

Hướng dẫn sử dụng bản gốc

Tài liệu được cung cấp bằng tiếng Anh

Tài liệu được xác nhận bằng chữ ký số

Tp Hà Nội ngày 21 tháng 04 năm 2022

REF C88033M



2 × 50 Tests

CE 0123

INTENDED USE

The iFlash-CMV IgM assay is a paramagnetic particle chemiluminescent immunoassay (CLIA) for qualitative determination of IgM antibody to cytomegalovirus (CMV) in human serum and plasma using the iFlash Immunoassay Analyzer. The iFlash-CMV IgM aids in the diagnosis of Cytomegalovirus infection and the determination of immunity.

SUMMARY AND EXPLANATION

Cytomegalovirus (CMV) is a member of the herpes virus family, which is common in all human populations, causing infections followed by life-long latency in the host with occasional reactivation as well as recurrent infection. The prevalence of this antibody in adults ranges from 40-100 % in different populations. CMV infections are usually mild and asymptomatic. However, primary maternal CMV infection during pregnancy carries a high risk of intrauterine transmission, which may result in severe fetal damage, including growth and mental retardation, jaundice and CNS abnormalities.

The determination of CMV IgG and IgM antibodies is used to assess the serological status of an individual and is indicative for an acute or past infection for CMV. Positive samples for CMV IgM antibodies indicate an acute, recent or reactivated infection. The determination of the CMV IgG avidity can be used for analysis of a primary CMV infection. Positive IgM in combination with low IgG is a strong indication of a primary CMV infection within the last 4 months. CMV IgM and IgG also indicate serologicaevidence of active infection.

ASSAY PRINCIPLE

The iFlash-CMV IgM assay is an indirect immunoassay.

- 1st incubation: Anti-CMV IgM in the sample and CMV antigen-coated paramagnetic microparticles react to form a complex.
- Wash: The unbound materials are washed away from the solid phase in a magnetic field.
- 2nd incubation: Acridinium-labeled anti-human IgM conjugate is added to form a reaction mixture.
- Another Wash.
- Trigger of signal: The Pre-Trigger and Trigger Solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs).
- A direct relationship exists between the amount of anti-CMV IgM in the sample and the RLUs detected by the iFlash optical system.
- Results are determined by comparing the RLUs of each sample to the cutoff signal obtained from a previous calibration.

REAGENTS

Reagent kit, 100 tests, 2 packs, 50 tests/pack

	CMV recombinant antigen-coated
R1	paramagnetic microparticles, 3.5 mL/pack, 0.05% ProClin 300.
R2	Acridinium-labeled anti-human IgM conjugate; 6.5 mL/pack; 0.05% ProClin 300.
R3	Sample diluent, phosphate buffer, goat serum, 6.5 mL/pack; 0.05% ProClin 300.
CAL1	Calibrator 1, 1 bottle, 1.0 mL, tris buffer, protein stabilizers, 0.05% ProClin 300.
	Calibrator 2, 1 bottle, 1.0 mL, anti-CMV IgM
CAL2	in tris buffer with protein stabilizers, 0.05% ProClin 300.

MATERIALS REQUIRED (BUT NOT PROVIDED)

REF C89999/C89959/C89949, iFlash Pre-Trigger Solution: hydrogen peroxide solution.

REF C89998/ C89958/ C89948, iFlash Trigger Solution: sodium hydroxide solution.

REF C89997, iFlash Wash Buffer: phosphate buffered saline solution with 0.05% ProClin 300.

REF C80001, iFlash Wash Buffer (10×): phosphate buffered saline solution with 0.05% ProClin 300.

REF C89996, reaction vessels.

WARNINGS AND PRECAUTIONS

IVD For in vitro diagnostic use

- The calibrator (CAL2) and controls have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg, anti-HCV, anti-HIV-1/2 and anti-TP by approved methods.
- No known test method can offer the complete assurance that products derived from human sources will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious.
- Exercise the normal precautions required for handling all laboratory reagents.
- Disposal of all waste material should be in accordance with local guidelines.
- Wear gloves when handling specimens or reagents.
- Clean and disinfect all spills of specimens or reagents using a suitable disinfectant.
- iFlash Trigger solution contains sodium hydroxide (NaOH) and should be avoided contact with eyes.
- For further information on warnings and precautions, see Annex B.

REAGENT HANDLING

- The reagents may not be used after the stated expiration date.
- Avoid the formation of foam with all reagents.
- The reagents in the pack and calibrators are ready for

use.

- Close the bottles of calibrator right after calibration and store at 2-8°C.
- Do not pool reagents within a reagent kit or between reagent kits.
- Prior to loading the iFlash-CMV IgM reagent pack on the system for the first time, resuspend the microparticles by inverting the reagent pack slightly.
- For further information on reagent handling precautions during system operation, refer to the iFlash system operating instruction.

STORAGE AND STABILITY

Storage:

- Store at 2-8°C in an upright position.
- The kit may be used immediately after removal from 2-8°C storage.

Stability:

- Unopened at 2-8°C: up to the stated expiration date, 12 months.
- Opened at 2-8°C: 28 days.
- Store on-board: 28 days.

SPECIMEN COLLECTION AND PREPARATION

- Serum or plasma (lithium heparin, sodium heparin potassium EDTA, and sodium citrate) are the recommended samples. Other anticoagulants have not been validated for use with the iFlash CMV IgM assay.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation.
- Centrifuge the specimens.
- Store specimens at room temperature (20 to 25°C) for no longer than 8 hours.
- If the testing will not be completed within 8 hours, refrigerate the samples at 2 to 8°C.
- If the testing will not be completed within 14 days, or for shipment of samples, freeze at -20°C or colder.
- Frozen specimens must be mixed thoroughly after thawing.
- The samples may be frozen for maximum 3 times.
- Centrifuge specimens with a lipid layer on the top, and transfer only the clarified specimen without the lipemic material.
- Ensure that residual fibrin and cellular matter have been removed prior to analysis.
- Use with caution in handling patient specimens to prevent cross-contamination.
- Do not use heat-inactivated samples.
- Ensure that the patient samples, calibrators and controls are at ambient temperature (20-25°C) before measurement.
- Due to the possible evaporation, specimens and calibrators on the analyzers should be measured within 2 hours.

ASSAY PROCEDURE

- Refer to the system operating instruction or the online help system for detailed information on preparing the system.
- The test-specific parameters stored in barcode on the reagent pack are read in. In cases the barcode cannot be read, enter the sequence numbers.
- Carry out calibration, if necessary.
- Place the calibrators CAL1 and CAL2 in the calibrator rack in the sample zone. Only keep calibrators open during calibration.
- Test application.
- Load samples (10 µL of sample is needed for each determination in addition to the sample container and system dead volumes).
- Click RUN, the iFlash System performs all the functions automatically and calculates the results.

CALIBRATION

- Every iFlash-CMV IgM reagent kit has a QR code label containing the specific information for calibration of the particular reagent lot.
- To perform an iFlash-CMV IgM calibration, test CAL1 and CAL2 in duplicate and the software calculate the cutoff value based on the RLUs of the two calibrators and information from the two-dimension code.
- Once an iFlash-CMV IgM calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
 - After 28 days when using the same reagent lot.
 - A reagent kit with a new lot number is used.
 - Controls are out of range.
 - Required by pertinent regulations.

QUALITY CONTROL

Quality control materials should be run as single determinations at least once every 24 hours when the test is in use, once per reagent kit and after every calibration. Include commercially available quality control materials that cover at least two levels of analyte. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results.

RESULT

Calculation:

The iFlash system automatically calculates the analytic concentration of each sample. The results are given in AU/mL.

Interpretation of Results

- Nonreactive: < 18.0 AU/mL
- Indeterminate: ≥ 18.0 - < 22.0 AU/mL
- Reactive: ≥ 22.0 AU/mL

Individuals with nonreactive results indicate the absence of acute infection.

Samples with indeterminate result should be retested. In case the result is still indeterminate, a second sample should be collected within an appropriate period of time (e.g. 2 weeks).

A reactive result indicates acute infection. Such individuals are potentially at risk of transmitting CMV infection.

LIMITATIONS

- The iFlash-CMV IgM assay is limited to the determination of CMV IgM in human serum or plasma (lithium heparin, sodium heparin, potassium EDTA, and sodium citrate). It has not been validated for use with other types of plasma.
- The use of serum separator (gel) blood collection tubes has been validated for use with this assay; however it is not possible to survey all manufacturers or tube types.
- If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, the results should be interpreted in light of the total clinical presentation of the patient, including symptoms, clinical history results.
- Specimens from heparinized patients may be partially coagulated and erroneous results could occur due to the presence of fibrin.
- The results from an alternative assays (i.e. EIA or RIA) may not be equivalent and cannot be used interchangeably.
- The assay is unaffected by icterus (bilirubin < 30 mg/dL), hemolysis (Hb < 1500 mg/dL), lipemia (Intralipid < 1500 mg/dL) and total serum protein (< 10 g/dL).
- No interference was observed from anti-nuclear antibodies up to a concentration of 500 U/mL.
- No interference was observed from HAMA up to a concentration of 600 ng/mL.

PERFORMANCE CHARACTERISTICS

Below are the representative performance data, and the results obtained in individual laboratories may differ

Precision

The iFlash- CMV IgM is designed to have a precision of $\leq 10\%$ total CV.

Two serum samples, consisting low and high concentration of anti-CMV IgM were assayed.

The within run precision was determined by testing each sample in replicates of 10 (n = 10), and calculating percent coefficient of variation (%CV). The results of the study are shown below:

Sample	Mean (AU/mL)	SD	%CV
1	34.79	1.57	4.51%
2	98.51	3.97	4.03%

The between run precision was determined by testing each sample in duplicate, two separate runs daily for 20 days (n = 80), and calculating percent coefficient of variation (%CV). The results of the study are shown below:

Sample	Mean (AU/mL)	SD	%CV
1	14.59	0.91	6.24%
2	66.62	4.99	7.49%

Analytical Specificity

The analytical specificity of iFlash-CMV IgM assay was evaluated with viral antibody specimens. The nonreactive CMV IgM status of each specimen was verified using a commercially available CMV IgM assay.

Clinical Category	Number of Specimens Tested	iFlash CMV IgM Nonreactive
Toxoplasma gondii	5	5
Rubella Virus	5	5
Herpes Simplex Virus	5	5
Cytomegalovirus IgG	5	5
Epstein-Barr Virus	10	10
<i>Mycoplasma pneumoniae</i>	5	5
Rheumatoid factor	5	5
Total Samples Tested	40	40

Relative Sensitivity

Relative sensitivity of iFlash CMV IgM assay was determined by testing samples that were found reactive in a commercially available CMV IgM assay. A total of 153 samples including sequential and single samples were tested with iFlash CMV IgM assay.

Clinical Category	Number of Specimens tested	Number of Reactive Specimens	Relative Sensitivity
CMV infected	153	148	96.73%

Relative Specificity

Relative specificity of iFlash CMV IgM assay was determined by testing samples that were found nonreactive in a commercially available CMV IgM assay. A total of 345 samples were tested with iFlash CMV IgM assay.

Clinical Category	Number of Specimens tested	Number of Non-reactive Specimens	Relative Specificity
Hospitalized patients	345	343	99.42%

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ANNEX A:

Explanation of abbreviation

Abbreviation	Explanation
	Product No.
	Calibrator
	Reagent
	Number of tests
	Manufactured by
	EU Representative
	EC Declaration of Conformity
	Caution
	Instructions for use
	In vitro diagnostic medical device
	Lot No.
	Date of manufacture

	Expiry date
	Biohazard Symbol
GHS07 	Pictograms for Caution
GHS09 	Pictograms for Hazardous to the aquatic environment

ANNEX B:

WARNINGS AND PRECAUTIONS (Proclin 300)

- Hazardous Component: 0.05% Proclin 300
(Reaction mass of: 5-chloro-2-methyl-4-isothiazolin [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 200-239-6] (3:1))
- Hazard Statement:
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H410: Very toxic to aquatic life with long-lasting effects.
- Precautionary Statement:
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P264: Wash hands thoroughly after handling.
P272: Contaminated work clothing should not be allowed out of the workplace.
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.
P337+P313: If eye irritation persists: Get medical advice/attention.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P321: Seek immediate care from a doctor.
P363: Wash contaminated clothing before reuse.
P273: Avoid release to the environment.
P391: Collect spillage.
P501: Dispose of contents/container in a safe way.