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

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 **C88051** Σ **2×50 Tests**

INTENDED USE

The iFlash-HIV Combo assay is a paramagnetic particle chemiluminescent immunoassay (CLIA) for the qualitative determination of Human Immunodeficiency Virus (HIV) P24 antigen, HIV-1(M/O) antibody and HIV-2 antibody in human serum and plasma using the iFlash Immunoassay Analyzer.

SUMMARY AND EXPLANATION

Acquired immunodeficiency syndrome (AIDS) is caused by two types of human immunodeficiency viruses, HIV-1 and HIV-2. Phylogenetic analysis classifies HIV-1 into groups M (major), N (non-M, non-O), and O (outlier). Group M viruses have spread throughout the world to cause the global AIDS pandemic. In contrast, groups N and O are relatively rare and endemic to West Africa. However, group O infections have been identified in Europe and the USA. Human immunodeficiency virus type 2 (HIV-2) is similar to HIV-1 in its structure, genomic organization, in vitro cytopathogenicity, transmission routes and ability to cause AIDS. HIV-2 is less pathogenic than HIV-1, and HIV-2 infections have a longer latency period, lower viral titers, and lower rates of vertical and horizontal transmission. HIV-2 is mainly found in West Africa, but it also has been identified in the USA, Europe, Asia, and other regions of Africa.

Serological cross-reactivity between HIV-1 and HIV-2 has been shown to be highly variable from sample to sample. This variability requires the inclusion of antigens to both HIV-1 and HIV-2 for the screening of antibodies to HIV-1 and HIV-2. The presence of HIV-1 and/or HIV-2 antibodies and/or p24 antigen in the blood indicates potential infection with HIV-1 and/or HIV-2. Early after infection with HIV, but prior to seroconversion, HIV antigens may be detected in serum or plasma specimens, e.g. the most common antigen - p24. The iFlash-HIV Combo can detect HIV-1, HIV-2 antibodies together with p24 antigen, which can shorten the sero-conversion window and improve early detection of HIV infection.

ASSAY PRINCIPLE

The iFlash-HIV Combo assay is an indirect immunoassay.

- 1st incubation: HIV Combo in the sample, antigen and antibody-coated 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 HIV antigen and antibody 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-HIV Combo 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	HIV-1/HIV-2 antigen and HIV P24 antibody-coated paramagnetic microparticles, 3.5 mL/pack, 0.05% ProClin 300.
R2	Acridinium-ester-labeled HIV-1/HIV-2 antigen and HIV P24 antibody conjugate; 4.0 mL/pack; 0.05% ProClin 300.
R3	Sample diluent, 4.0 mL/pack; 0.05% ProClin 300.
R4	Assay diluent, 4.0 mL/pack; protein stabilizers, 0.05% ProClin 300.
CAL1	Calibrator 1, 1 bottle, 1.0 mL, Human plasma, protein stabilizers, 0.05% ProClin 300.
CAL2	Calibrator 2, 1 bottle, 1.0 mL, HIV Combo in Human plasma 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 calibrators (CAL1and 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-TP by approved methods.
- However, no known test method can offer the complete assurance that products derived from humanized 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-HIV Combo reagent pack on the system for the first time, resuspend the microparticles by inverting the reagent pack.
- 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-HIV Combo 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.
- Centrifuged specimens with a lipid layer on the top, should be transferred 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 case the barcode cannot be read, enter the sequence numbers.
- Carry out calibration, if necessary.
- Place the calibrators CAL1and CAL2 in the calibrator rack in the sample zone. Only keep calibrators open during calibration.
- Test application.
- Load samples (110 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-HIV Combo reagent kit has a QR code label containing the specific information for calibration of the particular reagent lot.
- To perform an iFlash-HIV Combo 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-HIV Combo 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: < 1.0 COI
- Reactive: ≥ 1.0 COI

A nonreactive result indicates the sample is considered negative for HIV Combo.

A reactive result indicates the sample is considered positive for HIV Combo.

LIMITATIONS

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

The precision of iFlash-HIV Combo was determined using HIV Combo reagents, samples and controls.

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	11.77	0.55	4.67
2	10.81	0.40	3.70

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	23.38	1.50	6.42
2	55.82	4.09	7.33

Analytical Specificity

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

Clinical Category	Number of Specimens	iFlash-HIV Combo Nonreactive
Ⅰ/Ⅱ human T-lymphotropic virus	5	5
Influenza A virus	4	4
Hepatitis A virus	5	5
Hepatitis B virus	20	20
Hepatitis C virus	8	8
Cytomegalovirus	20	20
EB virus	10	10
Systemic Lupus Erythematosus	6	6
Rheumatoid factor	6	6
Antinuclear antibodies	6	6
Total Samples	90	90

Relative Sensitivity

A relative sensitivity of iFlash-HIV Combo assay was determined by testing samples that were found reactive in a commercially available HIV Combo assay. A total of 333 samples including sequential and single samples were tested with iFlash-HIV Combo assay.

Clinical Category	Number of Specimens	Reactive Specimens	Relative Sensitivity
Pre-screening Positive samples	333	333	100%

Relative Specificity

A relative specificity of iFlash-HIV Combo assay was determined by testing samples that were found nonreactive in a commercially available HIV Combo assay. A total of 969 samples were tested with iFlash-HIV Combo assay.

Clinical Category	Number of Specimens	Non-reactive Specimens	Relative Specificity
Blood donors	969	964	99.48%

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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
	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.