INTENDED USE

The VIRGO® Cytomegalovirus (CMV) indirect fluorescent antibody (IFA) test is intended for detection and titration of cytomegalovirus IgG or cytomegalovirus IgM antibody in human sera.

This product is not FDA cleared for use in testing blood or plasma donors.

SUMMARY AND EXPLANATION

Throughout most the world, cytomegalovirus (CMV) infection is asymptomatically acquired during childhood. However, in affluent communities, primary infection may be delayed resulting in:

- infection during pregnancy leading to overt or delayed onset of congenital abnormalities in the newborn,
- infection following blood transfusions which may lead to CMV induced mononucleosis,
- infection following immunosuppression for organ transplantation which may lead to complications during recovery and/or loss of the organ.

Infection by CMV cannot be clinically diagnosed without confirmation by laboratory testing, such as the isolation of the virus or the demonstration of a serological rise in specific antibody titer.

In 1904, Rippert described the large inclusion containing cells which are CMV's primary anatomic pathological effect.[1] This herpes virus was first isolated fifty years later by Smith, but the descriptive term cytomegalovirus was coined by Weller.[2,3] CMV has the capacity to persist in its human host indefinitely as a latent infection in several glands and the kidneys. Unlike the other herpes viruses, CMV is slow growing, producing a delayed cytopathic effect in cell culture. Cytomegaly is characteristic of a CMV infection, resulting in swollen cells containing large nuclear inclusions.

Prevalence studies based on the frequency of seorpositive individuals in the general population (40-100%) show an inverse correlation between the acquisition of CMV infection and the socioeconomic condition of the population. Age-related incidence studies suggest increased risk of infection during both the perinatal and reproductive periods of the human lifecycle.[5] Perinatal infection can be acquired through cervical secretions and breast milk, while the sudden increase in seroconversion at sexual maturity is suggestive of a possible venereal transmission.

Though less frequent, prenatal CMV infection may result from transplacental transmission from mother to fetus and is the major infectious cause of mental retardation and other congenital defects in the newborn. Only 1 in 2,000 infants are born expressing the severe cytomegalic inclusion disease (CID), while ten times that many acquire an asymptomatic infection *in utero*. Medically, the asymptomatic or "silent" congenital disease is important because of possible long-term developmental effects and the lack of overt clinical signs to guide the physician's diagnosis.[6]

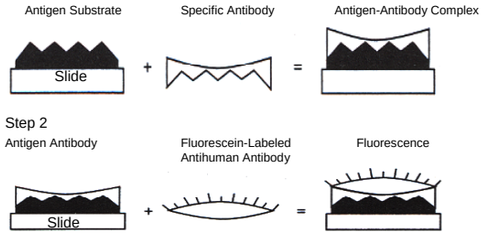
Additionally, two types of iatrogenic infection can occur. First, a recurrent or reactivated infection frequently follows the immunosuppressive therapy which typically accompanies organ transplantation[7] or cancer treatment.[8] Second, recipients of multiple transfusions usually acquire either a primary or reactivated infection.[9] These opportunistic infections are frequently subclinical, but the severity of the disease state depends on the dose received and the immune status and competence of the individual's immune system.

Since the presence of circulating IgG antibody to CMV is indicative of previous infection, screening pregnant women, organ transplant recipients and other immunosuppressed patients for seropositivity is a valuable tool for determining whether or not they have been previously infected.

PRINCIPLE OF THE TEST

The VIRGO fluorescent antibody assays utilize the indirect method of fluorescent antibody staining, first described by Weller and Coons in 1954.[10] The procedure is carried out in two basic reaction steps. In step one, the human serum to be tested is brought into contact with the antigenic substrate. Antibody, if present in the test serum, will attach to the antigen, forming an antigen-antibody complex. If the serum being tested does not contain antibody for this particular antigen, no complex is formed and all the serum components are washed away in the rinse step. The second step involves adding a fluorescein labeled anti-human antibody to the test wells. If the specific antigen-antibody complex is formed in step one, the fluorescein labeled antibody will attach to the antibody moiety of the complex in step two. A positive reaction, bright apple-green fluorescence, can be seen with the aid of a fluorescence microscope.

Principle of Indirect Fluorescent Antibody Testing



CONTENTS OF THE KIT

Kits are available with anti-IgG (heavy and light chains) or anti-IgM (μ-chain specific) conjugate.

Each IgG Kit contains:

902111	902113	Test Kit Product Number
96 Tests	200 Tests	Number of Tests per Kit
12	25	**8-Well Slides:** CMV infected (AD-169 strain) and uninfected cells
1	1	**Vial Positive Control:** Lyophilized human serum
1	1	**Vial Negative Control:** Lyophilized human serum
1	2	**Vial(s) FITC Conjugate:** Lyophilized, inactivated goat anti-human IgG (heavy & light chains) with counterstain
3	5	***Packages Powdered Phosphate Buffer:** (PBS) pH 7.4 ± 02
1	1	***Vial (2 mL) Buffered Glycerol**
2	3	***Packages (5 each) Blotters**

*These components may be interchanged between different master lots. Additional supplies are available from Hemagen Diagnostics, Inc.

Each IgM Kit contains:

902112	Test Kit Product Number
96 Tests	Number of Tests per Kit
12	**8-Well Slides:** CMV infected (AD-169 strain) and uninfected cells
1	**Vial Positive Control:** Lyophilized human serum
1	**Vial Negative Control:** Lyophilized human serum
1	**Vial(s) FITC Conjugate:** Lyophilized, inactivated goat anti-human IgM (μ-chain specific) with counterstain
3	***Packages Powdered Phosphate Buffer:** (PBS) pH 7.4 ± 02
1	***Vial (2 mL) Buffered Glycerol**
2	***Packages (5 each) Blotters**

*These components may be interchanged between different master lots. Additional supplies are available from Hemagen Diagnostics, Inc.

MATERIALS REQUIRED BUT NOT SUPPLIED

Test tubes and racks for making dilutions

Pipettes for preparing dilutions

Coverslips, 22 x 50 mm., No. 1 thickness

Humidified chamber

Magnetic stir plate (optional)

Staining dish and slide-holder rack

Fluorescence microscope. Refer to manufacturer's instruction manual for the filter system that gives optimum results for FITC (Maximum excitation wavelength = 490 nm. Mean emission wavelength = 520 nm.)

PRECAUTIONS

1. HANDLE ALL ASSAY SPECIMENS, SLIDES, POSITIVE AND NEGATIVE CONTROLS AS IF CAPABLE OF TRANSMITTING INFECTIOUS AGENTS.

   All human blood components of the kit have been tested by approved FDA methods and found to be negative for both hepatitis B surface antigen (HbsAg) and for antibodies to human immunodeficiency virus type 1. Because no test method can offer complete assurance that HIV, hepatitis B virus, or other infectious agents are absent, specimens and kit reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human serum or blood specimen.[11,12]
2. The antigenic substrates are fixed in acetone.
3. Do not pipette by mouth.
4. Do not smoke, eat, or drink in areas where specimens or kit reagents are handled.
5. All materials used in this assay, including reagents, samples and wiping materials should be disposed of in a manner that will inactivate infectious agents.

HANLDING PRECAUTIONS

1. **For *In Vitro* Diagnostic Use.**
2. Do not use the kit or individual reagents beyond their labeled expiration dates.
3. The components of this kit have been tested as a unit. **Do not** interchange components from other sources or from different master lots, except as noted.
4. Protect the conjugate from prolonged exposure to light.

REAGENT STORAGE AND STABILITY

1. Store kit at 2-8°C. Powdered PBS and Buffered Glycerol can be stored at 2-30°C if desired. The test kit can be used through the expiration date on the outer box label.
2. **After rehydration,** Positive Control, Negative Control and FITC Conjugate should be stored at 2-8°C or made up in aliquots and stored at -20°C or colder of not used within one week.

   NOTE: Precautions were taken in the manufacture of this product to protect the reagents from contamination. After reconstitution, care should be exercised to protect the reagents in this kit from contamination. If constant storage temperature is maintained, reagents and substrate will be stable for the dating period of the kit.

REAGENT PREPARATION

Allow reagents and slides to reach room temperature 15 to 30 minutes before use.

1. **Slides and Glycerol:** Ready to use.
2. **PBS:** Dissolve contents of one package in 1 liter of distilled or deionized water. Seal container to prevent contamination or evaporation.
3. ***Controls:** Rehydrate with 1 mL of PBS. The controls are now at the appropriate screening dilution. Aliquot for storage at -20°C if not used within one week.
4. **Conjugate:** Rehydrate with 2 mL of PBS. Aliquot for storage at -20°C if not used within one week.

*The IgM Positive Control should be rehydrated with 0.5 mL of PBS.

SPECIMEN COLLECTION AND HANDLING

1. Serum samples may be stored at room temperature for up to 24 hours. For longer term storage, they may be stored at 2-8°C (for up to three days), or frozen at -20°C or colder. Place at 37°C only until the samples are thawed. Remove and mix thoroughly before use. Self-defrosting freezers are not recommended. Avoid multiple free-thaw cycles.[13]
2. Optimal performance of the VIRGO CMV IFA depends upon the use of fresh serum samples. Specimens should be collected aseptically. Early separation from the clot prevents hemolysis of serum.[14]
3. For best results, another sample should be drawn if bacteriological contamination or lipids are present. If another sample cannot be obtain, filtering (0.45μ) or centrifugation (approximately 3000 x G for 10 minutes) is required.
4. Excess lipids in the test serum may produce a "filming" reaction. The lipids "stick" nonspecifically to the glass and are extremely difficult to remove. Experience will enable the trained technician to differentiate this "film" reaction from the specific reaction.
5. Occasionally, the specimen may contain certain proteolytic enzymes which attack and digest the substrate. This is especially true of specimens contaminated with microorganisms. Such specimens may be heated to 56°C for 30 minutes. If this fails to reduce the enzymatic activity, another sample should be obtained from the patient.

TEST PROCEDURE

Specimens may contain infectious agents and should be handled accordingly.

For optimal results, DO NOT allow substrate wells to dry out while performing the test.

1. **Remove the slides and required reagents from the refrigerator** and allow them to reach room temperature (15 to 30 minutes.
2. **Remove the slides from the pouch** just before use and label.
3. **Rehydrate the control to prepare the appropriate screening dilution:**

   IgG @ 1:16

   IgM @ 1:8

   These are now representative of typical positive and negative fluorescence patterns.
4. **Dilute the samples** with PBS to the appropriate screening dilution (1:16 for IgG; the dilution for IgM is dependent upon the pre-treatment method use), or prepare serial two-fold dilutions for quantitative determination.

   NOTE: Pre-treatment of sera prior to IgM testing is recommended at this point (see Limitations of Procedure).
5. **It is necessary to test 1 Positive Control, 1 Negative Control, and 1 PBS Buffer Control** for each batch of slides tested.
6. **Cover each well with diluted samples or controls** (~10-20 μL per well).
7. **Incubate in a humidified chamber at 20-25°C:**

   30 minutes for IgG

   60 minutes for IgM
8. **Rinse the slides briefly** in a light stream of PBS. Do not direct the stream into the wells.
9. **Rinse the slides thoroughly for 7 minutes** in a staining dish of PBS. **Change the buffer and wash for an additional 8 minutes.** Handle slides gently. Gentle agitation of the buffer is necessary for efficient slide washing.
10. **Blot the painted mask of the slide** with the blotters provided. **Do not allow the wells to dry before conjugate addition.**
11. **Cover each well with one drop** (~10 μL) **of the appropriate (IgG or IgM) FITC Conjugate.**
12. **Incubate in a humidified chamber at 20-25°C for 30 minutes.** Protect from intense light.
13. **Repeat steps 8 and 9. Blot the painted mask of the slide** with the blotters provided. **Do not allow wells to dry.**
14. **Place a small drop of Buffered Glycerol in each well** and cover with a coverslip.
15. For best results, **the slides should be read immediately at a magnification of 200-500X.** Alternatively, the slides may be read within 24 hours. However, they should be stored at 2-8°C in the dark, and sealed to prevent the mounting fluid from drying.

CRITERIA FOR GRADING FLUORESCENCE INTENSITY

4+ Brilliant apple-green fluorescence in diffuse nuclear inclusion bodies

3+ Bright apple-green fluorescence in diffuse nuclear inclusion bodies

2+ Clear distinguishable apple-green fluorescence in diffuse nuclear inclusion bodies

1+ Dull apple-green fluorescence, lacking in sharpness but readable in diffuse nuclear inclusion bodies

0 No fluorescence or barely visible fluorescence (any visible fluorescence is usually yellowish in color)

GUIDELINES FOR CHARACTERIZING FLUORESCENCE

CMV Associated Fluorescence

A positive reaction for CMV antibodies is characterized by the presence of diffuse nuclear inclusion bodies that exhibit bright apple-green fluorescence.

As an additional control, uninfected cells are mixed with the infected cells. Each high power field should contain cells that exhibit no inclusion specific fluorescence. These uninfected "negative" cells should exhibit dull red or orange staining of the cytoplasm with a greenish-black to black nucleus.

DIAGRAM GOES HERE.

Nonspecific Fluorescence

All the cells exhibit positive apple-green fluorescence, either nuclear, cytoplasmic, or both. A reaction produced by a disease state unrelated to or in addition to a CMV infection, e.g., antinuclear antibody or antimitochondrial antibody should be considered.[15,16]

No Fluorescence

Absence of or less than 1+ fluorescence in the inclusions within the nuclei. Yellowish to yellow-green areas with the cytoplasm only.

NOTES:

1. In quantitative determinations, the endpoint titer is the highest dilution showing a 1+ fluorescence in the inclusions.
2. Inclusion bodies are formed in the nuclei of human fibroblasts infected with CMV. It has been reported that CMV also induces receptors for the Fc portion of IgG molecules. Reaction in only the perinuclear (Golgi) region of infected cells should be considered unrelated to CMV antibody.[17,18] A counterstain employed with the conjugate tends to make this cytoplasmic fluorescence more yellow than green. Defined apple-green fluorescent diffuse inclusions in the nucleus must be present.

QUALITY CONTROL

1. The control sera are representative of positive and negative reactions. At the appropriate screening dilution, the Positive Control represents a strong (3-4+) reaction in the IgG testing and (2-3+) reaction in IgM testing. If the fluorescence intensity of the Positive Control is less than the acceptable range, the test is invalid and should be repeated.
2. Each lot of Positive Control must be titrated to an endpoint dilution. The endpoint titer must be within ± one two-fold serial dilution of the Positive Control titer reported in the VIRGO CMV IFA Kit Notice. If the results obtained are out of range, the test is invalid and should be repeated.
3. At the appropriate screening dilution, the Negative Control should not display diffused nuclear fluorescence characteristic of CMV. If such is observed, the test is invalid and should be repeated.
4. Quality Control results were obtained on a Nikon® microscope equipped for epiilliumination with a 50W HBO mercury ARC lamp, B filter system for FITC and a 40X dry objective (NA 0.65). Differences in endpoint reactivity and fluorescence intensity may be affected by the type and condition of fluorescence equipment used (see Microscope Specifications at the end of the package insert).

INTERPRETATION OF SAMPLE RESULTS

RESULTS	SIGNIFICANCE
IgG Screening:	
No fluorescence or fluorescence intensity < 1+ at the 1:16 screening dilution.	No detectable CMV IgG antibody. Susceptible to CMV infection.
≥1+ fluorescence at 1:16 or greater on a single serum sample.	Positive by IFA for CMV IgG antibody. Not diagnostic for recent or current infection without paired serum sample.

To confirm acute infection, paired samples are required. The first sample (acute) should be taken as soon as possible after clinical signs of infection. The second (convalescent) sample should be taken within 10-14 days of the first. Both samples must be tested at the same time using an identical lot of reagents.

IgG Paired Sera:	
Four-fold (or greater) dilution increase in titer of paired serum samples taken 10-14 days apart.	Diagnostic for recent or current infection.
IgM:	
No fluorescence or fluorescence intensity <1+ at the 1:8 screening dilution.	No detectable IgM antibody. Not indicative of current or recent infection.
≥ 1+ fluorescence at 1:8 or greater.	Positive for CMV IgM antibody. Usually indicative of current or recent infection.

LIMITATIONS OF THE PROCEDURE

1. The VIRGO CMV IFA Test Procedure and the Interpretation of Test Results must be followed closely to obtain reliable test results.
2. The results of a single antibody determination should not be used to diagnose recent infection. Paired samples (acute and convalescent) should be collected and tested concurrently to look for seroconversion or a significant rise in antibody level.
3. A significant rise in antibody level indicates recent antigenic stimulation but does not necessarily indicate active viral excretion. Since four-fold fluctuations in CMV IgG antibody levels have been noted in some apparently health individuals, the most definitive means of diagnosing active CMV infection is viral culture. However, asymptomatic viremia has also been described.[19,20,21]
4. Lack of a significant rise in antibody titer does not exclude the possibility of cytomegalovirus infection.
5. The presence of CMV IgG antibody does not assure protection from disease.
6. When measuring IgG antibody levels, positive results in neonates must be interpreted with caution since maternal antibody is transferred passively from the mother to the fetus before birth. IgM assays are generally more useful indicators of infection in children below the age of six months.
7. Samples collected very early in the course of an infection may not have detectable levels of IgM. In such cases, it is recommended that an IgG assay be performed, or a second serum sample be obtained at 10 to 14 days later to be tested in parallel with the original sample to look for seroconversion, which is indicative of a primary infection.
8. When the CMV IgG and CMV IgM tests are both positive, the possibility of a false positive exists due to the presence of rheumatoid factor.[22,23] This reaction may also be observed in sera from some newborns, both normal and congenitally infected, and is due to production of IgM antibody against passively acquired maternal IgG.[24] Performing an assay for rheumatoid factor may resolve this phenomenon.
9. When false positive reactions due to rheumatoid factor or false negative reactions due to competitive of CMV IgG antibody are suspected, pre-treating the sera to separate the IgG and IgM fractions is recommended.
10. There are cases where a negative CMV IgM reaction is observed at lower dilutions while the reaction becomes positive at higher dilutions. This is the result of a quenching reaction caused by saturation. It is frequently observed in sera having high titers of CMV IgM antibody.[25,26,27]
11. Results of this test should be interpreted in the light of other clinical findings and diagnostic procedures.

MICROSCOPE SPECIFICATIONS

Comparable filter systems are shown below:

Transmitted Light Fluorescence:

Light Source	Exciter Filter	Barrier Filter
Mercury Vapor 200W 50W	**KP490 + BG38 (4 mm.) or BG12 (4 mm.) + BG38 (4 mm.)**	**KP510, K530**
Tungsten Halogen 50W 100W	KP490 + BG38 (4 mm.)	KP510, K515, K530

Incident Light Fluorescence:

Light Source	Exciter Filter	Dichroic Beam Splitting Mirror	Barrier Filter
Mercury Vapor 200W 100W 50W	**KP500 + BG38 (4 mm.) or BG23 (4 mm.) for stronger red suppression. Edgefilter 450 nm., 480 nm. For narrow band excitation, suppression of tissue auto-fluorescence**	**TK-510**	**K510 K520**
Tungsten Halogen 50W 100W	**KP500 + BG38 (4 mm.)**	**TK510**	**K510 K515 K530**

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SUMMARY OF HEMAGEN VIRGO CMV IgG IFA

IMPORTANT: It is recommended that one be familiar with the detailed procedure in the package insert before using this summary.

Cover wells with the appropriate screening dilution of sample or control. For quantitative determination, prepare serial two-fold dilutions.

↓

Incubate slides in a humidified chamber at 20-25ºC: 30 minutes for IgG or 60 minutes for IgM.

↓

Rinse slides briefly with PBS. Wash for 15 minutes, changing buffer 1X. Blot slides.

↓

Cover each well with the appropriate FITC Conjugate (IgG or IgM).

↓

Incubate slides in a humidified chamber at 20-25ºC for 30 minutes.

↓

Repeat wash step described above.

↓

Place a small drop of Buffered Glycerol on each well and cover with a coverslip.

↓

Read slides immediately at 200-500X magnification on fluorescence microscope.

Cytomegalovirus/
CMV IFA

Immunofluorescence
Test Kit for the Detection
of CMV Antibodies

FOR *IN VITRO* DIAGNOSTIC USE

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