Related Documents	
COSHH	anti HIV controls COSHH_167169 Chase buffer_COSHH_167192
Risk Assessments	POCT HIV Testing RA
Others	HIV POCT Results Register

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Significant changes from previous version:
Addition of results reporting responsibilities

Purpose
To describe the use of Determine® HIV-1/2 Ag/Ab Combo strips for HIV Ag/Ab detection using capillary whole blood *(fingerstick collection)*.

Clinical indications
Detemine® HIV-1/2 Ag/Ab Combo is an *In Vitro*, visually read, qualitative immunoassay for the simultaneous detection of HIV p24 antigen *(Ag)* and antibodies *(Ab)* to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect HIV antigen and antibodies to HIV-1/HIV-2 from infected individuals.
Acquired Immunodeficiency Syndrome *(AIDS)* is characterized by changes in the population of T-cell lymphocytes. In an infected individual, the virus causes depletion of helper T-cells, which leave the person susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists as two related types know 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.

Principles of method
Determine® HIV-1/2 Ag/Ab Combo is an immunochromatographic test for the qualitative detection of p24 antigen and antibodies to HIV-1 and HIV-2.
Specimen is added to the sample pad. The specimen mixes with a biotinylated anti-p24 antibody and selenium colloid-antigen conjugate. This mixture continues to migrate through the solid phase to the immobilized avidin, recombinant antigens and synthetic peptides at the patient window sites.
If antibodies to HIV-1 and/or HIV-2 are present in the specimen, the antibodies bind to the antigen-selenium colloid-antigen and to the immobilized recombinant antigens and synthetic peptides, forming one red bar at the patient HIV Antibody window side. If antibodies to HIV-1 and/or HIV-2 are absent the antigen-selenium colloid flows past the patient window, and no red bar is formed at the patient HIV Antibody window site.
If p24 antigen is present in the specimen, the antigen binds to the biotinylated anti-p24 from the sample pad and the selenium colloid anti-p24 antibody and it binds to an immobilized avidin forming a red bar at the

patient HIV Antigen window site. If p24 antigen is not present both the biotinylated anti-p24 and selenium colloid anti-p24 antibody flow past the patient window, and no red bar is formed at the patient HIV Antigen window site.
To ensure assay validity, a procedural control bar is incorporated in the assay device.

Specimen requirements.

The test requires a 50ul whole blood.

Reagents

The POCT Team is responsible for ordering reagents through a POCT Managed Service Contract. Stocks of all reagents are kept in the laboratory within the Department of Sexual Health on ext: 2626.

Third Party Supplier of HIV kits and consumables:
Alere Ltd
Pepper Road
Hazel Grove
Stockport
SK7 5BW
United Kingdom

The Reagents and lancets are obtained from Roche Diagnostics on a monthly standing order.

Roche Diagnostics Ltd
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY
United Kingdom

Determine HIV 1/2 Ag/Ab Combo strips
Determine® HIV-1/2 Ag/Ab Combo 20 Test *(7D2646)* or 100 Test *(7D2647)*

- Determine® HIV-1/2 Ag/Ab Combo Test Card, 2 or 10 cards *(10tests/card)* coated with HIV-1/2 recombinant antigen and synthetic peptides, anti p24 antibodies and avidin.

For testing Whole Blood samples
Chase Buffer_1 bottle *(2.5mL)* Chase Buffer *(7D2243)* prepared in phosphate buffer. Preservatives: Antimicrobial Agents.
Whole Blood *(fingerstick assay)*
EDTA Capillary Tubes 7D2227
Roche Safe T Pro Lancets

Quality Control

To ensure assay validity, a procedural control is incorporated in the device and is labelled “Control”. Any visible line (even very faint) in the control window should be interpreted as a valid result. If the control bar does not turn red by assay completion, the test result is invalid and the sample should be retested.

Internal Quality Control

Positive and negative controls must be performed weekly. Controls (serum) are provided by the Virology department. Analyse the solutions as for patient samples (no chase buffer required for serum samples) and record the results in the Internal Quality Control Log Book. If the results do not give the expected positive or negative result, DO NOT use the test strips. Contact GUM lab/POCT staff immediately. See Contact Details for a list of support staff.

External Quality Control
The GUM POCT HIV service is enrolled on both the quarterly NEQAS (Ab) and bimonthly WEQAS (Ab/Ag) EQA schemes.

Performing a patient test.

Specimen Collection
The blood is collected, via fingerstick, into an anticoagulant *(EDTA - ethylenediaminetetraacetic acid)* coated capillary tube. The test is performed immediately after collection.
A clean collection tray must be used for each procedure.

Have all test requirements at hand:
EDTA capillary tube
Finger lancets
Test Strip

Method
Only staff who has received training from GUM/Virology can use the Determine HIV-1/2 Ag/Ab combo strips.

1. Obtain informed consent. Staff member wash hands and cover any cuts/grazes etc with a waterproof dressing, put on a pair of protective gloves/PPE.
2. Remove test cards from foil pouch.
3. Check expiry date on Determine™ HIV1/2 Ab/Ab test card to check it is in date.
4. Remove the test strip starting from the right hand to preserve the lot number which appears on the left hand side.
5. Peel back the cover from the test strip, indicated by a triangle.
6. Lay on contained *(e.g tray)* flat surface at room temperature.
7. Add 50ul of whole blood *(fingerstick or venous)* serum or plasma using capillary tube.
8. If using whole blood, leave for one minute and then add 1 drop of chase buffer from the dropper bottle *(if using serum or plasma, skip this step and directly to the next step 1.10)*.
9. Leave on a flat surface at room temperature, start timer for 20 minutes
10. Read the results after 20 minutes(30 minutes max) and interpret according to Rapid HIV Screening Guide – Reading and Interpretation of Test. Results to be verified by 2 persons, at least one being a BMS.
11. Dispose of the test strip and all other contaminated material in the clinical waste.
12. Record the patient result in his/her medical records and logbook.
13. Communicate the result to the patient following the Clinic and CDC Guidelines as outlined in the Rapid HIV Screening Guide.

Invalid Test – if appropriate repeat POCT or collect venous blood and send to Virology for HIV test.

Reactive Test – Collect venous blood and send to Virology for confirmation.
Confirmation Test – Positive venous samples from GUM should be confirmed using POCT Determine testing strips.

Reporting results

Responsibilities of personnel in authorising reporting and monitoring reports:

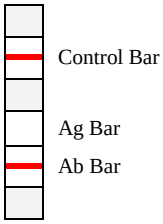
(i) Users are responsible for ensuring results are communicated to the relevant member of staff (Doctor or Senior nurse), as highlighted in training and in accordance with the Trust POCT Policy.

(ii) Users are also responsible for ensuring results are recorded in the patient notes, in accordance with the Trust POCT Policy.

(iii) Any therapeutic decision based on the POCT result is the responsibility of the Clinical Director, as highlighted in the Trust POCT Policy.

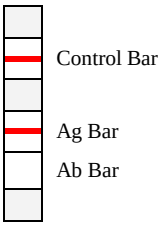
Interpretation of Results

ANTIBODY REACTIVE *(Two Bars – Control and Ab Bars)*
Red bars appear in both the control window *(labelled "Control")* and in the Ab bar window *(labelled "Ab")* of the strip. Any visible red *(or grey-red)* colour in the patient window should be interpreted as positive.



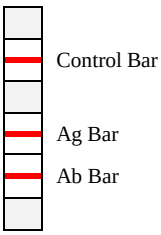
Antibody Positive

ANTIGEN *(p24)* REACTIVE *(Two Bars – Control and Ag Bars)*
Red bars appear in both the control window *(labelled "Control")* and in the Ag bar window *(labelled "Ag")* of the strip. Any visible red *(or grey-red)* colour in the patient window should be interpreted as positive. The presence of only an antigen response suggests that the infection is at an early stage. Follow up testing may be suggested in order to track the expected future detection of antibodies.



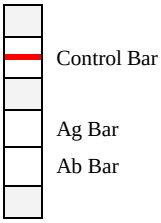
Antigen Positive

ANTIBODY REACTIVE AND ANTIGEN *(p24)* REACTIVE *(Three Bars – Control, Ab and Ag Bars)*
Red bars appear in both the control window *(labelled "Control")*, the Ab bar window *(labelled "Ab")* and Ag bar window *(labelled "Ag")* of the strip. Any visible red *(or grey-red)* colour in the Ab bar and Ag bar windows should be interpreted as positive. The presence of an antigen response suggests that the infection is at an early stage.



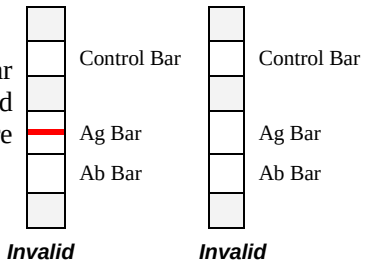
Antigen & Antibody Positive

NEGATIVE *(One Bar)*
One red bar appears in the control window of the strip *(labelled "Control")*, and no red bar appears in the patient windows of the strip *(labelled "Ag" and "Ab")*



Negative

INVALID *(No Bar)*
If there is no red bar in the control window of the strip and even if a red bar appears in one of the patient windows of the strip, the result is invalid and should be repeated. If the problem persists, contact your local distributor or call Alere Technical Support on:
+44 (0) 1234 835959 or email: product.support@invmed.com.



NOTES:

- The tests result is positive even if the patient bars appear lighter or darker than the control bar.
- If an invalid test result occurs repeatedly, or for technical assistance, contact your local distributor or call Technical Support as detailed above.

Turnaround Time
POCT HIV Tests results available the same day.

Storage and stability
Determine® HIV-1/2 Ag/Ab Combo Test Cards and Chase Buffer must be stored at 2-30°C until expiration date.

- Kit components are stable until expiration date when handled and stored as directed. Do not use kit components beyond expiration date.
- Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing seal from end to end to close.
- Do not use devices that have become wet or if the packaging has become damaged.

Health and Safety
The HIV testing kits and consumables must be treated as biohazardous waste. Users must be aware that any object being exposed to human blood is a potential source of infection. To reduce the risk of infection users must:

- Wear gloves
- Do not pipette by mouth.
- Clean and disinfect all spills of specimens or reagents using suitable disinfectant, such as 0.5% sodium hypochlorite, or other suitable disinfectant.
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in yellow bags for incineration.
- Use a new lancet for each patient. Dispose of used lancets in yellow sharps container.

Performance criteria
The performance of Determine® HIV-1/2 Ag/Ab Combo has been determined by testing specimens from random blood donors, from patients with HIV infection or in other clinical categories and commercial seroconversion panels. The performance evaluations were conducted in nine clinical studies in Europe, Africa, Asia and South America.

Limitations of the Procedure

Determine® HIV-1/2 Ag/Ab Combo is designed to simultaneously detect antibodies to HIV-1 and/or HIV-2 and HIV p24 antigen in human serum, plasma and whole blood. Other body fluids or pooled specimens may not give accurate results and should not be used.

The intensity of the Ab and Ag bars does not correlate to the titer of antibody and antigen in the specimen.

No test provides absolute assurance that a specimen does not contain low levels of HIV p24 antigen and/or antibodies to HIV-1 and HIV-2 such as those present at a very early stage on infection. A negative result for both antibodies to HIV and p24 antigen does not preclude the possibility of exposure to/or infection with HIV-1 or HIV-2 viruses. A positive result for antibodies to HIV with a negative result for p24 antigen does not preclude the possibility of acute infection.

Positive results should be confirmed using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made.

Adverse Incident Reporting

Report any adverse incident to Departmental/Ward Manager, Clinician or POCT.

Quarantine both the test kit and chase buffer and send to the POCT Team, Clinical Chemistry Department Tel ext 5587

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Severe incidents should be reported on the internal DATIX system.

Health and safety

All COSHH and risk assessment documents for POCT HIV testing are available from POCT if required (see contacts).

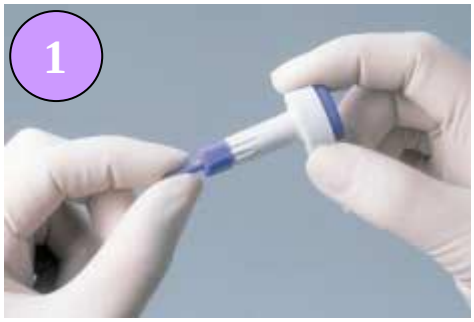
Contact details

Specialty Manager, Virology Karen Scott	Tel ext 4719
GUM Lab Team Leader, Pam Roberts	Tel ext 2626
Matron, Liverpool Centre for Sexual Health (GUM) Kathy Jones	Tel ext 2644
Trust POCT Manager Kath Ashton	Tel ext 5587

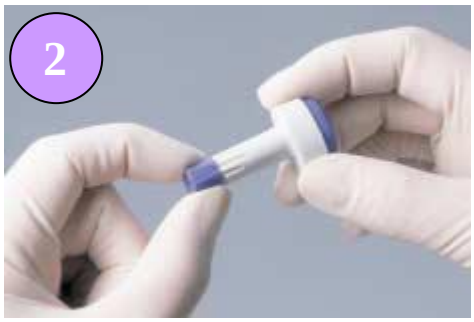
ACCU-CHEK® Safe-T-Pro Plus Lancets

Quick Reference Guide

Three simple steps:

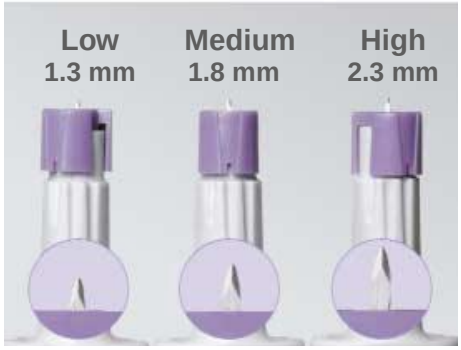


Hold the device and twist off the sterility cap by twisting it in either direction.
Throw the sterility cap away.



The depth adjuster is preset at medium depth: Select the depth you want by turning the depth adjuster.

Ensure the finger is clean and dry (soap and water).
Hold the Accu-Chek Safe-T-Pro Plus firmly against the side of the finger and press the purple button.



Dispose of used lancets into a sharps container