

Abbott Determine HIV Early Detect Point Of Care Test

Document Author/Reviewer	Clemora Wilkinson/Jane Mason
Document Owner	Rachel Lampard
Approved By	Rachel Lampard
Review Interval	2 years

Changes from last version of this document

Table of Contents

1	Purpose and Principle	3
2	Patient Preparation & Sample Requirements	3
3	Tasks, Responsibilities and Authorisations	4
4	Equipment	4
5	Chemicals and Reagents.....	4
6	Risk Assessment (Environmental and Safety Controls)	5
7	Calibration	5
8	Quality Control.....	5
9	External Quality Assurance (EQA).....	5
10	Procedural Steps.....	6
11	Reporting of Results	7
12	Reference Intervals	8
13	Performance Characteristics.....	8
14	Known Limitations	8
15	Related Forms/Templates and Documents	9
16	References.....	9

1 Purpose and Principle

Abbott (previously Alere) Determine HIV Early Detect test strips is an *in vitro*, visually read, qualitative immunoassay for the detection of for Antibodies (Ab) to HIV-1 or HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 Antigen (Ag) in human capillary and venous whole blood, plasma or serum. Therefore, any reactivity on 1) the Ab alone 2) the Ag alone or 3) both the Ag and Ab simultaneously is considered a reactive result suggestive of infection with HIV.

AIDS (Acquired Immunodeficiency Syndrome) is characterized by changes in the population of T-cell lymphocytes. In an infected individual, the virus causes depletion of helper T-cells, which leaves the person susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists as two related types known as HIV-1 and HIV-2. The presence of HIV first elicits the secretion of p24 antigen followed by the production of specific antibodies to either HIV-1 or HIV-2.

Method: The specimen mixes on the pad with biotinylated anti-p24 Ab and selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O Ag, synthetic HIV-2 peptide and anti p24 mouse monoclonal Ab. This mixture continues to migrate through the solid phase to the immobilized recombinant HIV-1/HIV-1 group O Ag and synthetic HIV-1/HIV-2 peptides at the Ab window, immobilized avidin at the Ag window. If Ab to HIV-1 and/or HIV-2 are present they will bind, forming a red band at the Ab window site. If free HIV-1 p24 Ag present it will bind to form a red band at the Ag window site. To ensure assay validity, a procedural control band is incorporated in the assay device at the 'control' window.

Scope: This standard operating procedure is written to allow the use of point of care HIV testing in the following situations

- Clinic setting where a rapid turnaround of the results is desirable
- Community testing sites
- Urgent source testing in the cases of exposure incidents
- Needle phobic patients

2 Patient Preparation & Sample Requirements

- 50uL of sample is required to fill the test strip
- Fingerprick whole blood capillary should be analysed immediately
- Venous/capillary whole blood taken into EDTA labelled with patient details can be stored at 2-8C for 7 days
- Serum/plasma labelled with patient details can be stored at 2-8C for 7 days
- Serum/plasma samples labelled with patient details can be frozen after 7 days at -20C or below, but avoid freeze/thaw cycles
- Bring samples to room temperature before analysis
- No other anti-coagulants should be used

3 Tasks, Responsibilities and Authorisations

- A log of training is recorded in Cobas as a certificate. 2 yearly recertification is required to maintain competency.

Tasks	Responsible	Authorised
HIV testing on Abbott Determine Early Detect Kit	Trained healthcare professionals	Signed off by POCT team or HIV link trainer signed off by POCT
HIV testing on Abbott Determine Early Detect Kit	Trainee and student healthcare professionals	Must only carry out tests under direct supervision of trained and competent HIV test kit user

4 Equipment

- Abbott Determine HIV Early Detect 20 Test incl buff& Capil: SB0119
 - This includes Determine HIV Early Detect Test Device (7D2846) (10 tests/card, 2 cards/pack)
- Chase buffer 100T (2.5mL): 7D2243
- EDTA capillary tubes (7D2227)
- Kits are stored at 2-30°C until expiry date stated on the packaging
- Kits are ordered by the POCT team at York Hospital contact 01904 725890 or yhs-tr.POCT.Team@nhs.net

5 Chemicals and Reagents

The Safety Data Sheet MSDS does not highlight any specific hazards.

The test strips are impregnated with dried reagent:

EC Classification No. 1272/2008

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	EC Classification and Risk Phrases	%W/W
Triton X-100*	9002-93-1	-	Not available	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411	0.1 - 0.5

There is no reagent preparation involved with this test.

Strips should be handled and disposed of as per local guidance for clinical & chemical waste.

6 Risk Assessment (Environmental and Safety Controls)

See : PC/RA/YS-2 for specific risk assessment for use of this test.



Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

N/A – there is no calibration required for this test kit.

8 Quality Control

- Each test strip has a procedural control window incorporated into the device to assess validity. If no control line visible the test is invalid and should be discarded.

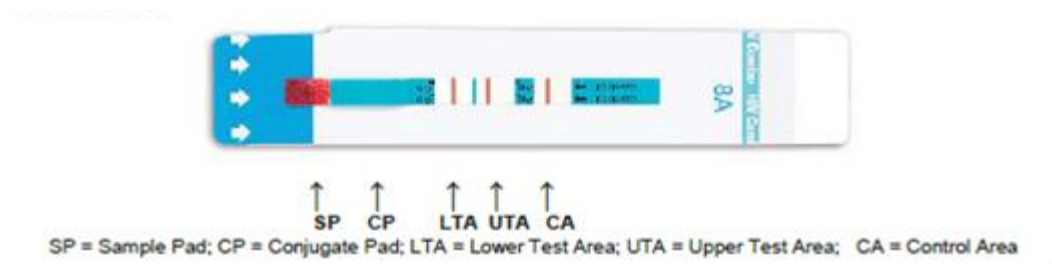
9 External Quality Assurance (EQA)

- External Quality Assurance (EQA) by WEQAS. Samples are sent out every 2 months from POCT on behalf of the national EQA scheme provider. Performance is monitored by the POCT team.

10 Procedural Steps










The sample may be taken at the same time as the samples obtained for other laboratory tests. Please keep all samples together until the rapid HIV test has been completed. Ensure testing takes place in a well-lit area.

1. Remove the desired number of test strips from the test card by tearing at the perforation from the right hand side to preserve the kit lot number (NB: we recommend having a timer ready)
2. Ensure samples have come to room temperature prior to analysis and are thoroughly mixed
3. Remove the protective foil seal from the strip (strip must be used within 30 minutes of foil removal)



4. For whole blood capillary using EDTA Capillaries collection:
 - a. Confirm correct patient and obtain verbal consent by explaining the procedure.
 - b. Ensure your own PPE
 - c. Choose finger for sampling
 - d. Clean patients' hands and finger with alcohol and allow to dry
 - e. Use a single use lancet to puncture the finger
 - f. Wipe away the first drop of blood with a sterile gauze
 - g. With the finger held lower than the elbow, apply gentle intermittent pressure to the base of the punctured finger several times.
 - h. Touch the tip of the EDTA capillary tube to the drop of blood – avoiding air bubbles
 - i. Fill the tube with blood between the 2 marked lines
 - j. Place the capillary tube containing 50uL blood sample onto the HIV strip sample pad, allowing all blood to transfer before lifting the capillary away to prevent bubble formation (this can cause invalid results)
 - k. Immediately apply 1 drop of Chase Buffer to the sample pad holding the bottle upright vertically
 - l. Wait a minimum of **20 minutes** from addition of sample (**up to 40 minutes**) and read result
5. For serum/plasma samples:
 - a. Apply 50uL of sample to the sample pad marked by the arrow
 - b. Wait a minimum of **20 minutes** from addition of sample (**up to 40 minutes**) and read result
6. Dispose of sample, capillary tube and used strip in clinical chemical waste as per local guidance.

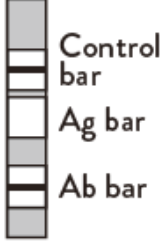
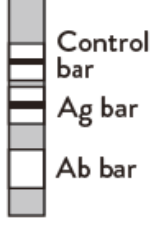
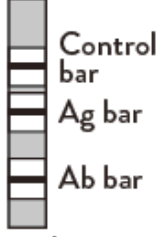
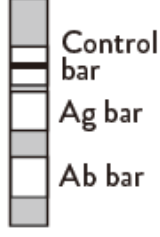
11 Reporting of Results

Line	Reactive	Non-reactive	Invalid
Control			
Ag			
Ab			

NB: all results should be read by two trained members of staff

Do not read test strip after 40 minutes

- To ensure validity of the test there **MUST** be a line visible in the Control 'C' zone of the strip. If there is no line visible here at the end of the test the test is invalid and should not be reported. Repeat the test with a fresh strip
- Any reactivity line, however dark or faint, on **1)** the Ab area alone **2)** the Ag area alone or **3)** both the Ab and Ag area is considered a reactive result suggestive on infection with HIV.

<p>1) ANTIBODY REACTIVE – red line in control window 'C' and in antibody window 'Ab'</p>  <p>Antibody Reactive</p>	<p>2) ANTIGEN (p24) REACTIVE – red line in control window 'C' and in antigen window 'Ag'</p>  <p>Antigen Reactive</p> <p>The presence of only an antigen response suggests that the infection is at an early stage.</p>
<p>3) ANTIBODY AND ANTIGEN (p24) REACTIVE – red line in control window 'C', in antibody window 'Ab' and in antigen window 'Ag'</p>  <p>Antigen and Antibody Reactive</p>	<p>NON-REACTIVE – red line in control window 'C' ONLY. If no red lines appear, the test is invalid.</p>  <p>Non-Reactive</p>

- Record result in the patients' sexual health hospital notes, signed by both members of staff who read the test
- All reactive results must be relayed to a member of the HIV team by the staff reporting the POC HIV test
- Confirmatory tests should be sent to the microbiology laboratory with a request form with:
 - Result, kit lot number and expiry of POC HIV test written on the form
 - Mark samples as urgent if POC HIV = reactive, mark samples as routine if POC HIV = non-reactive
 - Needle phobic patients may deny laboratory confirmation if POC HIV results were non-reactive, but all reactive results MUST be confirmed with the microbiology lab
- Inform patient of the POC HIV test result and that confirmation venous sample has been sent to the lab which can take 7-10 days, if the result was reactive inform patient that there is rate of approximately 1% of false reactive results on a POC HIV test.

12 Reference Intervals

N/A – qualitative results

13 Performance Characteristics

Manufacturer states:

- Antibody diagnostic sensitivity on HIV Ab positive specimens (n=682) = 100%
- Analytical sensitivity of HIV-1 p24 Ag = 2IU/mL
- Specificity (n=2469): 99.6% for Ab line, 99.76% for Ag line
- See PC/VV/YS-1 for inhouse verification, available on request from POCT Coordinator.

14 Known Limitations

- Other bodily fluids not stated in this SOP or kit insert should not be used.
- No anticoagulants other than those stated in this SOP or kit insert should be used.
- Do not use on infants 18months and younger.
- Known HIV- positive patients taking anti-retroviral medication have been shown to produce false negative results when tested by rapid diagnostic tests.
- Biotin >20mg per day may lead to decreased Ag line intensity. Biotin concentration up to 200 ng/mL in serum or plasma did not impact sensitivity. There is no impact to Ab line by biotin
- The intensity of the Ab and Ag bars does not necessarily correlate to the titer of antibody and antigen in the specimen, respectively.
- A positive result for antibodies to HIV with a negative result for p24 antigen does not preclude the possibility of acute infection.
- A negative result does not exclude the possibility of infection with HIV in the following cases:
 - Very low levels of Ag/Ab in the very early stages of infection
 - When high levels of Ab against the p24 antigen are present in the blood after seroconversion, the antibodies tend to bind to the antigens, forming immunocomplexes. Determine HIV Early Detect detects only non-immunocomplexed (free) antigens; it does not detect immunocomplexed (bound) antigens.

15 Related Forms/Templates and Documents

- PC/FOR/YS-30 Audit sheet
- PC/COM/YS-9
- PC/RA/YS-2
- PC/INF/YS-30 Link trainer guide
- PC/VV/YS-1

16 References

- The test IFU can be found with each strip of test kits and can be obtained directly from Abbott
- Abbott Determine HIV kit insert (PC/ED/YS-15)
- Abbott Determine verification (PC/VV/YS-1)
- COSHH information in MSDS is available from manufacturer or can be requested from POCT (saved in X Drive > Biochemistry > POCT > HIV)