

# Authorisation and Quality Assessment for Laboratories Undertaking HIV Antibody Testing in Victoria

December 2003

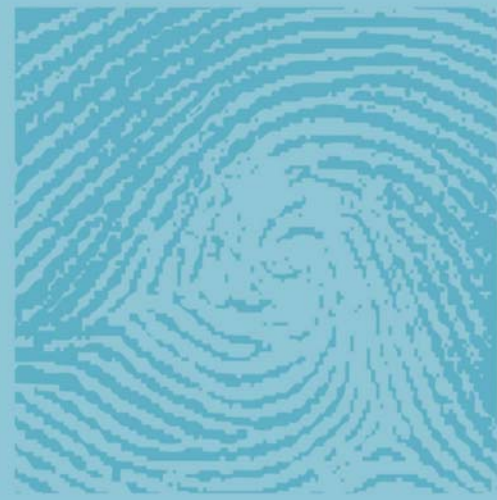
This policy has been developed by:

BBV/STI Program, Communicable Diseases Section, Disease Control and Research Branch

in consultation with the following organisations:

- National Association of Testing Authorities
- National Serology Reference Laboratory
- TGA approved HIV test kit suppliers, and the
- Victorian Infectious Diseases Reference Laboratory

# Authorisation and Quality Assessment for Laboratories Undertaking HIV Antibody Testing in Victoria—December 2003



## 1. Introduction

In a long-standing arrangement with the Commonwealth government, the Department of Human Services (DHS) has administered a procedure for the authorisation of laboratories that conduct HIV screening tests. This process is intended to protect the public interest by ensuring that all laboratories applying for authorisation to perform anti-HIV testing demonstrate competence prior to their authorisation. Following authorisation it is important to monitor laboratories' continued competence. This is achieved by the regular distribution of External Quality Assessment Schemes (otherwise known as quality assessment programs or proficiency testing). These Schemes aim specifically to help laboratories in their efforts towards continuous improvement, are based on a philosophy of education, and are not designed to be punitive.

This document describes procedures and clarifies roles and responsibilities in relation to:

- the authorisation of Victorian laboratories to conduct HIV screening tests, and
- the External Quality Assessment Schemes (EQAS) used to periodically monitor each laboratory's testing process.

### 1.1 National Serology Reference Laboratory, Australia (NRL)

The NRL is charged with the responsibility for the evaluation and post-market monitoring of anti-HIV test kits in Australia to ensure their continued compliance with standards of quality. This is achieved by the mandatory participation of laboratories using the test kits in the NRL's anti-HIV quality assurance program, which includes quality assessment and quality control programs. Hence all laboratories performing anti-HIV testing in Australia participate in the NRL's National Quality Assurance Program.

### 1.2 Victorian Infectious Diseases Reference Laboratory (VIDRL)

VIDRL is a DHS Victoria funded public health reference laboratory. The Victorian HIV Reference Laboratory is one of VIDRL's core programs and includes distribution of EQAS, reference laboratory testing, disease surveillance, applied research and test development, maintenance of reference collections and provision of expert advice.

## 2. The Authorisation of Laboratories to Conduct HIV Screening Tests

The procedure for the authorisation of laboratories to conduct HIV screening tests involves a two-part process. Under this scheme, applying laboratories must first demonstrate competence in HIV testing prior to receiving full DHS authorisation.

### 2.1 Provisional Authorisation

[Please refer to schematic representation on page 5]

This stage entails provisional authorisation to conduct HIV antibody testing for the purpose of demonstrating competence.

DHS will grant provisional authority on the condition that the applicant agrees to abide to *Conditions of Authorisation* that apply to all approved laboratories (see 2.1.1 Conditions of Authorisation). A letter of provisional authority will allow a laboratory to purchase commercial HIV serology test kits. These can then be used in testing HIV serology quality assessment samples, provided by the Victorian HIV Reference Laboratory of the VIDRL, in order to demonstrate proficiency in testing.

Laboratories cannot perform HIV antibody testing for diagnostic purposes until they have been fully authorised.

#### 2.1.1 Conditions of Authorisation

Laboratories must:

- write to the National Association of Testing Authorities (NATA) to request HIV testing accreditation **and** provide DHS with a copy of this letter<sup>1</sup>;
- undergo a pre-authorisation quality assessment process conducted by the Victorian HIV Reference Laboratory of the Victorian Infectious Diseases Reference Laboratory (VIDRL) to demonstrate competency;
- conduct testing according to the test kit manufacturer's instructions without modification;
- refer all reactive HIV screening test results to the VIDRL—**No reports of HIV reactive or positive results can be issued by laboratories unless they have been confirmed by the VIDRL**;
- supply basic data for epidemiological purposes, as outlined in section 130 of the Health Act 1958, to The Macfarlane Burnet Institute for Medical Research and Public Health (see Box 1 below);
- comply with section 128 of the Health Act 1958. That is, to take all reasonable steps to protect the privacy of individuals;
- take part in an ongoing EQAS for HIV testing, coordinated by the NRL in collaboration with the VIDRL. EQAS panels will be sent to laboratories for testing every 4 months. Results must be returned by the specified deadline for all EQAS panels for authorisation to be maintained. Quality control (QC) samples for regular monitoring of assay performance will also be issued to laboratories by the NRL as required, the results of which will be monitored using EDCNet;

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<sup>1</sup> Laboratories of the Australian Red Cross Blood Service-VIC are part of a national blood service and are accredited through the Therapeutic Goods Administration (TGA). As such they are exempt from this condition.

- provide DHS with the appropriate documentation confirming that the HIV screening test has been added to the laboratory's NATA scope of accreditation; and
- agree to the notification of DHS should any of their EQAS results be unsatisfactory.

### **Box 1. Section 130 (2) of the Health Act 1958**

Under Section 130 (2) of the *Health Act 1958* a person in charge of a prescribed place in which the testing of the blood of humans for HIV is carried out must keep or ensure that a written record is kept with the prescribed particulars for each prescribed period containing as far as is possible the following information;

The number of tests carried out on human blood for HIV, and

The number of persons in respect of whom test have been carried out who fall into each particular prescribed category:

In accordance with Regulation 17 (Records) of the *Health (Infectious Diseases) Regulations 2001*

(b) The prescribed period is 3 months.

(c) Prescribed categories are:

- Homosexual male contact;
- Coagulation factor recipient;
- Injecting drug user;
- Transfusion recipient;
- Heterosexual contact;
- Occupational contact; and
- Screening recipient.

## 2.2 Full Authorisation

[Please refer to schematic representation on page 5]

DHS will consider advice from the VIDRL regarding the applying laboratory's performance on the above provisional authorisation quality assessment samples as either satisfactory or unsatisfactory as defined in Box 2. Definitions of satisfactory and unsatisfactory performance.

Provisionally authorised laboratories demonstrating competency in the quality assessment testing will be fully authorised by DHS to commence clinical testing for diagnostic purposes.

Full authorisation may take place prior to the laboratory achieving expanded NATA accreditation to include HIV testing. In accordance with the Conditions of Authorisation (see 2.1.1 Conditions of Authorisation) the applying laboratory must provide DHS with the appropriate documentation once NATA has confirmed that the HIV screening test has been added to the laboratory's scope of accreditation. NATA will inform DHS of any unsuccessful applications in relation to HIV testing and DHS in turn will inform VIDRL and NRL.

## **Box 2. Definitions of satisfactory and unsatisfactory performance**

Satisfactory performance is defined as:

The applying laboratory's quality assessment test results all conform with those obtained by the reference laboratory.

Unsatisfactory performance is defined as:

One or more of the applying laboratory quality assessment test results do not conform with those obtained by the reference laboratory.

When satisfactory performance is achieved:

- VIDRL recommends to DHS that laboratory may commence diagnostic testing;
- DHS informs the applying laboratory that they are fully authorised;
- DHS informs the NRL of a newly authorised anti-HIV testing laboratory, and
- The applying laboratory must provide evidence to the HIV test kit supplier and NATA that they have received full authorisation by DHS.

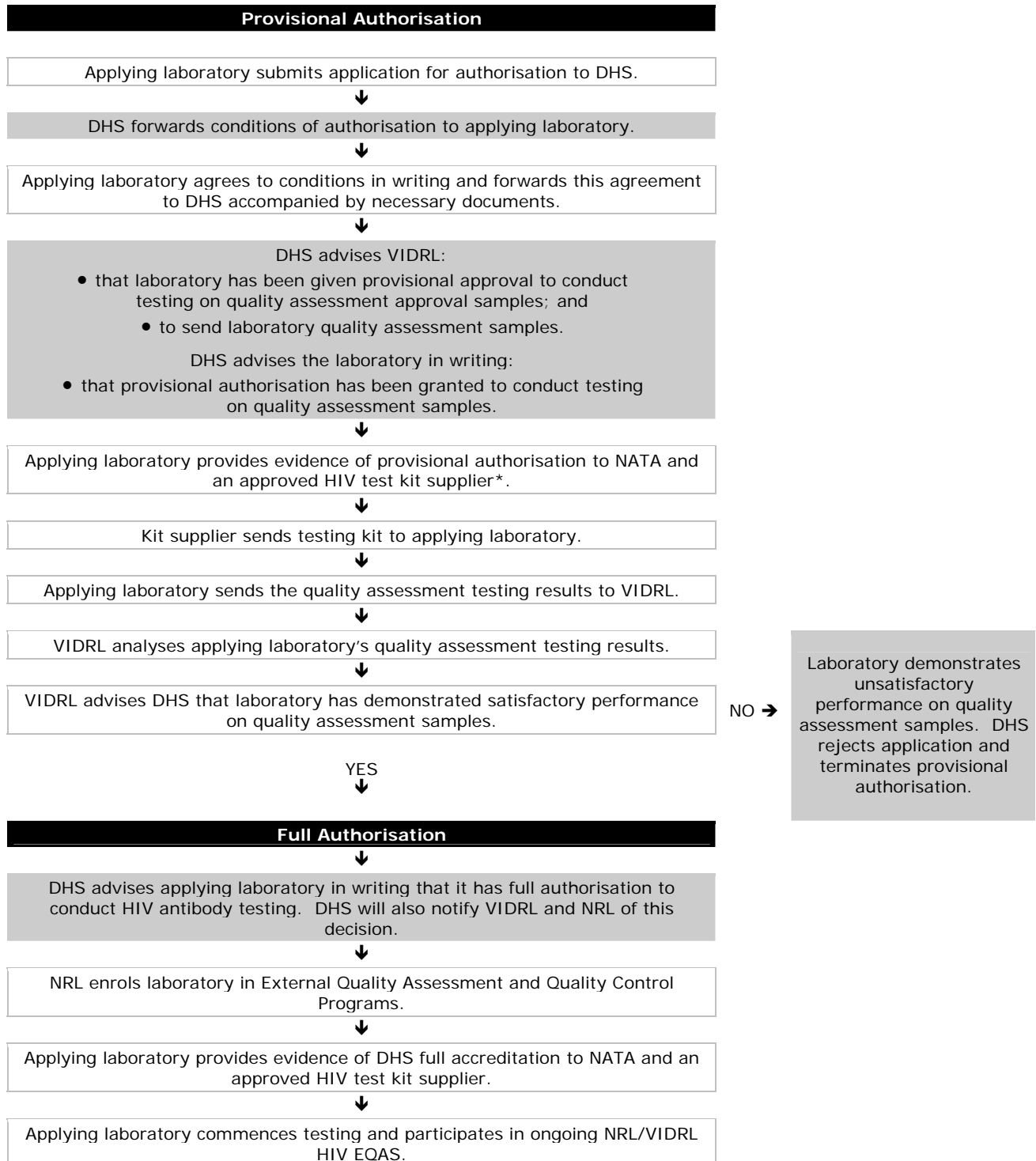
When unsatisfactory performance has been demonstrated:

- DHS informs NATA and the applying laboratory that its provisional authorisation is terminated, and
- DHS will seek further advice from VIDRL in relation to the acceptability of the laboratory's re-application for provisional authorisation status.

## **2.3 List of authorised HIV testing laboratories**

A list of authorised laboratories is available on request from the Communicable Diseases Section of the Department of Human Services.

**Figure 1. Flow Chart for DHS authorisation of laboratories to conduct HIV antibody screening tests**



## 3. External Quality Assessment Scheme

### 3.1 Introduction

External Quality Assessment Schemes (EQAS), also known as proficiency testing, are an important element of quality assurance. Panels of samples are distributed regularly to participating laboratories, which are asked to treat the samples as if they had been submitted for routine diagnosis. EQAS reports presenting collated results allow participants to compare their results with those of the reference laboratory and with those of other participants.

EQAS are a vital tool for ensuring continual improvement. The aim of participation is to provide a measure of the effectiveness of laboratories' internal quality control procedures and supporting quality assurance initiatives. As part of this process, laboratories may identify additional areas of laboratory practice that require review. The testing laboratory shall respond to any testing errors that are identified by improving its procedures or training. To this end it is important that staff of testing laboratories feel free to seek advice where necessary, without fear of immediate penalty, if problems in laboratory processes are identified. The EQAS provider shall similarly inform the participants of any occurrence that may have compromised the accuracy of laboratories' results or of the EQAS report.

It should be noted however, in addition to the EQAS process, laboratories should be reviewing their practices and procedures regularly to ensure continuous improvement.

### 3.2 Background

Under the Therapeutic Goods Act 1989, laboratories undertaking human immunodeficiency virus (HIV) screening tests using anti-HIV-1/2 test kits must participate in the National HIV Quality Assurance Program<sup>1</sup>. In Victoria, the NRL coordinates the External Quality Assessment part of this program in collaboration with the Victorian HIV Reference Laboratory of the VIDRL.

Participation in this collaborative EQAS is obligatory for all laboratories that are authorised by DHS to conduct HIV screening tests. This program is intended to help ensure a uniform high standard of laboratory performance.

### 3.3 EQAS Process

EQAS panels are distributed every four months to laboratories. Each EQAS panel consists of samples from NRL and from VIDRL. The distribution of the samples is coordinated by NRL. Following testing, each laboratory sends results to the NRL who will forward the test results on those samples originating from VIDRL to the VIDRL for analysis. Results on samples originating from the NRL will be analysed by NRL.

VIDRL will provide DHS as well as the participating laboratories with a written report summarising the EQAS data derived from the samples originating from VIDRL. This summary will be forwarded to DHS as soon as results become available. Further, VIDRL will notify DHS of any laboratory demonstrating unsatisfactory EQAS performance as described in 3.5.2.

A summary of EQAS data from the samples originating from the NRL will be posted on their website <http://www.nrl.gov.au/>. It will be the responsibility of DHS staff to peruse these summary data on the website however NRL will notify DHS of any laboratory demonstrating unsatisfactory EQAS performance as described in 3.5.2.

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<sup>1</sup> Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989, effective 1 July 1995.

## 3.4 EQAS Results

DHS will consider advice from the NRL and VIDRL regarding the laboratories' performance on the EQAS.

### 3.4.1 Satisfactory EQAS performance

Satisfactory EQAS performance is defined as *all results in concordance with reference results obtained by the NRL and VIDRL*. However, discordant results that are found to be clearly attributable to assay performance will not be considered as unsatisfactory laboratory performance. For example, if all participating laboratories using a particular assay obtain the same erroneous result on the same specimen, then this may suggest an assay problem rather than an individual laboratory's error.

### 3.4.2 Unsatisfactory EQAS performance

Unsatisfactory EQAS performance is defined as:

- Any false negative result obtained by participating laboratories;
- False positive results on more than three samples from an individual laboratory in one EQAS panel;
- Six or more false positive results from an individual laboratory in total over three successive EQAS panels, or
- Unsatisfactory performance on repeat or supplementary EQAS panel testing (see 3.5.2).

## 3.5 Procedure following unsatisfactory performance in a EQAS

### 3.5.1

Sample(s) producing erroneous results will be identified as originating from NRL or VIDRL.

### 3.5.2

The laboratory will be asked by the NRL or VIDRL, whichever originated the sample(s), to immediately perform repeat testing on the same panel. It is in a laboratory's interest to retain remaining unused EQAS samples, as this may assist with the troubleshooting process if required. If the repeat test indicates that there has been a laboratory error, DHS will be informed and a supplementary panel will be sent by VIDRL to the laboratory for testing as soon as possible.

### 3.5.3

VIDRL will prepare a written report advising DHS of the results of the supplementary testing, potential reasons for the erroneous result/s and corrective actions that the laboratory will undertake immediately. Further, DHS will seek advice from VIDRL on whether a follow-up meeting is required between DHS, the relevant laboratory, NRL and VIDRL to discuss the recommendations outlined in the VIDRL report.

### 3.5.4

DHS in collaboration with VIDRL will determine, on a case-by-case basis, if further action is warranted in relation to the laboratory's HIV testing practices. For example, the laboratory in question may be required to participate in one or more of the following:

- a parallel testing program (see 3.7.2 Parallel testing);
- an external audit (see 3.7.3 External audit);

- validation panel testing (see 3.7.4 Validation panel testing), and
- look back testing (see 3.7.5 Look back testing).

### 3.6 Persisting unsatisfactory EQAS performance

Persisting unsatisfactory EQAS performance is defined as an individual laboratory demonstrating unsatisfactory EQAS performance more than once, over three successive EQAS panels. In this case, DHS will immediately coordinate a meeting between the relevant laboratory, VIDRL and NRL to discuss potential reasons for the persistent erroneous results/s and corrective actions that the laboratory **will undertake immediately**. Further, the laboratory will participate in a parallel testing program, an external audit, validation panel testing and look back testing (see 3.7 Actions).

### 3.7 Actions

#### 3.7.1 Immediate corrective actions undertaken by the laboratory

DHS will request that the laboratory investigates the potential problems (if this has not already taken place) that may have lead to erroneous results. The laboratory will be asked to provide DHS with a written report documenting this investigation and the corrective action undertaken as soon as possible. The VIDRL will provide advice to DHS regarding the acceptability of the investigation, the report, and the corrective action undertaken.

#### 3.7.2 Parallel testing

DHS will ask the laboratory to send patient samples to VIDRL who will perform parallel testing until continuous satisfactory performance is achieved. The laboratory **may not give out test results until verified against VIDRL results**.

#### 3.7.3 External audit

VIDRL, in collaboration with NRL, will conduct an independent audit of laboratory processes in relation to HIV testing. The audit team will then provide a written report that includes recommendations for improvements to the laboratory's HIV testing practices to both DHS and the laboratory in question.

#### 3.7.4 Validation panel testing

NRL, in collaboration with VIDRL, will distribute *validation* panels to the laboratory. These panels will be tailored to the suspected problem and will consist of a sufficient number of positive sera to adequately assess the HIV testing process. To achieve meaningful results, it is imperative that a minimum of two different laboratory operators undertakes testing of a validation panel. A minimum of 200 validation samples in total will need to be completed successfully.

#### 3.7.5 Look back testing

DHS will take advice from the VIDRL and NRL if a *look back and re-testing* of samples previously tested by the involved laboratory should be undertaken. A decision will be made on a case-by-case basis in relation to the sera samples that will be re-tested from the time of the failed EQAS.

Look back may also include examination of the QC sample results the laboratory has entered into EDCNet over the period since the satisfactory EQAS performance was demonstrated.

Re-testing will occur at VIDRL unless otherwise agreed by the parties.

The Chief Health Officer will be consulted and further action will be taken if the *look back* testing does not achieve 100 per cent concordance with results obtained by the involved laboratory.

### 3.8 Resumption of normal testing

To cease parallel testing, DHS must be satisfied that the laboratory has demonstrated 100 per cent performance<sup>2</sup> on the validation panel and has addressed or is addressing any issues raised by the external audit conducted by VIDRL in collaboration with NRL. DHS will notify the laboratory, VIDRL and NRL in writing of the laboratory's entitlement to resume normal testing.

### 3.9 Persistent unsatisfactory performance

DHS reserves the right to request the laboratory's immediate cessation of diagnostic testing for HIV if there are ongoing concerns regarding the laboratory's performance. Further, DHS may request assistance for the laboratory from NATA in planning and implementing corrective action.

### 3.10 Other concerns regarding HIV testing practices

NRL or VIDRL will notify DHS if either become aware of other evidence of significant unsatisfactory performance in relation to a laboratory's HIV testing practices.

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<sup>2</sup> All results are in concordance with reference results obtained by the NRL and VIDRL (See Box 2).