NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

GUIDELINES FOR THE USE OF LIQUID BASED COLLECTION SYSTEMS AND SEMI-AUTOMATED SCREENING DEVICES IN THE PRACTICE OF GYNAECOLOGICAL (CERVICAL) CYTOLOGY

Supplement to:

Requirements for Gynaecological (Cervical) Cytology

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Contents

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Commonwealth, States and Territories on matters relating to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. An ongoing function of NPAAC is to formulate standards, and to initiate and promote guidelines and educational programs relating to the performance of pathology tests.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to laboratories and accrediting agencies as to the minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Introduction

This document was produced to supplement the standards provided in the National Pathology Accreditation Advisory Council's document *Requirements for Gynaecological (Cervical) Cytology.*

The supplement's guidelines relate to contemporary laboratory practice where liquid based systems and semi- automated screening devices are used as adjunctive tests.

Current equipment to which these requirements may apply includes:

- automated slide preparation technologies such as SurePath® and ThinPrep®; and
- semi-automated screening devices such as Focal Point and ThinPrep® Image Analyzer.

The headings and numbering of this supplement corresponds to that of the original parent document except where new requirements have been added. The numbers then follow on from previous numbering contained in *Requirements for Gynaecological (Cervical) Cytology.*

While this document is for use in the accreditation process, any comment from users would be appreciated and can be directed to:

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REQUIREMENT 1 STAFF

1.2 Scientific and technical staff

1.2.3 In addition to requirements 1.2.1 and 1.2.2 specified in the *Requirements for Gynaecological (Cervical) Cytology*, laboratory staff employed in screening gynaecological samples derived from liquid based technologies or semi- automated screening techniques must be trained in the operation of the device, and the interpretation of results obtained from those technologies.

1.3 Staff establishment

1.3.1 The maximum workload for any person involved in manual primary screening of slides prepared by liquid based technologies should not exceed 70 slides per day.

1.3.2 The maximum workload for any person reporting slides prepared by liquid based technologies and analysed (pre-screened) using semi-automated imaging techniques should not exceed 150 slides per day.

However, the number of slides screened by an individual should be governed by the relative skill and experience of the screener and assessed against their performance in internal quality control processes (* see footnote).

1.4 Education

1.4.3 Documentation should be kept, confirming that a pathologist has received specific training relevant to the use of liquid based collection systems and semi-automated devices being employed within the laboratory for the preparation and screening of gynaecological slides.

1.4.4 Documentation should be kept, confirming that all scientists who issue reports have received appropriate and specific training relevant to the use of liquid based collection systems and semi-automated devices being employed within the laboratory for the preparation and screening of gynaecological slides.

REQUIREMENT 2 CONSULTATION

There are no additional guidelines to supplement this requirement.

* Management should not regard this figure (70/ 150 slides per day) as an expectation.

REQUIREMENT 3 FACILITIES

Where a laboratory uses liquid based cytology, automated slide preparation may be performed at a site other than that of the reporting laboratory.

Any processing performed at a site other than that of the reporting laboratory must be in premises accredited by NATA/RCPA or equivalent.

REQUIREMENT 4 HEALTH AND SAFETY

There are no additional guidelines to supplement this requirement.

REQUIREMENT 5 SPECIMENS

5.1 Adequacy

The laboratory must be able to provide written advice on procedures for taking satisfactory liquid based samples for gynaecological cytology.

5.1.1 Instructions should specify the most appropriate method to optimise the cell sample and make reference to the recommendations for sample collection issued by the suppliers of sampling devices.

5.1.2 Instructions shall include appropriate adherence to expiry dates of any media used, and to storage and transport procedures recommended by the suppliers of media.

5.3 Retention

5.3.1 To enable further analysis of a sample following consultation with a clinician, the primary liquid based cytology sample should be retained for a period of one month.

REQUIREMENT 6 EQUIPMENT AND INSTRUMENTATION

There are no specific requirements for gynaecological cytology over and above those generally required for pathology laboratories.

REQUIREMENT 7 METHODS

Should a method be altered from the manufacturer's instructions, the altered method should be validated and documented.

REQUIREMENT 8 QUALITY CONTROL

8.1 External quality assurance programs

8.1.1 Where available, a laboratory must be enrolled, participate and remain in an external quality assurance program (QAP) that is appropriate to the technologies utilised in the laboratory and complies with NPAAC and RCPA criteria.

8.1.5 Records should be kept for results, which allow separate identification of the results obtained using conventional cytology, new technologies or combination of technologies to enable aggregate data to be determined for each methodology used.

REQUIREMENT 9 REPORTING

9.2 Content

The Cytology report should be in the format outlined in section 9.2 of the *Requirements for Gynaecological (Cervical) Cytology*. The report should specify if liquid based collection systems and/or semi-automated instruments are utilised and state the technologies used in generating the result.

REQUIREMENT 10 RECORDS RELATING TO PATIENTS, RESULTS AND QUALITY CONTROL

There are no additional guidelines to supplement this requirement.