July 30, 2018

Siemens Healthcare Diagnostics, Inc.
Kira Gordon
Sr. Regulatory Affairs Specialist
511 Benedict Ave
Tarrytown, New York 10591

Re: K181213
Trade/Device Name: ADVIA Centaur CMV IgG
ADVIA Centaur CMV IgG Quality Control
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus serological reagents
Regulatory Class: Class II
Product Code: LFZ, QCH
Dated: May 1, 2018
Received: May 7, 2018

Dear Kira Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181213

Device Name
ADVIA Centaur® CMV IgG
ADVIA Centaur® CMV IgG Quality Control

Indications for Use *(Describe)*

ADVIA Centaur CMV lgG:
The ADVIA Centaur® CMV IgG (CMV lgG) assay is for in vitro diagnostic use in the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human pediatric and adult serum and plasma (dipotassium EDTA, lithium heparin) using the ADVIA Centaur XP system. The assay is used to determine CMV lgG serological status and as an aid in the diagnosis of CMV infection in individuals for whom a CMV IgG test was ordered, including pregnant women. The ADVIA Centaur CMV IgG assay is not intended for blood and tissue donor screening.

ADVIA Centaur® CMV IgG Quality Control:
The ADVIA Centaur® CMV IgG (CMV IgG) Quality Control material is for in vitro diagnostic use for monitoring the performance of the ADVIA Centaur CMV IgG (CMV IgG) assay on ADVIA Centaur systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Applicant:**

Contact: Kira Gordon, PhD
Sr. Regulatory Affairs Specialist
Address: Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY 10591
Phone: (914) 524-2996
FAX: (914) 524-3579
Email: kira.gordon@siemens-healthineers.com

2. **Date:** May 01, 2018

3. **Proprietary and Established Names:**
ADVIA® Centaur CMV IgG
ADVIA® Centaur CMV IgG Quality Control

4. **Regulatory Information:**

Classification Names:	Cytomegalovirus serological reagents
Regulation Number:	21 CFR § 866.3175
Classification:	Class II
Product Code:	LFZ
Panel:	Microbiology (83)

4. **Predicate Device:**
Device Name: bioMerieux VIDAS CMV IgG (CMVG) Assay
510(k) Number: k920661
Manufacturer: bioMerieux

5. **Indications for Use:**
ADVIA Centaur CMV lgG:
The ADVIA Centaur® CMV IgG Assay is for in vitro diagnostic use in the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human pediatric and adult serum and plasma (dipotassium EDTA, lithium heparin) using the ADVIA Centaur XP system. The assay is used to determine CMV IgG serological status and as an aid in the diagnosis of CMV infection in individuals for whom a CMV IgG test was ordered, including pregnant women.

The ADVIA Centaur CMV IgG assay is not intended for blood and tissue donor screening.

ADVIA Centaur® CMV IgG Quality Control:
The ADVIA Centaur® CMV IgG (CMV IgG) Quality Control material is for in vitro

diagnostic use for monitoring the performance of the ADVIA Centaur CMV IgG (CMV IgG) assay on ADVIA Centaur systems.

9. **Device Description:**
CMV IgG Assay Kit (100-Tests) consists of 1 ReadyPack containing ADVIA Centaur CMV IgG Lite Reagent and Solid Phase reagent, and 1 ReadyPack ancillary reagent pack that contains ADVIA Centaur CMV IgG Diluent, and a set of Calibrators (1 vial each of Low and High, with fill volume of 2 mL each). The reagents and calibrators are packaged together in the ADVIA Centaur CMV IgG Assay kit, while the associated ADVIA Centaur CMV IgG Quality Control is packaged separately.

10. Test Principle
The ADVIA Centaur CMV IgG assay is a fully automated, 2-step sandwich immunoassay using indirect chemiluminometric technology. The patient specimen is diluted with ADVIA Centaur CMV IgG Diluent and incubated with the Solid Phase reagent. The Solid Phase reagent contains a heterogeneous mixture of biotinylated CMV viral lysate antigens, preformed to streptavidin-coated magnetic particles. The antigen-coated particles subsequently capture CMV-specific antibodies in the specimen. The antibody-antigen complex is washed and Lite reagent is added. The Lite reagent consists of an acridinium-ester (AE)-labeled anti-human IgG mouse monoclonal antibody. The entire complex is washed and the signal is generated in the presence of Lite Reagent bound to the Solid Phase via the CMV IgG-CMV antigen complex.
The system automatically performs the following steps:

- Dispenses 20 µL of sample into a cuvette.
- Dispenses 195 µL of ADVIA Centaur CMV IgG Diluent into the cuvette with the sample.
- Removes 100 µL of the diluted sample from the cuvette and dispenses it into a second cuvette.
- Dispenses 200 µL of Solid Phase and incubates the mixture for 18.0 minutes at 37°C.
- Separates the Solid Phase from the mixture and aspirates the unbound reagent.
- Washes the cuvette with ADVIA Centaur Wash 1.
- Re-suspends the washed particles in 250 µL of ADVIA Centaur Wash 1.
- Dispenses 100 µL Lite Reagent and incubates the mixture for 18.0 minutes at 37°C.
- Separates the Solid Phase from the mixture and aspirates the unbound reagent.
- Washes the cuvette with ADVIA Centaur Wash 1.
- Dispenses 300 µL of ADVIA Centaur Acid Reagent and 300 µL of ADVIA Centaur Base Reagent to initiate the chemiluminescent reaction.
- Reports results according to the selected option, as described in the system operating Instructions.

A direct relationship exists between the amount of bound anti-CMV IgG present in the patient specimen and the amount of relative light units (RLUs) detected by the system. A result of reactive or nonreactive is determined according to the Index Values established with the calibrators:

- Samples with an Index Value of < 1.00 are considered nonreactive for CMV

IgG antibodies.
- Samples with an Index Value of ≥ 1.00 are considered reactive for CMV IgG antibodies.

11. Substantial Equivalence Information:

Device Name: bioMerieux VIDAS CMV IgG (CMVG)
Assay 510(k) Number: k920661
Comparison with Predicate:

Item	**New Device:**	**Predicate Device:**
Intended Use	The ADVIA Centaur® CMV IgG Assay is for in vitro diagnostic use in the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human pediatric and adult serum and plasma (dipotassium EDTA, lithium heparin) using the ADVIA Centaur XP system. The assay is used to determine CMV IgG serological status and as an aid in the diagnosis of CMV infection in individuals for whom a CMV IgG test was ordered, including pregnant women. The ADVIA Centaur CMV IgG assay is not intended for blood and tissue donor screening.	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.
Instrument	ADVIA Centaur	VIDAS/mini-VIDAS
Measurement	Qualitative	Semi-Quantitative
Technology	Chemiluminescense	enzyme-linked fluorescent immunoassay
Assay Protocol	sandwich immunoassay	sandwich immunoassay
Sample type	Serum, Plasma	Serum
Cut-Offs	< 1.0 (Index) - nonreactive ≥ 1.0 (Index) - reactive	< 4 AU/mL - negative ≥ 4 to < 6 AU/mL - equivocal ≥ 6 AU/mL - positive
Sample Volume	20 µL	100 µL
Calibrators matrix	Human plasma	Human serum
Calibrator fill volume	Liquid, 2 mL	Liquid, 2 mL
Controls	Negative and Positive	Negative and Positive

Non-Clinical Studies

a. Assay Cut-off

A comparison study between ADVIA Centaur CMV IgG assay and a comparator CMV IgG assay was performed to determine the placement of the cutoff value at a 1.00 Index by testing 389 remnant clinical samples. Of these, 196 samples were negative, 186 samples were positive, and the rest were equivocal by the comparator device. The cutoff value was set at ≥ 95% positive agreement and ≥ 95% negative agreement to the comparator device. Assigned values for

calibrators and controls are based on the cutoff Index determination.

b. Precision

Precision was evaluated according to CLSI document EP05-A3. Repeatability and Within-Lab imprecision were evaluated by testing 5 serum-based samples (serum sample pools), and 2 plasma-based samples (controls. negative and positive). The samples were assayed in duplicate over the course of 20 days, 2 runs per day, for a total of 40 runs and 80 replicates. The results

are shown below

Sample Type	N	Mean	Repeatability		Between-Run		Between-Day		Within-Lab	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV
Control 1 (negative)	80	0.08	0.00	NA[a]	0.00	0.0	0.00	0.0	0.01	NA
Control 2 (positive)	80	4.54	0.09	2.0	0.12	2.6	0.09	2.0	0.18	3.9
Serum Pool 1	80	0.07	0.00	NA	0.00	0.6	0.00	NA	0.01	NA
Serum Pool 2	80	0.90	0.02	2.1	0.01	1.3	0.02	2.3	0.03	3.4
Serum Pool 3	80	1.36	0.03	2.5	0.02	1.1	0.02	2.1	0.05	3.5
Serum Pool 4	80	2.70	0.06	2.2	0.07	2.5	0.07	1.7	0.10	3.7
Serum Pool 5	80	9.68	0.20	2.1	0.12	1.3	0.12	1.8	0.29	3.0

[a] NA = not applicable

c. Reproducibility

The reproducibility study was conducted at three external sites using 2 reagent lots. The protocol was run over 5 days, 2 runs per day, and 3 replicates per run for the sample pools, and 6 replicates per run for the negative and positive control materials. Reproducibility data was pooled for each reagent lot across three sites. Data is presented for 1 representative reagent lot.

Sample Type	N	Mean	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Control 1 (negative)	180	0.10	0.01	NA[a]	0.00	NA	0.00	NA	0.02	NA	0.02	NA
Control 2 (positive)	180	4.55	0.12	2.7	0.07	1.5	0.02	0.3	0.15	3.4	0.21	4.6
Serum Pool 1	90	0.10	0.01	NA	0.00	NA	0.00	NA	0.01	NA	0.01	NA
Serum Pool 2	89[b]	0.80	0.01	1.8	0.02	1.9	0.01	1.1	0.05	6.1	0.05	6.7
Serum Pool 3	90	1.23	0.02	1.9	0.02	2.0	0.00	0.0	0.07	5.4	0.07	6.0
Serum Pool 4	90	2.98	0.06	1.9	0.06	1.9	0.05	1.7	0.13	4.2	0.16	5.3
Serum Pool 5	90	25.25	0.45	1.8	0.40	1.6	0.26	1.0	1.64	6.5	1.77	7.0

[a] NA = not applicable.

[b] One run had 2 replicates instead of 3.

d. Interference

Interference by endogenous substances in the ADVIA Centaur CMV IgG assay was evaluated at four CMV IgG levels (low negative, high negative, low positive, and high positive). Interfering substances at the levels indicated were tested as described in CLSI Document EP07-A2. There was no change in clinical interpretation throughout the assay range at the levels indicated.

Interferent	Concentration
Hemolyzed	500 mg/dL of hemoglobin
Icteric	20 mg/dL of conjugated bilirubin
Icteric	20 mg/dL of unconjugated bilirubin
Lipemic	3000 mg/dL of intralipids (Triglycerides)
Total Protein*	9g/dL of protein
Immunoglobulins*	3g/dL of immunoglobulin
Biotin	4500 ng/mL of biotin
Cholesterol	400 mg/dL of cholesterol

* Total protein and immunoglobulins were tested using clinical samples with high serum protein and samples from multiple myeloma patients respectively.

e. Cross-reactivity

The ADVIA Centaur CMV IgG assay was evaluated for potential cross-reactivity in specimens with other viral and microbial antibodies and other disease states. The CMV IgG status of each

sample was compared using the comparator assay.

Clinical Category	Number Tested	ADVIA Centaur CMV IgG Reactive	Comparator CMV IgG Reactive
Chlamydia IgG	11	4	4
CMV IgM	10	6	6
Epstein-Barr virus (EBV) IgG	13	0	0
Epstein-Barr virus (EBV) IgM	10	4	4
Graves' disease	3*	0	0
Hepatitis A infection (HAV) IgG	10	3	3
Hepatitis B Core (HBc) IgG	10	3	4
Hepatitis C infection (HCV) IgG	10	1	1
Herpes simplex virus 1 (HSV1) IgG	13	3	3
Herpes simplex virus 2 (HSV2) IgG	12	0	0
Human anti-mouse antibody (HAMA)	14	7	6
Human chorionic gonadotropin (hCG)	11	0	0
Human herpes virus (HHV6) IgG	11	0	0
Human immunodeficiency virus (HIV) Antibodies	16	9	9
Influenza Antibodies	11	7	7
Measles IgG	11	0	0
Multiparity	20	18	18
Multiple myeloma	23	11	11
Parvovirus B19 IgG	11	3	3
Rheumatoid factor (RF)	10	1	1
Rubella IgG	13	0	0
Sjogren's Syndrome	4*	0	0
Systemic lupus erythematosus (SLE)*	3*	0	0
Syphilis IgG	11	4	4
Toxoplasma IgG	10	4	4
Varicella zoster virus (VZV) IgG	16	0	0
Total	**297**	**88**	**88**

*Results may not be conclusive due to low number of samples tested.

f. *Matrix Comparison*

The ADVIA Centaur CMV IgG assay was evaluated using different specimen matrices.

ADVIA Centaur CMV IgG results that ranged from 0.74–28.55 Index were analyzed using orthogonal regression. The following results were obtained:

Serum (x) vs.	N	Mean (Index)	Slope	Intercept (Index)	Correlation Coefficient (r)
Dipotassium EDTA plasma	38	10.76	1.01	-0.08	0.99
Lithium heparin plasma (y)	38	10.76	1.01	-0.07	0.96

12. Clinical Studies

a. Method Comparison with predicate device

Percent agreement was determined by comparing the performance of the ADVIA Centaur CMV IgG assay to a comparator CMV IgG assay. A total of 1842 samples that were sent for CMV IgG testing were analyzed, including:

- 1699 prospectively collected specimens
  - 684 general population subjects sent for CMV IgG testing
  - 348 pregnant subjects
  - 229 pediatric subjects (2–21 years old)
  - 44 HIV-positive subjects
  - 394 transplant-patient subjects
- 143 retrospective HIV-positive specimens

Prospective Study

A total of 1699 clinical routine specimens (from people aged 6 months–91 years, both male and female) were obtained from 6 collection sites in the United States. The specimens were from subjects sent for CMV IgG testing, pediatric subjects (aged 2–21 years), pregnant women, HIV-positive subjects, and transplant patients. The following results were obtained:

Prospective Study - Combined Population

ADVIA Centaur CMV IgG Assay	Comparator-CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	1037	11	10	**1058**
Nonreactive	1	3	637	**641**
Total	**1038**	**14**	**647**	**1699**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	99.6% (1037/1041)	99.0%–99.9%
Negative agreement	96.8% (637/658)	95.2%–98.0%

Note: Fourteen samples that tested equivocal on the comparative assay were further tested on 2 other CMV IgG comparator assays. Of these 14 samples, 10 remained equivocal, 3 agreed and 1 did not agree with the ADVIA Centaur CMV IgG assay when compared to the two out of three consensus result.

The results obtained with the different subgroup prospective populations are presented in the

sections that follow.

Subjects Sent for CMV IgG Testing

A total of 684 general population prospective serum samples sent for CMV IgG testing were analyzed. The following results were obtained:

Subjects Sent for CMV IgG Testing

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	375	6	7	**388**
Nonreactive	1	1	294	**296**
Total	**376**	**7**	**301**	**684**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	99.5% (375/377)	98.1%–99.9%
Negative agreement	95.8% (294/307)	92.9%–97.7%

Note: Seven samples that tested equivocal on the comparator assay were further tested on 2 other CMV IgG assays. Of these 7 samples, 5 remained equivocal and 2 agreed with the ADVIA Centaur CMV IgG assay when compared to the two out of three consensus result.

Pregnant Women Subgroup

Serum samples sent for CMV IgG testing from 348 pregnant women were prospectively collected from 4 sites and tested. The following results were obtained:

Pregnant Women Subgroup

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	287	0	1	**288**
Nonreactive	0	0	60	**60**
Total	**287**	**0**	**61**	**348**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	100.0% (287/287)	98.7%–100.0%
Negative agreement	98.4% (60/61)	91.2%–9.9%

Pediatric Subgroup

A total of 229 pediatric prospective serum samples were tested at 3 sites. Specimens were obtained from 4 sites, from males, and from females who were not pregnant. The subjects' ages

ranged from 2–21 years. The following results were obtained:

Pediatric Subgroup

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	80	1	1	**82**
Nonreactive	0	1	146	**147**
Total	**80**	**2**	**147**	**229**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	98.8% (80/81)	93.3%–99.9%
Negative agreement	98.6% (146/148)	95.2%–99.8%

Note: Two samples that tested equivocal on the comparator assay were further tested on 2 other CMV IgG assays and the two out of three consensus result remained equivocal.

Human Immunodeficiency Virus (HIV) Patient Subgroup

Serum specimens sent for CMV IgG testing were prospectively collected at 5 sites, from 44 HIV-positive patients and tested. The following results were obtained:

HIV-Positive Patient Subgroup

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	43	0	0	**43**
Nonreactive	0	0	1	**1**
Total	**43**	**0**	**1**	**44**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	100.0% (43/43)	91.8%–100.0%
Negative agreement	100.0% (1/1)	2.5%–100.0%

Transplant Patient Subgroup

Serum samples from 238 preoperative transplant patients from 3 sites were tested. The

following results were obtained:

Transplant Patient Subgroup - Preoperative

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	151	0	0	**151**
Nonreactive	0	0	87	**87**
Total	**151**	**0**	**87**	**238**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	100.0% (151/151)	97.6%–100.0%
Negative agreement	100.0% (87/87)	95.8%–100.0%

Serum samples from 156 transplant patients were collected from 3 sites that perform kidney, pancreas, bone and marrow stem cell, liver, face and limb, heart, and lung transplants. After testing the following results were obtained

Transplant Patient Subgroup - Postoperative

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	101	4	1	**106**
Nonreactive	0	1	49	**50**
Total	**101**	**5**	**50**	**156**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	99.0% (101/102)	94.7%–99.9%
Negative agreement	90.7% (49/54)	79.7%–96.9%

Note: Five samples that tested equivocal by the comparator assay were further tested on 2 other CMV IgG assays. Of these 5 samples, 3 remained equivocal, 1 agreed and 1 did not agree with the ADVIA Centaur CMV IgG assay when compared to the two of three consensus result.

Retrospective Study - HIV-Positive Patient Subgroup

A total of 143 retrospective remnant samples from the HIV-positive patient subgroup collected at 1

site were tested. The following results were obtained:

Retrospective HIV-Positive Patient Subgroup

ADVIA Centaur CMV IgG Assay	Comparator CMV IgG Assay			
	Positive	Equivocal	Negative	Total
Reactive	135	0	0	**135**
Nonreactive	0	0	8	**8**
Total	**135**	**0**	**8**	**143**

ADVIA Centaur CMV IgG Assay	Agreement (%)	95% Confidence Interval
Positive agreement	100.0% (135/135)	97.3%–100.0%
Negative agreement	100.0% (8/8)	63.1%–100.0%

g. Centers for Disease Control (CDC) Panel:

A panel of 80 previously characterized serum samples was obtained from the CDC and evaluated with the ADVIA Centaur CMV IgG assay to determine the performance of the assay. There was 100% agreement with the serological status provided by the CDC.

ADVIA Centaur CMV IgG Assay	Expected CDC Panel Results		
	Positive	Negative	Total
Reactive	39	0	39
Nonreactive	0	41	41
Total	**39**	**41**	**80**

Note: The results are presented as a means to convey further information on the performance of this assay with a characterized serum panel from the CDC. This does not imply an endorsement of the assay by the CDC.

13. Conclusions

From the above comparative testing results of the ADVIA Centaur CMV IgG assay we conclude that it is substantially equivalent to the bioMerieux VIDAS CMV IgG Assay.