

**TECHNICAL REQUIREMENTS FOR LIQUID BASED
CYTOLOGY SYSTEMS FOR CERVICAL SCREENING**

**LBC Implementation Guide No 1
Version 1: January 2004**

Published by:

NHS Cancer Screening Programmes
The Manor House
260 Ecclesall Road South
Sheffield S11 9PS

Tel: 0114 271 1060

Fax: 0114 271 1089

Email: nhs.screening@sheffield-ha.nhs.uk

Website: www.cancerscreening.nhs.uk

© NHS Cancer Screening Programmes 2004

CONTENTS

	Page No
1. INTRODUCTION	1
2. EQUIPMENT REQUIREMENTS	1
2.1 Throughput	1
2.2 Adjunctive equipment	1
3. SYSTEM DESIGN	2
3.1 Installation and commissioning	2
3.2 System operation	2
3.3 System consumables	3
3.4 Collection vials	3
3.5 System maintenance and servicing	3
4. SYSTEM FEATURES	4
4.1 Sampling devices	4
4.2 Sampling technique	4
4.3 Slide supply	4
4.4 Slide preparation	4
4.5 Labelling	5
4.6 Quality control	5
4.7 Health and safety	5
4.8 CE marking	6
4.9 HAZMAT	6
5. INFRASTRUCTURE	6
5.1 Sample transportation	6
5.2 Waste management	6
6. SLIDE SETS FOR TRAINING	6
REFERENCES	7

1. INTRODUCTION

This is the first version of this guide, and it may be reviewed from time to time as the technology improves and the demands of the NHS Cervical Screening Programme (NHSCSP) change.

The guide takes into account the experience gained by laboratories, the works departments that monitor electrical safety performance and the service engineers who maintain the equipment. It is intended to assist prospective purchasers in drawing up their equipment purchasing specification, to provide equipment assessors with a common set of recommendations against which comparisons of different liquid based cytology (LBC) systems can be made and to inform equipment manufacturers of users' needs.

The recommendations are based on existing systems evaluated as part of the Department of Health LBC pilots in England.¹ These are the ThinPrep[®] system, supplied by Cytoc UK Ltd, and the Sure-Path[™] LBC system, supplied by Medical Solutions plc. Note that the recommendations in this guide are in addition to the particular requirements of *IEC 60601-1:1990 (BS 5724-1:1989) Medical Electrical Equipment: General Requirements for Safety*,² the *EC Medical Devices Directive*³ and the *EC In Vitro Diagnostic Directive*.⁴

The NHS will continue to evaluate the performance range of the systems available. Where minimum requirements are met, all systems will be tested under NHS conditions in order to provide advice in the context of the NHSCSP. Before purchasing any new equipment, laboratories and commissioners should ensure that their particular requirements are met.

2. EQUIPMENT REQUIREMENTS

2.1 Throughput

- The production throughput capacity of the system, from vial to coverslipped and labelled slide, should be stated.
- The timings, and whether or not staining is included in this process, should be specified.
- Any system must be automated to a degree that comfortably permits the processing of 20 sample vials per hour by a single operator.

2.2 Adjunctive equipment

- The preparation must be compatible with staining regimes that are acceptable within the NHSCSP.

- If slide staining forms part of the system, it must produce preparations that meet the standards for liquid based cytology as defined in the *External Quality Assessment Scheme for the Evaluation of the Papanicolaou Staining in Cervical Cytology: Protocol and Standard Operating Procedures*.⁵
- The slide produced and associated slide carriage devices should be suitable for use with automated staining and/or automated coverslipping devices unless the system incorporates such modules.
- The system should be compatible with future requirements for either automated testing and/or for other tests (eg human papillomavirus testing) that may need to be performed on the same sample.

3. SYSTEM DESIGN

3.1 Installation and commissioning

- The information displayed on the unit must include the serial number and model number.
- The system should be capable of operating over a range of laboratory temperatures (15–35°C) and under typical laboratory humidity.
- The requirements for space, floor type and loading, drainage, water, electrical supply and waste disposal must be described.
- Voltage, current and fusing requirements must be stated and must be compliant with British Standards. An uninterrupted power supply and electrical filter should be provided if required.
- The equipment must be installed by the supplier's own service engineers or their appointed agent.
- The supplier must be able to provide advice and support in the event that the instrument has to be moved after installation.
- The supplier must state the assistance and support to be provided during the commissioning phase, acceptance testing and validation of performance.
- The supplier must satisfactorily demonstrate that the equipment is fully functional and capable of performing to required standards before formal handover.

3.2 System operation

- The system must be easily operable and routinely maintained by laboratory staff (biomedical scientists and/or medical laboratory assistants).
- The supplier must provide full training and comprehensive operator manuals in English.
- The operator manual must include details of start-up and calibration, sample processing, decontamination and fault recognition and handling.
- The supplier must document the system features that minimise the risk of carry-over between specimens.
- The equipment should provide messages that identify common errors to operators. Corrective actions must be documented in the operator manual.
- Start-up and shut-down (including decontamination procedures) should not take longer than 15 min per day. Ideally, the system should be capable of running directly from standby.

- All service reports and data relating to routine performance, planned and unplanned maintenance, and fault rectification must be provided by the supplier and its service agent.

3.3 System consumables

- Working reagents must be supplied ready prepared, or in appropriate volumes and containers and be simple to prepare.
- The reagents should be stable on board the system for at least three days, and the shelf life of the reagents should be stated and should be at least three months upon delivery.
- All consumables must be readily available from the suppliers as stock items.

3.4 Collection vials

- Collection vials must be those in regular use throughout the NHS, or which can be supplied to the NHS in a reliable and regular manner to the required quantity and quality.
- Vials must be provided prefilled with collection fluid. There must be a mechanism to allow checking that the vial contains sufficient fluid and that there has been no contamination or fluid loss.
- The supplier must provide trays to assist the handling of multiple vials. These should be designed to minimise the risk of spillage and sample loss. A visual recognition system or colour coding system is desirable.
- The supplier must detail the storage requirements for vials and advise on any restrictions regarding the number of vials that can be stored together. *Control of Substances Hazardous to Health (COSHH) Regulations 2002*⁶ data must be available to both laboratories and sample takers.
- The supplier must detail any special requirements or restrictions for the transportation of vials, both before and after the addition of the sample. This should include the specification of suitable transport boxes.
- It should be clear to the sample taker when the vial lid is firmly closed.
- The vials should have a shelf life of at least 18 months from date of manufacture.
- The supplier must recommend and advise on appropriate disposal methods for vials and other consumables once testing is complete.

3.5 System maintenance and servicing

- The in-house maintenance procedures must be documented in English in a comprehensive manual together with an estimate of the time required.
- The external service requirements and contracts available must be described, together with guaranteed response times. The level of support outside normal working hours must be specified. Specific exclusions to the contract must be stated. Options for back-up/loan systems should be available should long-term down-time occur (two weeks or more).
- An English speaking point of contact must be provided.

4. SYSTEM FEATURES

4.1 Sampling devices

- The system must use either a broom or an extended tip spatula or a spatula/brush combination. The supplier must state the recommended device for the system and whether or not alternative devices can be used, and must provide reasons for this decision.
- Sampling devices must be those in regular use throughout the NHS, or which can be supplied to the NHS in a reliable and regular manner to the required quantity.
- The recommended sampling device or devices must be capable of transferring to the vial of liquid cells sampled from the transformation zone of the cervix in a proportion adequate for reporting purposes.

4.2 Sampling technique

- The supplier must provide detailed instructions on sampling technique and the method for transferring the specimen from the sampling device to the collection fluid.
- Any differences in methodology between recommended sampling devices should be specifically highlighted.

4.3 Slide supply

- Glass slides that are compatible with the system must be specified or supplied.

4.4 Slide preparation

The system process must:

- be suitable for use with all cervical cytology samples, including those which are heavily blood-stained or mucoid
- have the capability to remove a significant number of polymorphs, blood and mucus
- produce slides that are a representative sample of the epithelial cell content of the original sample
- be capable of allowing additional slides of equivalent content to be produced from the original sample (for training and quality assurance purposes)
- spread cells evenly on the slide in order to facilitate observation
- hold cells in position so that they do not move once the coverslip has been applied
- produce LBC preparations which are similar to each other when taken from women of the same age
- produce inadequate test rates within the 10th to 90th centile of performance in current LBC laboratories in England
- achieve a high grade pick up rate within the 10th to 90th centile of performance in current LBC laboratories in England; this should be demonstrated in both split sample and direct to vial stud-

ies in various asymptomatic populations, similar to that of the UK, and published in peer review journals or provided for peer review by the NHS

- achieve a low grade pick up rate within the 10th to 90th centile of performance in current LBC laboratories in England; this should be demonstrated in both split sample and direct to vial studies in various asymptomatic populations, similar to that of the UK, and published in peer review journals or provided for peer review by the NHS.

4.5 Labelling

- The vials must carry a preprinted label for documenting patient demographics conforming to UK standards. These must provide sufficient space to enter patient details and enable indelible marking with ballpoint pens.
- Systems that generate slide labels must ensure that the slide label always matches that generated for the vial.
- If bar code labels are used, the supplier must be able to provide a system that is compatible with UK systems of labelling, or recommend such a system that is available in the UK.

4.6 Quality control

- The reject rate for both single and multisample processors must be less than 2%.
- The methods for calibrating the system and quality control (QC) procedures must be stated. The system must provide process QC data including functionality and calibration.
- The QC results should be clearly indicated with appropriate status flags and should be available for long-term storage for accreditation compliance.
- The supplier should give details as to how the operator is alerted to QC and calibration failures.

4.7 Health and safety

- The supplier must confirm compliance of the system with relevant regulations for electrical, mechanical and biological safety.
- For all reagents, the supplier must confirm compliance with relevant regulations regarding shipping, labelling and information on hazardous substances. COSHH product data sheets and risk management information must be provided.
- A decontamination protocol should be available for the system with recommendations as to when it should be used. The supplier should recommend how 'high risk' samples are to be handled on the system and disposed of after testing.
- The system must comply with all UK and EC safety regulations and any guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA).
- The system must not generate dangerous aerosols.

4.8 CE marking

- All equipment and consumables, including sampling devices, must be CE marked where required.

4.9 HAZMAT

- Vial preservative solutions must inactivate viruses that model relevant human pathogens such as human immunodeficiency virus type 1 (HIV-1), hepatitis B virus (HBV) and hepatitis C virus (HCV). As it is not possible to culture HBV and HCV in vitro, models for these viruses which have similar physicochemical properties must be used.
- The following information must be available to prospective purchasers in the form of material safety data (MSD) sheets or comprehensive operator manuals: packaging, chemical composition, storage requirements, stability, handling/disposal and any interfering substances.

5. INFRASTRUCTURE

5.1 Sample transportation

- The system must have a means of sample transportation. Details of postal approval must be provided.

5.2 Waste management

- The supplier must make recommendations for safe and confidential methods of waste removal for the vials, their contents and other reagents after completion of the test.

6. SLIDE SETS FOR TRAINING

- Sufficient slides, in all diagnostic categories used in the UK, must be provided as training sets to allow laboratory staff to be trained in interpretation. The training sets should be made up of proportions of specimens in each category specified in the NHSCSP publication *Liquid Based Cervical Cytopathology Training Log*.⁷

REFERENCES

1. Moss SM, Gray A, Legood R, Henstock E. *First Report to the Department of Health on Evaluation of LBC* (unpublished report, December 2002).
2. *Medical Electrical Equipment: General Requirements for Safety*. BS 5724-1; 1989.
3. *Directive 93/42/EC* of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993) as amended (OJ L 331, 7.12.1998).
4. *Directive 98/79/EC* of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998).
5. *External Quality Assessment Scheme for the Evaluation of the Papanicolaou Staining in Cervical Cytology: Protocol and Standard Operating Procedures*. NHS Cancer Screening Programmes, 2004 (NHSCSP Publication No 19 in press).
6. *Control of Substances Hazardous to Health (COSHH) Regulations 2002*.
7. *Liquid Based Cervical Cytopathology Training Log*. NHS Cancer Screening Programmes, 2004.

