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 15 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

GIÁM ĐỐC

Trần Minh Khương

REF C88006G **2×50 Tests** CE

INTENDED USE

The iFlash-EB VCA IgG assay is a paramagnetic particle chemiluminescent immunoassay (CLIA) for the quantitative determination of antibody to viral capsid antigen of epstein-barr virus in human serum and plasma using the iFlash Immunoassay Analyzer.

SUMMARY AND EXPLANATION

Epstein-Barr virus（EBV）is generally acquired by oral transmission of infected saliva and genital secretions. It is a worldwide infectious agent that is the classic cause of infectious mononucleosis (IM). IM is often diagnosed based on the presentation of characteristic symptoms of sore throat, lymphadenopathy and fever and intimately associated with several human tumors, including African Burkitt lymphoma, nasopharyngeal carcinoma, Hodgkin's disease, and B-cell lymphomas.

EBV infects B cells of immune system and epithelial cells. Most people become infected with EBV and gain adaptive immunity. The diagnosis of EBV infections can be characterized based on several distinct EBV-associated antigen systems. The acute phase of infectious mononucleosis is characterized by rapid IgM and IgG antibody responses to VCA. The IgG response to this antigen usually peaks during the acute illness, declines slightly over the next few weeks to months, and then persists at a relatively stable level for life.

ASSAY PRINCIPLE

The iFlash-EB VCA IgG assay is an indirect immunoassay.

- 1st incubation: EB VCA IgG in the sample and EB VCA 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 EB VCA IgG in the sample and the RLUs detected by the iFlash optical system.
- Results are determined via a calibration curve, which is instrument-specifically generated by 3-point calibration and a master curve provided via the reagent QR code.

REAGENTS

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

R1	EB VCA 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, EB VCA IgG in Tris buffer with protein stabilizers, 0.05% ProClin 300.
CAL3	Calibrator 3, 1 bottle, 1.0 mL, EB VCA 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 C89996, reaction vessels.

WARNINGS AND PRECAUTIONS

IVD For in vitro diagnostic use

- The calibrator (CAL2) has 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.
- However, as 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 avoid contacting 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 to use
- Do not pool reagents within a reagent kit or between reagent kits.
- Prior to loading the iFlash-EB VCA IgG reagent pack on the system for the first time, suspend 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-EB VCA IgG 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 3 times in maximum.
- 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 when handling patient specimens so as 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, CAL2 and CAL3 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

- Traceability: This assay is traceable to a commercial available kit.
- Each iFlash-EB VCA IgG reagent kit has a QR code label containing the specific calibration information of particular reagent lot.
- To perform an iFlash-EB VCA IgG calibration, test CAL1, CAL2 and CAL3 in duplicate, and the predefined master curve is adapted to the analyzer.
- Once an iFlash-EB VCA 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 new lot reagent kit is used.
  - Controls are out of range.
  - Required by pertinent regulations.

MEASURING RANGE

- 10-750 U/mL

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 U/mL

Interpretation of Results

- Nonreactive: < 20 U/mL
- Reactive: ≥20 U/mL

LIMITATIONS

- The iFlash-EB VCA IgG assay is limited to the determination of EB VCA 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.
- 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 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-EB VCA IgG is designed to have a precision of ≤10% total CV.

The precision of iFlash-EB VCA IgG was determined using EB VCA IgG reagents, samples and controls. Two serum samples, consisting low and median concentration of EB VCA 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 (U/mL)	SD	%CV
1	51.6	2.15	4.17%
2	421.6	15.86	3.76%

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 (U/mL)	SD	%CV
1	52.3	2.28	4.36%
2	419.2	27.88	6.65%

Analytical Sensitivity

The detection limit representing the lowest measurable analyte level is 10 U/mL, which can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard of the master curve (standard 1 + 2 SD, n = 20).

Analytical Specificity

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

Clinical Category	Number of Specimens	iFlash-EB VCA IgG Nonreactive
EB VCA IgM	3	3
EB NA IgG	5	5
VZV IgG	6	6
Toxo IgG	7	7
Rubella IgG	5	5
CMV IgG	13	13
HSV-1/2 IgG	8	8
Total Samples	47	47

Relative Sensitivity

Relative sensitivity of iFlash-EB VCA IgG assay was determined by testing samples that were found reactive in a commercially available EB VCA IgG assay. A total of 150 samples including sequential and single samples were tested with iFlash-EB VCA IgG assay.

Clinical Category	Number of Specimens tested	Number of Reactive Specimens	Relative Sensitivity
EB VCA infected	765	758	99.08%

Relative Specificity

Relative specificity of iFlash-EB VCA IgG assay was determined by testing samples that were found nonreactive in a commercially available EB VCA IgG assay. A total of 279 samples including blood donors and hospitalized patients were tested with iFlash-EB VCA IgG assay.

Clinical Category	Number of Specimens	Number of Non-reactive Specimens	Relative Specificity
Blood donors Hospitalized patients	208	205	98.56%

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ANNEX A:

Explanation of abbreviation

Abbreviation	Explanation
REF	Product No.
CAL	Calibrator
R	Reagent
Σ	Number of tests
	Manufactured by
EC REP	EU Representative
CE	EC Declaration of Conformity
	Caution
	Instructions for use
IVD	In vitro diagnostic medical device
LOT	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.