VIDAS® CMV IgG (CMVG)

IVD

The VIDAS® CMV IgG (CMVG) Assay is intended for use on the instruments of the VIDAS family (Vitek® ImmunoDiagnostic Assay System) as a semi-quantitative automated enzyme-linked fluorescent immunoassay (ELFA). It is intended for use in determination of CMV immunological experience from a single serum sample, or as an aid in the diagnosis of current CMV infection through evaluation of paired sera for a significant increase in CMV-specific IgG. It is not intended for use in testing (screening) blood or plasma donors.

SUMMARY AND EXPLANATION OF THE TEST

Cytomegalovirus (CMV) is a herpesvirus which can be a serious pathogen for infants and adults. As all herpesviruses, CMV persists in the human body and can cause recurrent infections.

CMV infections are quite common. It is believed that 60 to 85% of the population has been infected by age 18, but 95% of all cases are asymptomatic.

Adults and children may suffer from a persistent febrile state (2 to 4 weeks), a mononucleic syndrome, constant fatigue, headaches, and neuralgia. After a period of 15 to 20 days, clinical signs decrease; anti-CMV antibodies remain (6,7).

Infection in pregnant women can lead to congenital infection. In most cases (95%), the neonate appears clinically normal. However, the other 5% have severe consequences such as jaundice, hepatosplenomegaly, intracerebral calcification, hydrocephalia, thrombocytopenia purpura, and ocular lesions. These infants may die soon after birth (3,7,10).

CMV also causes severe infections in the immunocompromised (HIV positive, heart or kidney transplanted patients).

Biological diagnosis of CMV infection can be performed in three different ways:

- Direct staining of infected cells, using monoclonal antibodies conjugated with fluorescein,
- Culture and viral isolation from urine, semen, and bronchial wash specimens. Human fibroblast cells such as MRC5, WI-38, or IMR-90 are most often used for diagnostic purposes. Cytopathic effects can be seen within 1 to 3 weeks or more rapidly using a stain containing monoclonal antibodies conjugated with fluorescein (6,7).
- Serological methods are simple techniques for aiding in the diagnosis of CMV infection. Complement fixation is easy to perform but has low sensitivity. Indirect hemagglutination is more sensitive but less reproducible (1). Latex agglutination and ELISA are the two most commonly used methods.

PRINCIPLE OF THE PROCEDURE

The VIDAS CMV IgG (CMVG) 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. Reagents for the assay are available in the sealed Reagent Strips.

After a sample dilution step, the sample is cycled in and out of the SPR for a specified length of time. Anti-CMV IgG antibodies present in the specimen will bind to the purified CMV antigen coating the interior of the SPR. Unbound sample components are washed away.

A monoclonal anti-human IgG conjugated with alkaline phosphatase is cycled in and out of the SPR and will attach to any human IgG bound to the SPR wall. 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 (450 nm). The intensity of the fluorescence is measured by the optical scanner in the instrument; it is proportional to the quantity of CMV IgG found in the sample.

When the VIDAS CMV IgG (CMVG) Assay is completed, the results are analyzed automatically by the computer. The quantity of anti-CMV IgG present in the sample is calculated in reference to a calibration curve stored in the instrument. A report is printed for each sample.

KIT COMPOSITION (60 tests):

60 CMVG Reagent Strips	STR	Ready to use.
60 CMVG SPRs 2 x 30	SPR®	Ready to use. The interior of the SPR is coated at the time of manufacture with purified and inactivated CMV antigen (Strain AD 169).
CMVG Positive Control 1 x 1.5 mL	C1	Ready to use. Human serum* with anti-CMV IgG and 1 g/L sodium azide. MLE data indicate the titer in U/mL ("Control C1 (+) Dose Value Range").
Negative Control 1 x 1.9 mL	C2	Ready to use. Phosphate buffer + protein stabilizer of animal origin + preservatives.
CMVG Calibrator 1 x 2.0 mL	S1	Ready to use. Human serum* with anti-CMV IgG and 1 g/L sodium azide. MLE data indicate the calibrator titer in U/mL (standardized against Regional Blood Bank of France Standard) ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value" ("Calibrator (S1) RFV Range").
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 purified CMV antigen. Each SPR is identified by the "CMVG" 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 CMV IgG (CMVG) Reagent Strip

Wells	Reagents
1	Sample well
2	Sample diluent: 300 µL of phosphate (10mM) buffered saline (pH 7.2) with Tween and protein and chemical stabilizers, and 1 g/L sodium azide
3	Pre-wash: 600 µL of phosphate (10mM) buffered saline (pH 7.2) with Tween and protein and chemical stabilizers and 1 g/L sodium azide
4 - 5	Wash: 600 µL of TRIS (10mM) buffer (pH 7.2) with protein and chemical stabilizers and 1 g/L sodium azide
6	Conjugate: 400 µL of mouse monoclonal anti-human IgG conjugated with alkaline phosphatase and 1 g/L sodium azide
7 - 8	Wash: 600 µL of TRIS (10mM) buffer (pH 7.2) with protein and chemical stabilizers and 1 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, refer to the Instrument User Manual.
- Instrument of the VIDAS family.

WARNINGS AND PRECAUTIONS

- **For *in Vitro* Diagnostic Use only.**
- **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).**
- 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, do not inhale).
- Consider all patient specimens potentially infectious and observe routine biosafety precautions. Though the CMV virus coating the inside of the SPR has been inactivated, handle the SPRs as if they were infectious. Dispose of all used components and other contaminated materials by acceptable procedures for potentially biohazardous human blood products.
- 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 (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped 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 User 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 User Manual for the appropriate procedures.

STORAGE AND HANDLING

- Store the VIDAS® CMV IgG (CMVG) 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.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.

SPECIMEN COLLECTION AND PREPARATION

Whole blood should be collected and the serum separated by standard procedures. Samples containing particulate matter should be clarified by centrifugation or filtration prior to testing. Serum should not be heated.
If specimens cannot be tested on the day of collection, they should be stored at 2-8° C in stoppered tubes for up to five days. If longer storage is required, the sera should be frozen at -25 ± 6°C (but only once). Avoid repeated cycles of freezing and thawing.
The use of plasma has not been established for this test.
Specimens with obvious microbial contamination should not be tested.
Paired serum specimens should be tested concurrently.

INSTRUCTIONS FOR USE

For complete instructions, see the User 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 (refer to the User Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed upon receipt of a new lot of reagents 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 User Manual). The calibrator 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 "CMVG" strip and one "CMVG" SPR for each sample, control or calibrator 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 code "CMVG" on the instrument (to do so, refer to the Instrument User Manual). The calibrator 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 is to be tested, it should be identified by C2.
5. If needed, label the "CMVG" Reagent Strips with the appropriate sample identification numbers.
6. Mix the calibrator, control, and sera 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 "CMVG" 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 as directed in the User 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 SPRs and strips into an appropriate recipient.

QUALITY CONTROL

One positive control and one negative control are included in each VIDAS CMV IgG (CMVG) 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 the presence of 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 Fluorescent Value (RFV) for the test result.
A test value is generated for each sample by comparing the RFV of the sample to a calibration curve stored in the computer. The corresponding quantity of anti-CMV IgG is calculated and compared to a set of thresholds and a final result is interpreted (see the following table).

Test Value Thresholds AU/mL *	Interpretation
< 4 AU/mL	Negative
≥ 4 to < 6 AU/mL	Equivocal
≥ 6 AU/mL	Positive

NOTE: AU = Arbitrary Unit.

Interpretation

Due to the absence of International Units, the VIDAS® CMV IgG (CMVG) Arbitrary Units used are proportional to the units used by the Lille Blood Bank (regional blood bank in France).
It is necessary to repeat all specimens with equivocal results (test values between 4 and 6 AU/mL) using a fresh specimen. The new specimen should be collected within one week of testing the original specimen.

Results Beyond Curve Range

For all samples with CMV IgG concentrations greater than 400 AU/mL, if desired, dilute these samples 1/4 (1 volume of sample and 3 volumes of physiological saline solution) and retest. If the dilution factor has not been entered when the analysis has been requested (see User Manual), multiply the result by the dilution factor to obtain the CMV IgG sample concentration in AU/mL.

Critical Ratio

The Critical Ratio determines a significant increase in antibody level, comparable to a four-fold increase in antibody titer. This increase is indicative of an active infection, and is calculated as follows:

$$\text{Critical Ratio} = \frac{\text{convalescent AU/mL}}{\text{acute AU/mL}}$$

Critical Ratio	Interpretation
< 2	No significant change in antibody level
2 - 4	Suggestive of an increase in antibody level. An additional sample should be obtained and tested in 7-14 days, and used with the first sample to recalculate a Critical Ratio.
> 4	Highly significant increase in antibody level

It is recommended that acute and convalescent samples be tested in the same run. The Critical Ratio is used in conjunction with the test results (AU/mL). For example, a convalescent antibody level of > 6 AU/mL combined with a critical ratio ≥ 2 may indicate seroconversion. However, samples with critical ratios ≥ 2 with antibody levels in the negative range should be considered suspicious, and another sample should be obtained in 7 - 14 days for follow-up testing. A three-week period between collection of acute and convalescent specimens is necessary to note an increase in the anti-CMV IgG titer.

LIMITATIONS OF THE TEST

1. Sera collected very early in the acute stage of disease may have IgG levels < 4 AU/mL.
2. The VIDAS CMV IgG (CMVG) Assay demonstrates a linear dilution response to concentration. However, no international standard has been established.
3. Positive test results from cord blood should be interpreted with caution. The presence of total or IgG CMV antibodies in cord blood is usually the result of passive transfer from the mother to the fetus. A negative test, however, may be useful in excluding current infection, but the most definitive diagnosis of active CMV infection requires viral culture.
4. The titer of a single specimen should not be used to aid in the diagnosis of recent infection. Paired (acute and convalescent) samples should be collected and tested concurrently to look for seroconversion which may be indicative of primary or recent infection.
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. Increases in antibody level or seroconversion may indicate recent antigenic stimulation but per se are not confirmatory either of recent primary infection or of reactivation of a pre-existing latent process with active viral excretion.
7. Lack of a significant increase in antibody level does not exclude the possibility of CMV infection.
8. No cross-reactivity has been observed with the VIDAS CMV IgG (CMVG) Assay. However, rare heterotypic responses of cytomegalovirus antibodies have been reported in conjunction with herpes simplex virus, influenza A virus, and *Mycoplasma pneumoniae*. The virus causing the infection may not always demonstrate the greater rise in antibody level. Frequently, a differential diagnosis can be made on the basis of the fact that antibody to the infecting virus type is absent or at a very low titer in the acute-phase specimen, whereas antibody to the viral heterotype is already present.

EXPECTED VALUES

CMV infections are quite common. Approximately 60-85% of the population is believed to be infected by age 18. Several studies suggest a relationship between CMV IgG antibody incidence, age, socioeconomic status, and geographical location of the population tested. At the VIDAS CMV IgG (CMVG) clinical trial sites, the positivity rate for CMV IgG was 73% in the midwestern US. At the trial site in central France, the positivity rate was 60%.

SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity/Specificity

One hundred ninety-nine serum samples were tested at a single site. Of the 199 samples, 113 (57%) were from organ transplant patients, 11 (6%) were from organ donors, 46 (23%) were from blood donors, 4 (2%) were from infants, 6 (3%) were from HIV patients, 2 (1%) were from cancer patients, and 17 (6%) were undefined. Each sample was tested using the VIDAS® CMV IgG (CMVG) Assay and 2 commercially available CMV IgG assays. A sample was considered to be positive if at least two of the three tests were positive. A sample was considered to be negative if at least two of the three tests were negative. If one of the test results was equivocal and the other two were discrepant, the sample was unresolved.
There were initially two (1.0%) equivocal VIDAS CMV IgG (CMVG) results. Both were equivocal upon retesting. One of the VIDAS equivocals was negative by one EIA and positive by the other. The second VIDAS equivocal was positive by both EIAs. There were no invalid results.
The following table shows the comparison of VIDAS CMV IgG (CMVG) compared to the final interpretation as described above.

199 samples tested
2 equivocal results (not included in calculations)

		EIA 1		EIA 2		Final Interpretation	
		+	-	+	-	+	-
VIDAS	+	145	1	145	1	145	1
CMV IgG (CMVG)	-	1	50	1	50	0	51
Rel. Sens.		99.3%		99.3%		100.0%	
Rel. Spec.		98.0%		98.0%		98.1%	
Rel. PPV		99.3%		99.3%		99.3%	
Rel. NPV		98.0%		98.0%		100.0%	
Rel. Agreement		99.0%		99.0%		99.5%	

Precision

Intra-assay precision was performed at two sites. At each site, positive, low positive, and negative control materials were each tested in a single work list of 22 replicates. The results are given below (Note: Different control materials were used at the two sites):

	Mean RFV	% CV
Site 1:		
Positive	993	3.96%
Low Positive	692	3.78%
Negative	3	*
Site 2:		
Positive	2278	5.3%
Low Positive	577	4.1%
Negative	28	**

* % CV not calculated due to low value for RFV; SD = 3.0
** % CV not calculated due to low value for RFV; SD =12.8

Inter-assay precision was performed at two sites. At each site, positive, low positive, and negative control materials were each tested in triplicate in a single work list for 10 consecutive days. The mean RFV for each day was used in the calculations.

The results are given below (Note: Different control materials were used at the two sites):

	Mean RFV	% CV
Site 1:		
Positive	991	7.45%
Low Positive	692	4.30%
Negative	6	*
Site 2:		
Positive	2778	3.10%
Low Positive	763	7.00%
Negative	24	**

* % CV not calculated due to low value for RFV; SD = 2.5

** % CV not calculated due to low value for RFV; SD =11.3

ASSAY SPECIFICITY

Cross-reactivity and Interference Testing

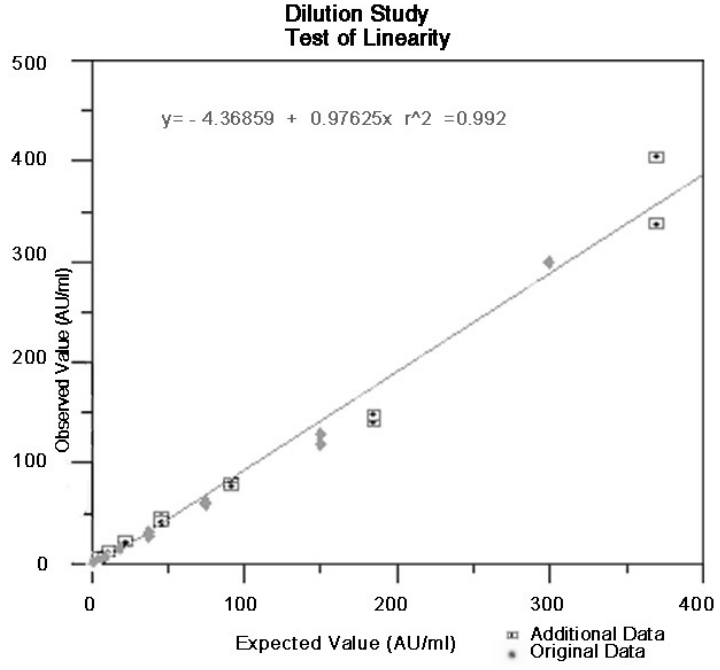
Samples from patients with the serological histories described below were tested in the VIDAS CMV IgG (CMVG) Assay to check for cross-reactivity and interference. CMV IgG positive samples were confirmed as positive by commercially available EIAs.

The results are shown in the following table:

Serological Status	VIDAS CMV IgG (CMVG) Results
ANA positive: CMV pos CMV neg	11/11 positive 5/5 negative
EBV positive: CMV pos CMV neg	2/2 positive 17/17 negative
HIV pos, CMV pos	30/30 positive
HSV positive: CMV pos CMV neg	5/5 positive 2/2 negative
HSV 1 positive: CMV pos CMV neg	5/5 positive 4/4 negative
HSV 2 positive: CMV pos CMV neg	5/5 positive 5/5 negative
RBG pos, CMV neg	5/5 negative
RF positive: CMV pos CMV neg	7/7 positive 2/2 negative
VZV positive: CMV pos CMV neg	6/6 positive 7/7 negative

LINEARITY

Two sera of known titer corresponding to the Lille Blood Bank standard were used for serial dilution studies. Two independent sets of dilutions were made from each serum. The results of testing these samples in the VIDAS® CMV IgG (CMVG) Assay were evaluated using linear regression analysis of observed arbitrary units versus the values expected. A high degree of linearity was demonstrated, as evidenced by a correlation coefficient of 0.99 and a slope of 0.97. The data are presented in the graph below.



PAIRED SERA STUDY

Ten sets of paired sera were tested at a clinical laboratory in France. These paired sera had been submitted for CMV testing per physician request. The time period between collection of acute and convalescent samples was 3-4 weeks. The pairs were tested in the same work list. The table below shows VIDAS results compared to those obtained with IFA. These results are also included in the table below.

Interpretations:

N = no significant change in antibody level
S = suggestive of an increase in antibody level
H= highly significant increase in antibody level

Patient #	VIDAS			IFA	
	Convalescent AU/ Acute AU	Critical Ratio	Interp.	Acute Titer	Conv. Titer
1	255/31	8.22	H	1:20	1:320
2	>400/75	>5.33	H	1:20	1:160
3	>400/65	>6.15	H	1:10	1:320
4	>1600/376	>4.26	H	1:20	1:80
5	211/38	5.55	H	1:20	1:80
6	183/24	7.62	H	1:10	1:80
7	382/70	5.46	H	1:10	1:80
8	>400/59	>6.78	H	1:10	1:80
9	>400/35	>11.43	H	1:10	1:40
10	650/40	16.25	H	1:20	>1:5120

As seen in the table above, VIDAS CMV IgG (CMVG) results agreed with the IFA results for all 10 sets of paired sera tested. The VIDAS CMV IgG (CMVG) Assay is capable of indicating an increase in antibody titer in paired sera.

ADDITIONAL DATA - EUROPEAN PERFORMANCE STUDY

Four hundred forty-five serum samples were tested at a single site. Of the 445 samples, 52 (11.7%) were from organ transplant patients, 44 (9.9%) were from pregnant patients, 43 (9.7%) were from infants, 16 (3.6%) were ANA positive, 40 (9.0%) were CMV positive, 19 (4.3%) were EBV positive, 30 (6.7%) were HIV positive, 26 (5.8%) were HSV positive, 5 (1.1%) were rubella IgG positive, 9 (2.0%) were RF positive, 13 (2.9%) were positive for VZV, and 148 (33.3%) were undefined.

Each sample was tested using the VIDAS® CMV IgG (CMVG) Assay and 2 commercially available CMV IgG assays available in Europe. A sample was considered to be positive if at least two of three tests were positive. A sample was considered to be negative if at least two of the three tests were negative. If one of the test results was equivocal and the other two were discrepant, the sample was unresolved.

There were 13 (2.9%) VIDAS equivocal results. None of the samples were available for retesting. Two of them were positive by both of the other EIAs. Seven were negative by both of the other EIAs.

Four had discrepant results between the other two EIAs, and therefore were unresolved. There were no invalid results.

The table below shows the VIDAS CMV IgG (CMVG) Assay compared to the combined standard as described above.

445 specimens tested
13 equivocal results (not included in calculations)

		EIA 1		EIA 2*		Final Interpretation	
		+	-	+	-	+	-
VIDAS	+	268	1	268	1	269	0
CMV IgG (CMVG)	-	5	158	2	159	1	161
Rel. Sens.		98.2%		99.3%		99.6%	
Rel. Spec.		99.4%		99.4%		100.0%	
Rel. PPV		99.6%		99.6%		100.0%	
Rel. NPV		96.9%		98.8%		99.4%	
Rel. Agreement		98.6%		99.8%		99.8%	

* 2 samples gave equivocal results with this assay

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 type 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
	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

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

Release date	Part Number	Change Type	Change Summary
2015/01	13678C	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) WARNINGS AND PRECAUTIONS
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