Hướng dẫn sử dụng bản gốc

Tài liệu được cung cấp bằng tiếng Anh

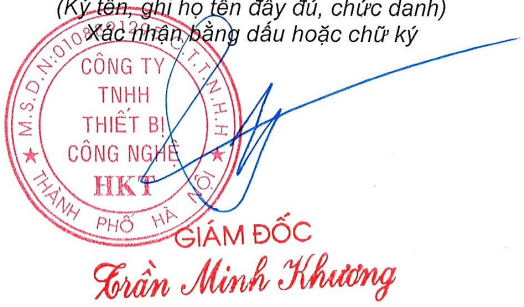
Tài liệu được xác nhận bằng chữ ký số

Tp Hà Nội ngày 18 tháng 04 năm 2022

Người đại diện hợp pháp của cơ sở

(Ký tên, ghi họ tên đầy đủ, chức danh)

Xác nhận bằng dấu hoặc chữ ký



REF **C88040G** **2×50 Tests** CE

INTENDED USE

The iFlash-HSV-1 IgG assay is a paramagnetic particle chemiluminescent immunoassay (CLIA) for the qualitative determination of IgG antibody to herpes simplex virus-1 (HSV-1) in human serum and plasma using the iFlash Immunoassay Analyzer.

The test is intended for use as an aid in the assessment of immune status and as an aid in the diagnosis of HSV infection.

SUMMARY AND EXPLANATION

Herpes simplex virus (HSV) is an enveloped, double-stranded DNA virus morphologically similar to other members of the *Herpetoviridae* family, containing HSV Type 1 (HSV-1) and HSV Type 2 (HSV-2). Recurrent infections often occur with both viral types despite the presence of circulating antiviral antibodies. HSV-1 generally infects the mucous membrane of the eye, mouth and mucocutaneous junctions of the face, and is also one of the most common causes of severe sporadic encephalitis in adults.

Rapid and accurate diagnosis of HSV infection is necessary to ensure early implementation of selective antiviral chemotherapy and to minimize spread of infection. The first humoral immune response to infection is the synthesis of specific anti-HSV IgM antibody which becomes detectable one week after infection. Specific IgG antibody generally appears two to three weeks after primary infection, but may fall in titre after a few months. Detection of IgG allows assessment of the patient's immune status and provides serological evidence of prior exposure to HSV. This may aid in the diagnosis of recent HSV infection in paired sera by the presence of seroconversion to HSV-1 or HSV-2 antibody.

ASSAY PRINCIPLE

The iFlash-HSV-1 IgG assay is an indirect immunoassay.

- 1st incubation: HSV-1 IgG in the sample and HSV-1 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 IgG 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 HSV-1 IgG in the sample and the RLUs detected by the iFlash optical system.

REAGENTS

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

R1	HSV-1 antigen-coated paramagnetic microparticles, 3.5 mL/pack, 0.05% ProClin 300.
R2	Acridinium-ester-labeled anti-human IgG conjugate, 6.5 mL/pack, 0.05% ProClin 300.
R3	Sample diluent, phosphate buffer, 6.5 mL/pack, 0.05% ProClin 300.
CAL1	Calibrator 1, 1 bottle, 1.0 mL, tris buffer with protein stabilizers, 0.05% ProClin 300.
CAL2	Calibrator 2, 1 bottle, 1.0 mL, HSV-1 IgG 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 C6100, 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 humanized 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-1 IgG 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-1 IgG assay.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. For patients undergoing heparin (anticoagulant) treatment, prolong the time for clot formation in serum specimens.
- Centrifuge the specimens.
- Store specimens at room temperature (20-25°C) for no longer than 8 hours.
- If the testing will not be completed within 8 hours, refrigerate the samples at 2-8°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.
- Centrifuge the specimens prior to test if clotted fibrin and cellular material exist, or after freeze-thawing.
- 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 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-1 IgG reagent kit has a QR code label containing the specific information for calibration of the particular reagent lot.
- To perform an iFlash-HSV-1 IgG calibration, test CAL1 and CAL2 in duplicate, the predefined master curve is adapted to the analyzer.
- Once an iFlash-HSV-1 IgG 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: < 0.9 COI
- Indeterminate: ≥ 0.9 - < 1.1 COI
- Reactive: ≥ 1.1 COI

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 past or acute infection. Such individuals are potentially at risk of transmitting HSV-1 infection.

LIMITATIONS

- The iFlash-HSV-1 IgG assay is limited to the determination of HSV-1 IgG 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.
- 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 AU/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-1 IgG is designed to have a precision of ≤10% total CV.

The precision of iFlash-HSV-1 IgG was determined using HSV-1 IgG reagents, samples and controls. Two serum samples, consisting low and high concentration of HSV-1 IgG 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	2.84	0.13	4.58%
2	13.21	0.65	4.92%

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	2.92	0.20	6.85%
2	13.32	1.00	7.51%

Analytical Specificity

The analytical specificity of iFlash-HSV-1 IgG assay was evaluated with viral antibody specimens. The nonreactive HSV-1 IgG status of each specimen was verified using a commercially available HSV-1 IgG assay.

Clinical Category	Number of Specimens Tested	iFlash-HSV-1 IgG Nonreactive
EB VCA IgG	6	6
HSV-2 IgG	9	9
HIV-1/2	6	6
Toxo IgG	7	7
Rubella IgG	11	11
CMV IgG	13	13
HSV-1 IgM	15	15
Total Samples Tested	67	67

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ANNEX A:

Explanation of abbreviation

Abbreviation	Explanation
REF	Catalogue number
CAL	Calibrator
R	Reagent

	Contains sufficient for <n> tests
	Manufacturer
	Authorized representative in the European Community
	CE Conformity Marking
	Caution
	Consult instructions for use
	In vitro diagnostic medical device
	Batch code
	Date of manufacture
	Use-by date
	Temperature limit (2-8°C)
	Biological risks
GHS07 	Pictograms for Caution
GHS09 	Pictograms for Hazardous to the aquatic environment
	This way up

AANNEX B:
WARNINGS AND PRECAUTIONS (Proclin 300)

- Hazardous Component: 0.05% Proclin 300

  (Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1))
- Hazard Statement:

  H317: May cause an allergic skin reaction.

  H410: Very toxic to aquatic life with long-lasting effects.
- Precautionary Statement:

  P261: Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

  P272: Contaminated work clothing should not be allowed out of the workplace.

  P273: Avoid release to the environment.

  P280: Wear protective gloves/protective clothing/eye protection/face protection.

  P302+P352: IF ON SKIN: Wash with plenty of soap and water.

  P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

  P321: Seek immediate care from a doctor.

  P363: Wash contaminated clothing before reuse.

  P391: Collect spillage.

  P501: Dispose of contents/container in a safe way.

  way.