BIO TECHNOLOGY boditech

Infection

ichroma™ HIV Ag/Ab

INTENDED USE

ichroma™ HIV Ag/Ab is a fluorescence Immunoassay (FIA) for the qualitative determination of human immunodeficiency virus (HIV) in human whole blood/serum/plasma. It is useful as an aid in screening of HIV infection.

For *in vitro* diagnostic use only.

INTRODUCTION

The human immunodeficiency virus (HIV) belongs to lentiviruses that causes acquired immunodeficiency syndrome (AIDS).[1] Around 0.6% of the world's population is infected with HIV (about 36.9 million people) and 1.2 million people died of the disease. Approximately 2 million people were newly infected with HIV-in 2014. HIV is divided into two types, HIV-1 and HIV-2. AIDS is mainly caused by HIV-1 is highly toxic and infectious. HIV-2 is weakly toxic and infectious, mainly distributed in West Africa. HIV‑1 can be divided into 3 distantly related groups: group M (for main), group N and group O. This classification is constantly evolving due to the continued diversification of the virus, especially in connection with viral recombination.[2] The 4th-generation HIV test can diagnose HIV infection about 6 to 7 days faster than the existing 3rd-generation of HIV test by detecting p24 antigen of HIV together IgG and IgM antibodies against HIV.[3] ichroma HIV Ag/Ab, 4th generation of HIV test, can detect antibodies to HIV-1/2 and HIV-1 p24 antigen simultaneously in a single test.

PRINCIPLE

Dried antibodies in the detector tube, once diluted with the diluent, bind with antigens in the sample to form antigen-antibody complexes. These complexes then migrate through the nitrocellulose matrix and are captured by another sets of immobilized antibodies on the test line.

The more antigens in the sample, the more antigen-antibody complexes, which leads to a stronger fluorescence signal. This signal then is interpreted by the reader to display 'HIV Ag/Ab positive' in sample.

COMPONENTS

ichroma™ HIV Ag/Ab consists of 'Cartridges', 'Dried detection Buffer Tubes', 'Diluent vial' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has HIV-1/2 antigen and streptavidin at each test lines (1 and 2), with chicken IgY at the control line respectively.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains dried detection buffer. There are contain HIV-1/2 antigen, anti-p24-fluorescence conjugate, anti chicken IgY- fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline (PBS).
- The dried detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packed in an aluminum foil pouch.
- The diluent contains a detergent and bovine serum albumin (BSA) as a stabilizer and sodium azide in sodium borate buffer as a preservative. The diluent is dispensed in a vial.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer, diluent) should agree.
- Do not interchange test components between different lots or use test components after the expiration date, either of which might yield misleading of test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with applicable local requirement. A Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, the detector and the sample reach the room temperature by leaving them in the room for approximately 30 minutes at the least.
- **ichroma™ HIV Ag/Ab** as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests may produce minor vibration.
- Used detection buffer tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **ichroma™ HIV Ag/Ab** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ HIV Ag/Ab** should be used only in conjunction with instrument for ichroma™ tests.
  - Any anticoagulants other than **EDTA, heparin, sodium citrate** should be avoided.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in the original aluminum foil pouch) if stored at 4-30 °C.
- The dried detection buffer pre-dispensed in a tube is stable for 20 months if stored at 2-8 °C.
- The diluent dispensed in a vial is stable for 20 months if stored at 2-8 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antigens.
- The test may yield false negative result. The non-responsiveness of the antibodies to the antigens is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antibody unrecognizable by the antigens.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF CFPC-58

Components of **ichroma™ HIV Ag/Ab**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Aluminum Pouch containing Detection Buffer Tubes
  - Detection Buffer tubes (Dried) 25
- Dilution Buffer Vial Pouch
  - Diluent Vial 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ HIV Ag/Ab**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ II** REF FPRR021

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ HIV Ag/Ab** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20 °C.
- Samples stored frozen at -20 °C for 2 months showed no performance difference. However, the whole blood sample should not be kept in a freezer in any case.
- Once the sample was frozen, it should be thawed only once and only for test, because repeated freezing and thawing can result in the changed test values.

TEST SETUP

- Check the contents of **ichroma™ HIV Ag/Ab**: Sealed Cartridge, Detection Buffer Tubes, Diluent Vial and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the Instrument for ichroma™ tests.
- Insert the ID Chip into the ID chip port of the Instrument for ichroma™ tests**.**
- Press the 'Select' button on the Instrument for ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

1) Transfer 150 µL of diluent buffer to the detection buffer tube by using a pipette.
2) Transfer 30 µL of sample (whole blood/serum/plasma/control) using a transfer pipette to the detection buffer tube.
3) Mix well by pipetting 10-20 times. (The sample mixture must be used immediately.)
4) Pipette out 75 µL of a sample mixture and dispense it into the sample well on the cartridge.
5) Leave the sample-loaded cartridge at room temperature for 15 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
6) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
7) Tab the 'Start' icon on the screen.
8) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
9) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays "Positive"/"Negative"/ "Indeterminate".
- Ancillary value is served in the form of a cut-off index (COI).

Cut-off index (COI)	Result	Note
≤ 0.90	Negative for HIV Ag / Ab	No need to additional test.
> 0.90, < 1.0	Indeterminate	Need to retest.
≥ 1.0	Positive for HIV Ag / Ab	Need to confirmation test.

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **ichroma™ HIV Ag/Ab**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance. (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical Sensitivity**

- Antigen

To determine the limit of detection (antigen), the Meridian recombinant p24 antigen was tested with **ichroma™ HIV Ag/Ab**.

p24	Determine HIV-1/2 Ag/Ab combo	ichroma™ HIV Ag/Ab results	
		COI	CV (%)
8 IU/ml	Positive	2.57	8.6
4 IU/ml	Negative	1.74	10.1
2 IU/ml	Negative	1.31	13.5
1 IU/ml	Negative	0.64	67.4
0.5 IU/ml	Negative	0.42	81.1

- Antibody

To determine the limit of detection (antibody), the Seracare HIV-1/2 panel was tested with **ichroma™ HIV Ag/Ab**.

HIV-1	Determine HIV-1/2 Ag/Ab combo	ichroma™ HIV Ag/Ab results	
		COI	CV (%)
$1/2^{11}$	Positive	4.01	3.5
$1/2^{12}$	Positive	2.44	5.5
$1/2^{13}$	Positive	1.57	8.2
$1/2^{14}$	Negative	1.21	10.7
$1/2^{15}$	Negative	0.85	18.7

HIV-2	Determine HIV-1/2 Ag/Ab combo	ichroma™ HIV Ag/Ab results	
		COI	CV (%)
$1/2^6$	Positive	3.38	5.2
$1/2^7$	Positive	2.39	6.9
$1/2^8$	Negative	1.53	7.6
$1/2^9$	Negative	1.13	10.6
$1/2^{10}$	Negative	0.61	17.2

- **Analytical Specificity**

- Cross-reactivity
There was no significant cross reactivity from these materials with the **ichroma™ HIV Ag/Ab** test.

Clinical category	Results		
	Number of samples	Negative	Positive
CMV	19	19	0
EBV	20	20	0
HAV	28	28	0
HCV	10	10	0
HSV	19	19	0
Rubella	20	20	0
VZV	20	20	0
Syphilis	17	17	0
ANA	23	23	0
RF	23	23	0
Samples of pregnant women	39	39	0
Total	238	238	0

- Interference
There was no significant interference from these material with the **ichroma™ HIV Ag/Ab** test.

Materials	Concentration
Heparin	100,000 U/L
EDTA	5 µM
Sodium citrate	0.085 M
Bilirubin	500 µM
Hemoglobin	2 g/L
Triglycerides	1.5 mg/mL
Cholesterol	20 mM
Albumin	60 mg/mL

- **Precision**

- Between lot
One person tested three different lots of **ichroma™ HIV Ag/Ab**, ten times at each concentration of the control standard.
- Between person
Three different persons tested same lot of **ichroma™ HIV Ag/Ab**, five times at each concentration of the control standard.
- Between day
One person tested same lot of **ichroma™ HIV Ag/Ab** during three days, five times at each concentration of the control standard.
- Between site
One person tested same lot of **ichroma™ HIV Ag/Ab** in three different space, five times at each concentration of the control standard.

ichroma HIV Ag/Ab		Between lot		Between person		Between day		Between site	
		Positive /Number of tests	Positive rate (%)	Positive /Number of tests	Positive rate (%)	Positive /Number of tests	Positive rate (%)	Positive /Number of tests	Positive rate (%)
Negative		0/10	0	0/5	0	0/5	0	0/5	0
p24	Mid	10/10	100	5/5	100	5/5	100	5/5	100
	Low	10/10	100	5/5	100	5/5	100	5/5	100
HIV1	Mid	10/10	100	5/5	100	5/5	100	5/5	100
	Low	10/10	100	5/5	100	5/5	100	5/5	100
HIV2	Mid	10/10	100	5/5	100	5/5	100	5/5	100
	Low	10/10	100	5/5	100	5/5	100	5/5	100

- **Comparability with reference product**

		Reference product		
		Positive	Negative	Total
ichroma™ HIV Ag/Ab	Positive	100	1	101
	Negative	0	110	110
	Total	100	111	211

- Positive Comparability: 100 %
- Negative Comparability: 99.1 %
- Total Comparability: 99.5 %

REFERENCES

1. Emerging concepts in the immunopathogenesis of AIDS., Annu Rev Med, 2009; 60: 471-84.
2. A new subtype of human immunodeficiency virus type 1 (MVP-5180) from Cameroon. J Virol, 1994; 68(3): 1581-1585.
3. Reduction of Diagnostic Window by New Fourth-Generation Human Immunodeficiency Virus Screening Assays, J. Clin. Microbiol, 1998; 36: 2235-2239.

Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse

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