

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 05 tháng 04 năm 2022

REF C88039M



2 × 50 Tests



INTENDED USE

The iFlash-HSV-2 IgM assay is a paramagnetic particle chemiluminescent immunoassay (CLIA) for the qualitative determination of IgM antibody to herpes simplex type 2 virus (HSV-2) in human serum and plasma using the iFlash Immunoassay Analyzer.

SUMMARY AND EXPLANATION

Herpes simplex virus 2 (HSV-2) is one member of the herpesvirus family, Herpesviridae, that infect humans. HSV-2 (which produces most genital herpes) is ubiquitous and contagious. HSV-2 is periodically shed in the human genital tract, most often asymptotically, and most sexual transmissions occur during asymptomatic shedding.

The clinical course of HSV infection is extremely variable, and may be mild enough to be unrecognized in a majority of cases. Clinically apparent infection may range from mild pharyngitis to severe generalized disease that causes death. The major clinical conditions associated with HSV infections are gingivostomatitis, keratitis and conjunctivitis, vesicular eruptions of the skin, aseptic meningitis, encephalitis, genital tract infections, and neonatal herpes. Infection in the newborn may be localized to the skin or generalized, seriously involving the central nervous system, eyes, and skin, as well as other organs.

The determination of HSV-2 IgM is utilized in the diagnosis of HSV-2 infection and as an aid in the diagnosis of herpes related disease.

ASSAY PRINCIPLE

The iFlash-HSV-2 IgM assay is an indirect immunoassay.

- 1st incubation: Anti-HSV-2 IgM in the sample and HSV-2 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-ester-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-HSV-2 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

| | |
|------|--|
| R1 | HSV-2 antigen-coated paramagnetic microparticles, 3.5 mL/pack, 0.05% ProClin 300. |
| R2 | Acridinium-ester-labeled anti-human IgM conjugate, 6.5 mL/pack; 0.05% ProClin 300. |
| R3 | Sample diluent, phosphate buffer, 6.5 mL/pack, goat anti-human IgG, 0.05% ProClin 300. |
| CAL1 | Calibrator 1, 1 bottle, 1.0 mL, tris buffer, human plasma in absence of HSV-2 IgM antibody, 0.05% ProClin 300. |
| CAL2 | Calibrator 2, 1 bottle, 1.0 mL, anti-HSV-2 IgM in tris buffer with protein stabilizers, 0.05% ProClin 300. |

MATERIALS REQUIRED (BUT NOT PROVIDED)

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

REF C89998, 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 calibrators (CAL1 and CAL2) and controls have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg, anti-HCV, and anti-HIV-1/2 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-HSV-2 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.
- 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-HSV-2 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 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 case 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 (20 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-HSV-2 IgM reagent kit has a QR code label containing the specific information for calibration of the particular reagent lot.
- To perform an iFlash-HSV-2 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 QR code.
- Once an iFlash-HSV-2 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 analyte concentration of each sample. The results are given in COI.

Interpretation of Results

- Nonreactive: COI < 0.9
- Indeterminate: COI ≥ 0.9 - < 1.1
- Reactive: COI ≥ 1.1

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 HSV-2 infection.

LIMITATIONS

- The iFlash-HSV-2 IgM assay is limited to the determination of HSV-2 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 < 1,500 mg/dL), lipemia (Intralipid < 1,500 mg/dL) and total serum protein (< 10 g/dL).
- No interference was observed from rheumatoid factors up to a concentration of 2,000 IU/mL.
- 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-HSV-2 IgM is designed to have a precision of $\leq 10\%$ total CV.

The precision of iFlash HSV-2 IgM was determined using HSV-2 IgM reagents, samples and controls. Samples consisting low and high concentration of anti-HSV-2 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 (COI) | SD | %CV |
|--------|------------|------|------|
| 1 | 1.98 | 0.11 | 5.56 |
| 2 | 3.05 | 0.12 | 3.93 |

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 (COI) | SD | %CV |
|--------|------------|------|------|
| 1 | 1.99 | 0.16 | 8.04 |
| 2 | 3.03 | 0.20 | 6.60 |

Analytical Specificity

The analytical specificity of iFlash-HSV-2 IgM assay was

evaluated with viral antibody specimens. The nonreactive HSV-2 IgM status of each specimen was verified using a commercially available HSV-2 IgM assay.

| Clinical Category | Number of Specimens Tested | iFlash HSV-2 IgM Nonreactive |
|----------------------|----------------------------|------------------------------|
| EB VCA IgM | 3 | 3 |
| HSV- 1IgM | 9 | 9 |
| HIV-1/2 | 6 | 6 |
| Toxo IgM | 4 | 4 |
| Rubella IgM | 5 | 5 |
| CMV IgM | 12 | 12 |
| HSV-2 IgG | 18 | 18 |
| Total Samples Tested | 57 | 57 |

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ANNEX A:

Explanation of abbreviation

| Abbreviation | Explanation |
|--------------|-----------------|
| REF | Product No. |
| CAL | Calibrator |
| R | Reagent |
| Σ | 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 |
|  | Pictograms for Caution |
|  | Pictograms for Hazardous to the aquatic environment |

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.

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.