods such as indirect immunofluorescence, agglutination after denaturation of IgM with 2ME (mercaptoethanol), sensitized agglutination, the Sabin-Feldman dye test, and ELISA are frequently used (1,2).
The presence of anti-*Toxoplasma gondii* IgG at a stable rate confirms former immunity. The appearance of IgM followed by a net increase in IgG indicates a seroconversion (1,2).

PRINCIPLE OF THE PROCEDURE

The VIDAS® TOXO IgM (TXM) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipettor for the assay. The SPR is coated with goat anti-µ chain antibodies. The VIDAS TOXO IgM (TXM) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are in the sealed TXM Reagent Strips.
After a sample dilution step, the sample is cycled in and out of the SPR for a specified length of time. IgM antibodies present in the specimen will bind to the anti-µ chain antibodies coating the interior of the SPR. Unbound sample components are washed away. An immunocomplex of *T. gondii* antigen and mouse monoclonal anti-P30 antibodies conjugated with alkaline phosphatase is cycled in and out of the SPR and will attach to the human anti-*T. gondii* IgM bound to the SPR wall (Note: P30 is a major surface protein of the *T. gondii* tachyzoite, with molecular weight of 30,000 (5)). A final wash step removes unbound conjugate.
A fluorescent substrate, 4-methylumbelliferyl phosphate, is introduced into the SPR. Enzyme remaining on the wall of the SPR will catalyze the conversion of the substrate to the fluorescent product, 4-methylumbelliferone. The intensity of the fluorescence is measured by the optical scanner in the instrument.
When the VIDAS TOXO IgM (TXM) assay is completed, the results are analyzed automatically by the instrument, a test value is generated, and a report is printed for each sample.

KIT COMPOSITION (60 TESTS):

60 TXM Reagent Strips	STR	Ready to use.
60 TXM SPRs (2 x 30)	SPR®	Ready to use. SPRs are coated with goat anti-µ chain antibodies.
TXM Calibrator (1 x 1 ml)	S1	Ready to use. Human serum* with anti-*Toxoplasma gondii* IgM, with 1 g/L sodium azide.
TXM Positive Control (1 x 2 ml)	C1	Ready to use. Human serum* with anti-*Toxoplasma gondii* IgM. MLE data indicate the Test Value (TV) range: Control C1 (+) Test Value Range. Contains 1 g/L sodium azide.
TXM Negative Control (1 x 2 ml)	C2	Ready to use. Human serum* without anti-*Toxoplasma gondii* IgM. Contains 1 g/L sodium azide.
1 MLE Card (Master Lot Entry)		Specifications for the factory master data required to calibrate the test: to read the MLE data, please refer to the Operator's Manual.
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar codes printed on the box label.		
1 Package Insert provided in the kit or downloadable from www.biomerieux.com/techlib.		

* This product has been tested and shown to be negative for HBs antigen, antibodies to HIV1, HIV2 and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.

The SPR®

The interior of the SPR® is coated during production with anti-human µ chain antibodies (goat). Each SPR is identified by the "TXM" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening**.

The strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the VIDAS TOXO IgM (TXM) Reagent Strip

Wells	Reagents
1	Sample well
2	Sample diluent: 300 µl of TRIS buffered saline (0.05 mol/l, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide.
3	Pre-wash buffer: 600 µl of TRIS buffered saline (0.05 mol/l, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide.
4 - 5 - 7 - 8	Wash buffer: 600 µl of TRIS buffered saline (0.05 mol/l, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide.
6	Conjugate: 400 µl of immunocomplex of *T. gondii* antigen (RH Sabin strain) grown in mice (9) and mouse monoclonal anti-P30 antibodies conjugated to alkaline phosphatase with gentamycin 0.02% and 0,9 g/L sodium azide.
9	Empty well
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl-phosphate (0.6 mmol/L) + diethanolamine (DEA*) (0.62 mol/L or 6.6%, pH 9.2) + 1 g/l sodium azide (300 µl).

* Signal Word: **DANGER**

Hazard statement
H318 : Causes serious eye damage.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

For further information, refer to the Safety Data Sheet.

MATERIALS REQUIRED BUT NOT PROVIDED

- 100 µl pipettor or disposable transfer pipette which will dispense 100 µl.
- Powderless disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family: VIDAS, miniVIDAS or VIDAS 3.

WARNINGS AND PRECAUTIONS

- **For *In Vitro* Diagnostic Use Only.**
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - latest edition).**
- Consider all patient specimens potentially infectious and observe routine biosafety precautions. Dispose of all used components and other contaminated materials by acceptable procedures for potentially biohazardous human blood products**.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- WARNING: The VIDAS TOXO IgM (TXM) assay contains an aminoglycoside, a chemical known to the state of California (under Proposition 65) to cause birth defects or other reproductive harm.
- Do not mix reagents or disposables from different lots.
- Kit reagents contain 0.1% sodium azide which could react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- Powderless gloves are recommended as powder has been reported as a cause of false results in some enzyme immunoassays.
- The reading cuvette with Substrate (well 10) contains an irritant agent (diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5% sodium hypochlorite to inactivate infectious agents. See the Operator's Manual for cleaning spills on or in the instrument. Do not place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. See the Operator's Manual for the appropriate procedures.

STORAGE AND HANDLING

- Store the VIDAS® TOXO IgM (TXM) Kit at 2-8ºC. **Do not freeze reagents.** Return unused components to 2-8ºC.
- After opening the kit, check that the SPR® pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs and return the complete kit to 2-8ºC.
- All components are stable, when stored appropriately, until the expiration date printed on the label. Do not use components beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Whole blood should be collected and the serum separated by standard procedures. Serum should not be heated. Samples containing particulate matter should be clarified by centrifugation or filtration prior to testing.
If specimens cannot be tested on the day of collection, they should be stored at 2-8ºC for up to five days. If longer storage is required, specimens should be frozen at -25 ± 6 °C. Only one freeze-thaw cycle is recommended. The use of plasma has not been established for this test.

INSTRUCTIONS FOR USE

For complete instructions, see the Operator's Manual.

Reading Master lot data

Before each new lot of reagents is used, enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.

If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.

Note: the master lot data need only be entered once for each lot.
It is possible to enter MLE data **manually or automatically** depending on the instrument (for complete instructions refer to the Operator's Manual.).

Calibration

Calibration, using the standard provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.

The calibrator, identified by S1, must be tested in **duplicate** (see Operator Manual). The standard value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

ASSAY PROCEDURE

1. Remove necessary components from the kit and return all unused components to storage at 2-8ºC.
2. Allow components to reach room temperature (approximately 30 minutes).
3. Use one "TXM" strip and one "TXM" SPR for each sample, control or standard to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.**
4. The test is identified by the "TXM" code on the instrument. The standard must be identified by "S1", and tested **in duplicate**. If the positive control is to be tested, it should be identified by "C1". If the negative control needs to be tested, it should be identified by "C2".
5. In the space provided, label the "TXM" Reagent Strips with the appropriate sample identification numbers.
6. Mix the calibrator, controls, and patient serum using a vortex-type mixer (for serum separated from the pellet).
7. **For this test, the calibrator, control, and sample test portion is 100 µl.**
8. Insert the "TXM" Reagent Strips and SPRs into the appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
9. Initiate the assay processing as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument.
10. Reclose the vials and return them to 2–8°C after pipetting.
11. The assay will be completed within approximately 40 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
12. Dispose of the used
13. SPRs and strips into an appropriate recipient.

QUALITY CONTROL

A positive and a negative control are included in each VIDAS TOXO IgM (TXM) kit.

These controls must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using these controls. The instrument will only be able to check the control values if they are identified by C1 and C2.

Results cannot be validated if the control values deviate from the expected values.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

RESULTS AND INTERPRETATION

Two instrument readings for fluorescence in the Reagent Strip's reading cuvette are taken for each specimen tested. The first reading is a background reading of the cuvette and substrate before the SPR is introduced into the substrate. The second reading is taken after the substrate has been exposed to the enzyme conjugate remaining on the interior of the SPR. The background reading is subtracted from the final reading to give a Relative Fluorescence Value (RFV) for the test result.

A test value is generated for each sample by forming a ratio from the RFV of the sample to that of the calibrator or a stored calibrator result ("stored standard"). Test values from patient and control samples are compared to a set of thresholds stored in the computer. The thresholds were determined using preclinical study results, which were evaluated using logistic regression analysis. The thresholds and interpretations are given in the following table:

Test Value Thresholds	Interpretation
< 0.55	Negative (No anti-*T. gondii* IgM)
≥ 0.55 to < 0.65	Equivocal (Possible presence of anti-*T. gondii* IgM. Obtain a new sample within 3 weeks and retest.)
≥ 0.65	Positive (Presence of anti-*T. gondii* IgM)

NOTE: The magnitude of the measured result, above the cutoff, is not indicative of the total amount of antibody present.

Anti-*T. gondii* IgM Result	**Anti-*T. gondii* IgG Result**	**Report/Interpretation**
Negative	Negative	It is presumed the patient has not been infected with and is not undergoing an acute infection with *Toxoplasma gondii*. If symptoms persist, submit a new specimen within three weeks.
Negative	Positive	From this testing it cannot be determined whether the patient is or is not undergoing a reactivated *Toxoplasma gondii* infection. It appears the patient has been previously infected with *Toxoplasma gondii*. Infection occurred more than one year ago.
Negative	Equivocal	Obtain a new specimen for further testing. Patient may not be undergoing an acute infection with *Toxoplasma gondii*. Determining whether the patient has been previously infected with *Toxoplasma gondii* is not possible.
Equivocal	Negative	Obtain a new specimen for determination of IgM antibodies to *Toxoplasma gondii*. It cannot be determined if the patient is undergoing an acute *Toxoplasma gondii* infection. It appears the patient has not been previously infected with *Toxoplasma gondii*. If the new specimen result is positive or equivocal for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.
Equivocal	Positive	Obtain a new specimen for determination of IgM antibodies to *Toxoplasma gondii*. It cannot be determined if the patient is undergoing or has undergone an acute *Toxoplasma gondii* infection. It appears the patient has been previously infected with *Toxoplasma gondii*. If the new specimen result is equivocal or positive for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.
Equivocal	Equivocal	Obtain a new specimen for further testing. It cannot be determined if the patient is undergoing an acute infection or has been previously infected with *Toxoplasma gondii*. If the new specimen result is equivocal or positive for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.
Positive	Negative	Obtain a new specimen for further testing. The patient may or may not be acutely infected with *Toxoplasma gondii*. Since the IgG antibodies to *Toxoplasma gondii* are negative, the specimen may have been obtained too early in the disease process for an accurate determination. Retest the new specimen with a different anti-*Toxoplasma gondii* IgM assay. If the new specimen result is still positive for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.
Positive	Positive	The patient may or may not be acutely infected with *Toxoplasma gondii*. Obtain a new specimen for further testing. Since the IgG antibodies to *Toxoplasma gondii* are positive, it appears the patient may be acutely infected with *Toxoplasma gondii*. The new specimen should be repeated with a different anti-*Toxoplasma gondii* IgM assay. If the new specimen result is still positive for IgM and IgG antibodies to *Toxoplasma gondii*, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.
Positive	Equivocal	It cannot be determined if the patient is acutely infected with *Toxoplasma gondii*. Obtain a new specimen for further testing. Determining whether the patient has been previously infected with *Toxoplasma gondii* is not possible. The specimen may have been collected too early in the disease process for an accurate determination. Retest the new specimen with a different anti-*Toxoplasma gondii* IgM assay. If the new specimen result is still positive for IgM and the IgG is positive/negative/equivocal for antibodies to *Toxoplasma gondii*, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.

LIMITATIONS OF THE TEST

1. Interference may be encountered with certain sera containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history and the results of any other tests performed.
2. If a treatment is prescribed early enough, antibody production is decreased, IgG and IgM levels remain low and can coexist for years.
3. The VIDAS® TOXO IgM (TXM) assay results alone should not be used to diagnose recent infection. IgM antibodies to *T. gondii* can be demonstrated in serum for many months after infection (2).
4. Negative test results may occur if the specimen is collected too early in the course of the disease, before production of IgM. Also, during reactivation an IgM antibody response may not occur or may be below detectable levels.
5. Positive test results may not be valid in persons who have received blood transfusions or other blood products within the past several months.
6. The results of this test are qualitative and should be considered as either positive or negative for the presence of IgM antibodies to *T. gondii*.
7. Test results for specimens from immunosuppressed patients may be difficult to interpret.
8. Test results from the VIDAS TOXO IgM (TXM) assay should be evaluated in relation to patient symptoms and clinical history to establish a diagnosis.
9. With very low prevalence analytes there is the increased possibility that a positive result is truly a false positive, reducing the assay's positive predictive value.

EXPECTED VALUES

The prevalence of toxoplasmosis varies depending upon geographical location, age and gender of the population studied, specimen collection and handling, and other factors.

In Europe, the prevalence rate ranges from 20% to 85%. In the United States, the prevalence is lower - 12% to 41%. Prevalence in other countries can vary from 18% to 65%. Anti-*Toxoplasma gondii* IgM prevalence has not been determined in an asymptomatic "normal" population using the VIDAS VIDAS TOXO IgM (TXM) assay.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Four hundred seven repository serum samples were tested at a clinical research laboratory. (Due to the apparent low prevalence of anti-*Toxoplasma gondii* IgM in the United States, the specimens used in this study may not be representative of other institutions). Each sample was tested using the VIDAS VIDAS TOXO IgM (TXM) assay, a commercially available automated EIA, and EIA-IgM (Remington, see reference #8). There were initially 3 (0.7%) VIDAS equivocal results. Upon retesting, 1 repeated as equivocal. The following table shows the VIDAS TOXO IgM (TXM) assay compared to each of the EIAs tested.

407 samples tested
1 equivocal result (excluded from calculations)

		EIA 1*		EIA 2 (Remington)	
		+	-	+	-
VIDAS	+	203	9	204	14
TOXO IgM (TXM)	-	28	150	1	187
Rel.** Sensitivity		87.9%		99.5%	
Rel.** Specificity		94.3%		93.0%	
Rel.** Agreement		90.5%		96.3%	

* There were 16 samples with equivocal results in EIA1

** Please be advised that "relative" refers to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgement can be made on the comparison assay's accuracy to predict disease.

Additional Information for Discrepant Samples

For samples with discrepancies between VIDAS® and EIA 1, further information is provided in the following table. This table shows EIA 2, HS/AC (a test used to determine acute phase of *T. gondii* infection, see reference # 7), and EIA-IgA results.

# Spls	VIDAS Result	EIA 1 Result	EIA 2 Result	HS/AC Result	EIA-IgA Result
3	+	-	-	not acute	-
1	+	-	-	acute	-
2	+	-	+	acute	-
1	+	-	+	acute	+
1	+	-	+	acute	Equiv
1	+	-	+	not acute	-
24	-	+	-	not acute	-
1	-	+	-	not acute	+
2	-	+	-	not acute	Equiv
1	-	+	+	not acute	-

Method Comparison - VIDAS 3

A study was conducted to verify the correlation of the VIDAS TOXO IgM assay on the VIDAS 3 to the VIDAS TOXO IgM assay on the VIDAS. One reagent lot, one of each instrument and 198 serum samples were used. Results were evaluated according to CLSI EP9 and were as follows:

Contingency table:

		VIDAS			
		Positive	Equivocal	Negative	Total
VIDAS 3	Positive	93	0	0	93
	Equivocal	2	4	0	6
	Negative	1	0	98	99
	Total	96	4	98	198

Associated percent agreements and their 95% two-sided score confidence intervals are calculated in the table below :

Category	Samples of interest /Total	Percent Agreement 2-sided 95% CI
Negative	98/98	100% [96.2; 100.0] %
Positive	93/96	96.9% [91.2; 98.9] %

Precision - VIDAS / MINIVIDAS

Intra-assay precision was evaluated using high positive, low positive, and negative controls. Each control was tested in a single work list of 22 replicates. The results are given below.

	Mean Test Value	% CV
High Positive	1.93	4.8%
Low Positive	1.10	6.7%
Negative	0.08	6.1%

Inter-assay precision was evaluated using high positive, low positive, and negative controls. Each control was tested in triplicate in a single work list for 12 days. The mean Test Value for each day was used in the calculations. The results are given in the following table.

	Mean Test Value	% CV
High Positive	1.96	3.7%
Low Positive	1.03	7.5%
Negative	0.07	6.4%

Precision - VIDAS 3

Four serum samples were tested in 3 replicates twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The results were calculated according to CLSI EP5-A2 and the pre-defined acceptance criteria were met. The maximum %CV for all samples was less than 4%.

Cross-reactivity

Twenty-two samples from patients with RF, 7 samples from patients with ANA, and 13 samples from patients with EBV infection were tested in the VIDAS TOXO IgM (TXM) assay. No cross-reactivity was observed.

ADDITIONAL DATA

European Studies

The VIDAS TOXO IgM (TXM) assay was evaluated at two additional sites in France.
At the first site, 796 serum samples were tested using the VIDAS TOXO IgM (TXM) assay, a commercially available automated Toxo IgM EIA, and a manual Toxo IgM EIA available in Europe. At least two of the three test results had to agree for a confirmed result, or the sample was unresolved. There were 8 unresolved samples.

The performance of the VIDAS TOXO IgM (TXM) assay when compared to the confirmed results was as follows:

Relative Sensitivity = 97.7%
Relative Specificity = 99.4%
Relative Agreement = 99.2%

At the second site, 863 serum samples were tested using the VIDAS TOXO IgM (TXM) assay and a manual Toxo IgM EIA available in Europe. If the two results did not agree, IFA-M (Remington) was used to resolve discrepancies. At least two of the three test results had to agree for a confirmed result, or the sample was unresolved. There were 2 unresolved samples. The performance of the VIDAS TOXO IgM (TXM) assay when compared to the confirmed results was as follows:

Relative Sensitivity = 100.0%
Relative Specificity = 99.6%
Relative Agreement = 99.6%

LINEARITY – VIDAS/MINIVIDAS

Two sera were serially diluted to evaluate assay linearity. Each dilution was run in triplicate in the same VIDAS work list. Upon dilution, the decrease in signal was proportional for both sera. The data are shown in the table and figure below:

Dilution	Sample # 1		Sample # 2	
	Mean RFV	% Change	Mean RFV	% Change
1:1	3924	0	1774	0
1:2	3515	10	1494	16
1:4	3106	21	1235	30
1:8	2301	41	790	55
1:16	1424	64	516	71
1:32	853	78	306	83
1:64	462	88	212	88
1:128	275	93	166	91
1:256	186	95	145	92
1:512	152	96	133	93

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
Rx only	Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

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REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release date	Part Number	Change Type	Change Summary
2015/07	13699E	Technical	INDEX OF SYMBOLS REVISION HISTORY
		Administrative	KIT COMPOSITION (60 tests) MATERIALS REQUIRED BUT NOT PROVIDED WARNINGS AND PRECAUTIONS INSTRUCTIONS FOR USE PERFORMANCE CHARACTERISTICS

BIOMÉRIEUX

bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Etoile – France
673 620 399 RCS LYON
Tel. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
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