

BASHH Clinical Governance Committee

Guidance on the appropriate use of HIV Point of Care Tests

What is a “rapid HIV test”?

- This document deals with the practical and ethical implications of rapid ‘Point of care (POC)’ HIV tests using rapid test devices (RTD). These deliver results within about 20 minutes of a specimen being taken, so results are available within a single consultation.
- RTDs are typically capillary flow tests for use on whole blood (e.g. fingerprick), plasma or oral fluid. They detect HIV antibodies against HIV 1 and 2 antigens produced by oligopeptide synthesis or recombinant DNA technology. They are easily read by users and require no specialised equipment. Not all RTD are usable at the point of care (eg they require serum separation but still give results in a few minutes). ‘Rapid’ tests are not suitable for screening large numbers of people.

What tests are available?

- In the UK as of June 2006 at least four anti-HIV RTDs/POCTs marketed (see *appendix*).¹ These are:
 - Abbott Rapid Determine HIV-1/2
 - Core Diagnostics HIV 1 & 2
 - INSTI [™] HIV Antibody test
 - MiraCare [™] Rapid HIV Antibody Test
- All four devices carry the CE mark. The CE mark is a declaration by the manufacturer that the product meets all of the appropriate requirements of the In Vitro Diagnostic (IVD) Medical Device Directive (98/79/EC). It is illegal to place on the market or supply in the EU any IVD that is not CE marked.
- All the above require a finger-prick (whole-blood) sample or serum. There are no CE marked devices for rapid HIV testing on oral fluid, although OraQuick *ADVANCE* Rapid HIV-1/2 Antibody Test is marketed in the US for this purpose.

How do these tests compare to traditional laboratory tests?

- In the UK nineteen HIV RTDs have been evaluated by MIDAS². Of those evaluated only Abbott Determine HIV-1/2 and Core Diagnostics HIV 1&2 RTD are marketed.^{3,4}
- RTDs are generally satisfactory for detection of uncomplicated HIV infection (or its absence), but are less sensitive than lab-based EIAs and automated systems for detecting early infections (seroconversion). For example, with a seroconversion panel, Abbott Determine detected HIV about 3 days later than the most sensitive HIV antibody-only EIA tests.³
- Specificity of RTDs is lower than conventional EIAs although it can be improved by immediate repeat of all RTD positives. For example, Abbott Determine achieved a specificity of 99.4%.³
- In a low prevalence population of 0.1% (typical background UK HIV prevalence) a specificity of 99.4% leads to a positive predictive value (PPV) of just 14%. That is, six of every seven positive tests are false positives. PPV improves with rising prevalence, being 97% with a prevalence of 15% (typical HIV prevalence in London gay men). All positive rapid tests must be confirmed with conventional EIA testing.⁵

- Rapid tests are not suitable for screening large numbers of people as there is a limit to the number of tests that one user can read at any one time. Automated laboratory EIA testing is more suitable.

What situations are suitable for rapid HIV testing?

- **GUM clinics:** Rapid HIV tests provide a reliable negative result that allows the health care professional to complete HIV counselling and testing during a single visit. Rapid testing may also reduce the problem of patients failing to return to collect their positive results.
- **Obstetric settings:** especially women with risk factors for HIV infection but no recorded HIV status presenting in established labour where immediate decisions are needed on antiretroviral prophylaxis.
- **Health care worker occupational exposure:** where rapid testing of the source patient with consent may lead to early discontinuation of or prevent the need for post-exposure prophylaxis.
- **Outreach settings:** where specific services are established for at-risk populations, rapid testing removes the barrier of contacting the patient later with results.
- **Individuals presenting for PEPSE (post-exposure prophylaxis for sexual exposure):** where rapid testing is recommended to prevent inadvertent and unplanned treatment of pre-existing HIV infection.⁶

What practical implications are there with rapid HIV testing?

- HIV testing may not be reliable in the 'window' period and appropriate repeat testing should be advised. No currently available RTDs incorporate HIV p24 Ag detection in contrast to the commonly used conventional combination EIA laboratory tests which are more sensitive in early HIV infection.
- Operators require adequate training in safe handling and test interpretation. For example, the Abbott Determine test uses a glass capillary tube to obtain the correct amount of fingerprick blood, raising a potential risk of staff injury. One clinic uses an EDTA sample and a plastic pipette to minimise this risk.⁷ INSTI HIV Ab test has a plastic pipette pre-packed. Weakly reactive tests could be hard to read especially in some non-clinical outreach settings.
- Anyone using a near-patient rapid anti-HIV test requires training in giving positive HIV results and knowledge of appropriate local care pathways. These are often implicit in traditional laboratory results pathways where there is time to seek advice, e.g. by contacting a local HIV specialist, and if necessary arranging a skilled person to break the news.
- GUM clinics may be assessed by Clinical Pathology Accreditation UK (CPA UK) as part of an application for CPA by their local microbiology service. CPA state that the use of a nurse for interpretative work is not 'necessarily' inappropriate providing adequate training has been given and support is available. The CPA does not approve of non-state registered medical laboratory assistants performing such work.⁸
- The Medicines and Healthcare products Regulatory Agency (MHRA) recommends the formation of a multi-disciplinary POC test service committee, that includes representation from clinicians, nursing staff, health advisors and pathology services, and meets the following objectives:
 - establishes a system for auditing the service
 - sets up a process for quality control

- ensures that internal quality control and external quality schemes are employed effectively (NB standard IQCs for conventional EIA/automated systems are not suitable for RTDs)⁹
 - ensures that users are trained and certified in the use of POC HIV test
- Costs involved in establishing the service will include:
 - testing kits and consumables
 - accreditation scheme compliance
 - staff training
 - operator time
- The Institute of Biomedical Science has produced a helpful leaflet outlining practical help available from laboratory colleagues in setting up a PoC testing service which particularly focuses on training and quality control.¹⁰

What ethical implications are there with rapid HIV testing?

- Ease of testing might lead to people being tested without their voluntary, specific, informed consent. This is a particular risk where patients are anaesthetised (eg occupational exposure) or unable to communicate (eg woman in labour unable to speak English) or otherwise lack capacity to make decisions. GMC guidance clearly states that:

'If you are the doctor providing treatment or undertaking an investigation, it is your responsibility to discuss it with the patient and obtain consent.... You may delegate these tasks provided you ensure that the person to whom you delegate is suitably trained and qualified, has sufficient knowledge of the proposed investigation and understands the risk involved'. (GMC Seeking Consent, para 14)

You must obtain consent from patients before testing for serious communicable disease, except in rare circumstances..... Some conditions such as HIV have serious social and financial as well as medical implications. In such cases you must make sure that the patient is given appropriate information about the implications of the test, and appropriate time to consider and discuss them. (GMC Serious Communicable Diseases, para 4)

You must only test unconscious patients for serious communicable diseases, without their prior consent, where testing would be in their immediate clinical interests.... You should not test unconscious patients for other purposes. (Serious Communicable Diseases, para 7)
- The situation for testing an unconscious source patient involved in an occupational injury to a health care worker is more complex, and laid out in GMC booklet Serious Communicable Diseases, paras 8-12. The guidance suggests seeking consent once the patient has recovered consciousness and continuing prophylactic treatment meanwhile. If 48 hours elapses testing an existing sample can be reconsidered, after discussion with an 'experienced colleague' and where there is 'good reason' to suspect HIV in the source patient. However the GMC warns that taking a new blood sample for this purpose may leave you open to criminal charges. There is no case law on taking a fingerprick sample in this situation, but currently this would seem unwise as it could similarly be construed as assault.
- Rapid testing diminishes the time between information giving and receipt of results with less opportunity to abandon the test once initiated. Patients who fail to return for

traditional test results are exercising a right not to know. GMC guidance reminds us that:

'You should: ... allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex....' (GMC Seeking Consent, para 13)

- Rapid testing might potentially reduce patient confidentiality as it may be harder to conceal the positive result on a benchtop or outreach clinic area than to deal with a confidentially addressed paper result. Due consideration must be given to who has access to the testing area and with whom the immediate test results are discussed. Rapid testing however does reduce the chain of transmission of specimens to the laboratory and thus the total number of people involved in testing.
- The HIV Testing Kits and Services Regulations 1992 specify it is illegal to sell HIV testing kits directly to the public. The person carrying out the test must be registered or acting under the directions of a registered medical practitioner. Thus it would be illegal for non-medical community organisations to offer rapid anti-HIV testing without involving clinicians.

Conclusions

Accurate HIV rapid test devices are available in the UK but are not yet widely used. They may improve patient care especially in outreach settings for hard to reach groups and in obstetric management. The ethical framework surrounding informed consent for a rapid test is the same as for a standard blood test, but the dissemination of testing and potential lack of experience of staff administering tests and handling the results requires careful consideration.

Disclaimer

The recommendations in this guidance may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and available resources

References

- 1 Personal Communication – Dr Keith Perry, Head, MiDAS, HPA
- 2 HPA Microbiological Diagnostics Assessment Service;
<http://www.hpa-midas.org.uk/>
- 3 Abbott Determine HIV 1+2 simple/rapid HIV test device. MDA Evaluation Report 98/76
- 4 An assessment of the seroconversion sensitivity of the Core Diagnostics HIV 1&2 rapid test. MiDAS website (http://www.hpa-midas.org.uk/reports_hiv.asp)
- 5 JV Parry et al. Towards error-free HIV diagnosis: guidelines on laboratory practice. *Commun Dis Public Health* 2003; 6(4): 334-50
- 6 Fisher M *et al.* UK Guideline for the use of post-exposure prophylaxis for HIV following sexual exposure. *Int J STD&AIDS* 2006;17:81-92
- 7 Personal communication, Dr Paul Benn, Mortimer Market Clinic, London
- 8 Personal communication, Stephen Rice, Laboratory Manager, RF&UCMS, London; see also www.cpa-uk.co.uk
- 9 Personal Communication – Dr Keith Perry, Head, MIDAS, HPA
- 10 Point of care testing (near-patient testing) guidance on the involvement of the clinical laboratory. http://www.ibms.org/pdf/point_of_care_testing.pdf

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Useful information

Medicines and Healthcare Products Regulatory Agency

has produced two publications of interest downloadable from their web site: www.mhra.gov.uk

1. Management and Use of IVD Point of Care Test Devices' DB2002(03).
 - The importance of identifying a clinical need before setting up a service.
 - Clinical governance issues.
 - The need for training, updating and monitoring of all staff involved in the service.
 - The importance of health and safety.
2. POCT: Top Ten Tips leaflet

MiDAS - Microbiological Diagnostics Assessment Service

Health Protection Agency

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<http://www.hpa-midas.org.uk/>

Clinical Pathology Accreditation UK

www.cpa-uk.co.uk

Institute of Biomedical Science

Point of care testing (near-patient testing) guidance on the involvement of the clinical laboratory. http://www.ibms.org/pdf/point_of_care_testing.pdf

BASHH guidelines

Clinical Effectiveness Group. UK National Guideline on HIV Testing (draft).

http://www.bashh.org/guidelines/draft/hiv_testing_2005_draft5.doc

Clinical Effectiveness Group: Sexually Transmitted Infections Screening and Testing Guidelines (HIV) (draft). http://www.bashh.org/guidelines/draft/draft_sti_screen_v12_0106.pdf

Manufacturer's websites

Abbott Rapid Determine HIV-1/2	www.abbottdiagnostics.com/Your_Lab/default.cfm?syscat_id=7&path=0
Core Diagnostics HIV 1 & 2 Serum only	Marketed by Bio_Stat. Product code 59001 pack size 25 tests www.corediag.com/images/CORE_HIV_1_2-CE_mark.pdf www.bio-stat.com/show.asp?catid=16&prodid=98&level=2
INSTI HIV Antibody	Marketed by Pasante (www.pasante.com) from July 2006 Technical data at www.biolytical.com
MiraCare™ Rapid HIV Antibody Test	www.medmira.com/products/medmirah.html

Note that there is no central UK list or central approval/accreditation system for rapid diagnostic devices. This list may therefore be incomplete.

List of rapid HIV tests marketed worldwide:

<http://www.rapid-diagnostics.org/rti-hiv-com.htm>

http://www.who.int/diagnostics_laboratory/en/index.html