Guide-lines for near patient testing: haematology

Near Patient Testing Working Party

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Summary
These guide-lines provide a framework for the local arrangement of near patient testing (NPT) services for haematology tests. The guidance may be applied to medical and surgical units within hospitals (e.g. ITU, renal dialysis units, casualty) as well as general practitioners' surgeries, for blood counts and coagulation testing. The professional head of the central laboratory must take responsibility for all aspects of the NPT service, although there should be full discussion with the clinical departments involved and joint ownership of the results. NPT operators must be trained and accredited by the central laboratory. Equipment selected should normally have received a satisfactory evaluation report from the Medical Devices Agency (MDA), and should generate results that are comparable with those of the central laboratory. If a full MDA operation evaluation has not been performed, the purchaser should perform a local assessment according to the protocol in this document. The suitability of the equipment, imprecision, and comparability must be studied. The NPT equipment must be properly maintained and calibrated, and a record of patient identity, date and time of testing, reagent lot numbers, and operator must be kept. The central laboratory must participate in a suitable external quality assessment programme (EQA) and provide systems for EQA and internal quality control (IQC) of the NPT site.

Keywords near patient testing, equipment, external quality assessment

PART I: NEAR PATIENT TESTING

Introduction
The purpose of these guide-lines is to provide a framework for the provision of appropriate local arrangements for Near Patient Testing (NPT). This document embodies the philosophy agreed by the Joint Working Group (JWG) on External Quality Assessment (EQA) in Pathology (1992), and the national standards required for Clinical Pathology

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Accreditation (Clinical Pathology Accreditation Handbook 1993).


An example of the inherent problems of NPT is highlighted in a project to assess reliability of measuring
haemoglobin in Health centres, which was co-ordinated by the Health Services Research Unit of the University of Warwick (1992). In this instance the External Quality Assessment results were unsatisfactory confirming the need to monitor extra-laboratory testing. More recently, a major clinical trial has been undertaken into the value of near-patient testing in several general practices (Rink et al. 1993; Health Services Research Unit 1992). Other important factors are the efficacy of the procedures being undertaken (Goldie & Kemp 1993) and medico-legal and safety aspects (Goldie & Kemp 1993; Department of Health Hazard Notices 1987a & 1987b).

Scope

The scope of these guidelines relates to the management philosophy of NPT, the venues where NPT may be undertaken, the range of tests, the qualifications of the personnel involved and the timeliness of the service. Other aspects discussed are initiation of the service, training, equipment, results, monitoring of quality, accreditation, safety, and cost.

The document focuses on the delivery of an on-site service within a hospital environment, e.g. an intensive care unit. The guidelines do not specifically encompass general practitioners' surgeries nor other venues, e.g. pharmacies. However, much of the information could be applied to these other NPT sites and a section on key points for general practitioners considering NPT in their surgeries is included.

Sites for NPT could include:

- Intensive care units
- Accident and Emergency Departments
- Renal dialysis units
- Theatres
- Neonatal units
- Occupational health departments
- Research laboratories (undertaking clinical tests)
- General practitioners' surgeries and health centres
- Pharmacies

Other non-accredited commercial institutions may also wish to avail themselves of the professional expertise available in central clinical laboratories.

The range of services should be clearly defined and includes blood counts (haemoglobin) and coagulation testing (prothrombin time, activated partial thromboplastin time, thrombin time and activated clotting time).

Range of equipment

The type of equipment used ranges from simple haemoglobinometers for the measurement of haemoglobin to small analysers that can produce a full blood count. Coagulation equipment ranges from simple instruments providing activated clotting times or prothrombin time estimation to mini analysers producing prothrombin, thrombin, and activated partial thromboplastin times. These are generally used for monitoring heparin or oral anticoagulant therapy. For blood counts, it is strongly recommended that near patient investigators use only instrumentation which employs primary sampling (automated systems) and do not use instrumentation which involves dilution of whole blood in the pre-analytical phase (semi-automated systems).

Examples of users

The types of personnel involved may include:

- Medical practitioners
- Nurses
- Healthcare assistants
- Physiological measurement technicians
- Medical technical officers (MTOs)
- Other non-laboratory personnel

Philosophy

The principal philosophy is that NPT sites must work in partnership with the central laboratory. The cornerstone of this joint service should be embodiment of the philosophy in a Service Level Agreement, which defines the range of services, operational details and the responsibilities of both central haematology laboratory staff and the on-site staff. The agreement should also define the times when the service is available, for example, 9am–5pm or a 24 hour service and full weekend service. Ownership of the results should belong jointly to the central haematology laboratory and the senior clinical staff of the department which is delivering the on-site service. In this way a high level of quality will be maintained.

Management

Whilst the on-site staff may understand the day-to-day operation and provision of results, the professional head of the central laboratory must take responsibility for all aspects of this service, after discussion with the clinicians concerned. This will include selection and procurement of the most appropriate equipment for the task in hand and assessment of the infrastructure of the on-site environment, which must meet basic laboratory standards.

Standard Operating Procedures (SOPs) must be written and signed by an appropriate senior member of the central
laboratory staff. These SOPs will include details of procedures relating to service performance, delivery and safety regulations (Health Services Advisory Committee 1990; HMSO 1988). Protocols must also be produced for training of staff, monitoring performance of equipment, and handling of results.

A Directorate of Laboratory Medicine may wish to nominate or employ a peripatetic MLSO who takes responsibility for monitoring the quality of the on-site service, perhaps in several locations.

The management arrangements should be clearly documented together with appropriate lines of accountability. Job descriptions should contain appropriate sections on NPT.

Training

Training protocols must be established and all potential operators must achieve an adequate level of competence. This should include the basic principles of measurement, appropriate use of the equipment and consequences of inappropriate use, knowledge of normal and abnormal results, the importance of record keeping, the importance of Internal Quality Control (IQC) and EQA, and safety procedures (Kennedy 1992). Trainees should also be awarded a certificate of competence by the central laboratory and a list of authorized users must be drawn up and approved by the head of the central laboratory. It would also be useful to make trainees aware of the recent code of conduct for NPT (Council for Professions Supplementary to Medicine 1994). Arrangements must also be in hand for continuing professional development of the staff delivering the service, with regular training updates. Secondment of on-site staff to the central laboratories may be an appropriate method of training and continuing staff development.

Equipment

Equipment selected for on-site investigations will usually have been evaluated by the Medical Devices Agency (MDA) at the Department of Health. Potential users must ensure that equipment is safe and that results are comparable with results from instruments in the central laboratory. Central laboratory staff must take responsibility for the initial installation, setting up and calibration of equipment. It is also essential that equipment has a preventative maintenance schedule, and service contract, together with a log-book documenting operational details, faults, repairs or other corrective action. Appropriate 'back-up' arrangements for equipment must be made.

Reagents should be procured by the central laboratory and supplied in a cost-effective manner to the clinical unit concerned. A log book of the shelf life of reagents and batch numbers used must be maintained by on-site staff.

Safety

Standard Operating Procedures must be available for the collection, transportation, processing and disposal of specimens. Other protocols should be available for containment of spillages and a clearly identified policy for containment of 'high risk' samples must be defined. All procedures must conform to the policy for 'Safe working and the prevention of infection in clinical laboratories' (Health Services Advisory Committee 1990). Ideally, specimen analysis should be by 'closed vial sampling'. Dilution of whole blood, in the pre-analytical phase, is not recommended for the NPT environment.

Protocols must also be available for the disinfection and decontamination of equipment and laboratories. Each procedure must have undergone a full Control of Substances Hazardous to Health (COSHH) assessment. For example, if cyanide reagents are used in the determination of haemoglobin, all procedures should conform to the appropriate legislation (Health Services Advisory Committee 1990; HMSO 1988; Department of Health 1987c; HMSO 1974).

Results

It is essential that results of tests are documented. For most investigations, for example blood counts, some form of 'request form' would be appropriate and these 'requests' should include full patient identity details (name, hospital number, date of birth, location, date, time). In the absence of appropriate computer systems, results must be documented in a log book, which also identifies reagent batch numbers and the name of the operator: results must be returned to the clinician in a written format, with appropriate biological reference ranges. A system must be in place to ensure that results are comparable with central laboratory results and integrated with these into the case notes of the patient. When computers are available, for example Order Communications Systems, NPT results must be integrated with central laboratory results into the clinical computer and their origin appropriately identified. The units used for reporting results must be the same as those in the central laboratory.

A system must also be defined where results are validated by satisfactory performance in IQC and EQA schemes. Abnormal results must be appropriately flagged. Moreover, mechanisms must be agreed for appropriate referral, to the central laboratory, of 'out-of-limits' results for further
Coagulation testing

Similar EQA schemes and samples to those used in hospital laboratories for traditional tests may be used on NPT instruments utilizing citrated plasma. True like-with-like EQA of instruments using non-anticoagulated whole blood is impossible: the performance of these instruments must therefore be monitored by comparable tests in the central laboratory using a citrated venous sample collected simultaneously. A proportion of the daily or weekly workload must be compared with results from the central laboratory.

For some instruments, commercial lyophilized blood preparations with normal and abnormal clotting times are available. These mimic fresh whole blood and can be used for EQA as well as precision studies. An additional way of providing EQA may be the use of stabilized red cells (van Dijk-Wierda et al. 1978), which can be recombined with stabilized or lyophilised normal or abnormal plasmas.

Accreditation

The Near Patient Testing service must be considered for National Accreditation (Clinical Pathology Accreditation Handbook 1993) as part of the central laboratories accreditation submission. All appropriate accreditation standards must be adhered to.

Finance

In some circumstances a cost-benefit analysis may need to be undertaken. This must include amortization of the equipment, transport costs and should also take account of cost, quality, timeliness and appropriateness of the service.

General practitioners’ surgeries

Key points*

General practitioners should:

(i) seek the advice and involvement of their local haematologist if they are considering NPT, in order to achieve optimum quality and cost effectiveness.

(ii) decide whether they wish to undertake procedures for diagnosis, screening for occult disease or to monitor disease or the effect of treatment, before embarking on NPT. For example, haemoglobinometry does not serve any particular function as a single

* Others considering NPT in a non-hospital setting, e.g. pharmacists may also find these key points useful.

measurement for diagnosis: some patients with serious illnesses, such as leukaemia, may have a normal haemoglobin (Reiman 1992).

(iii) decide which investigations they wish to perform bearing in mind the turn-around-time of their local laboratory and patient convenience.

(iv) consider the recent study, which offered a clear message that there is only a weak case for equipping general practices with the means of doing a wide range of investigations in-house (Rink et al. 1993; Health Services Research Unit 1992).

(v) be aware that investigative rates and costs may rise (Rink et al. 1993; Health Services Research Unit 1992).

(vi) be aware of the full costs of NPT including purchase price, consumables, maintenance contracts, equipment replacement costs and the cost of staff time.

(vii) evaluate the safety of the testing procedures in their surgeries, including the evident risks of HIV and hepatitis from specimens during analysis.

(viii) recognize the possibilities of litigation ensuing from erroneous results.

(ix) recognize the need to use only trained operators.

(x) recognize the need for training programmes (including ongoing training) for their staff and ensure an appropriate match between the equipment and the skills available.

(xi) ensure comparability of results with the local haematology laboratory service.

(xii) take into account the need for good internal quality control and external quality assessment programmes.

(xiii) be aware of the technical difficulties which may be encountered from NPT such as specimen mixing, carry-over and specimen storage and disposal problems.

(xiv) ensure that their staff will be available for 'on demand' analyses.

(xv) ensure that the analytical system is robust.

(xvi) recognize the need for back-up arrangements.

(xvii) be aware of the high quality and close operational control of laboratory testing already available in their local central laboratory.

(xviii) be aware that many local haematology services will have undergone 'peer review' for the national accreditation scheme.

The problems arising from NPT are not inconsiderable, but many of them can be overcome by involving the local haematologist in the initial decisions and ongoing provision of NPT.

PART II: OPERATIONAL EVALUATION

Introduction

Near Patient Testing equipment requires evaluation at three levels:

1. A full national evaluation by the Medical Devices Agency (MDA) at one of the national evaluation centres. Such evaluations usually assess performance under optimal conditions (Optimal Conditions Variance). This will continue to be necessary even after the date when (for marketing in EC countries) all medical devices will have to carry a CE mark indicating that the performance claims have been validated by the manufacturer.

2. A second operational evaluation, by MDA, which assesses the equipment in a manner commensurate with the intended operational use under routine conditions (Routine Conditions Variance). This assesses the system's suitability for its intended use.

3. If an MDA operational evaluation has not been undertaken, the local purchaser should perform an evaluation to the same standard. If an MDA operational evaluation has been carried out, the local purchaser may wish to perform a brief local assessment, which appraises certain aspects of the equipment in its intended location, which are of particular importance to the site in question.

The National Evaluation is carried out in accordance with the protocol for blood counters produced by the International Council for Standardization in Haematology (ICSH 1994) or in accordance with the protocols for coagulation instruments (Giddings et al. 1989; Mackie 1994). Reports of these evaluations are readily available (Medical Devices Agency) and they assess the following: general operational aspects, the effects of dilution, precision, carry-over, accuracy, comparability (relative accuracy), linearity, sensitivity, specificity, reliability.

The Operational Evaluation would normally be undertaken by MDA, after the full National Evaluation using competent staff. The evaluation would be performed in a location equivalent to the intended operational site. The following guide-lines are designed for the MDA Operational Evaluation to assess the clinical utility of the equipment in the near patient location, but could also be adapted for use in the local purchaser assessment. These guide-lines are designed as the minimum criteria for the operational evaluation and a more detailed evaluation may be necessary in certain circumstances.

Principles of the MDA operational evaluation

1. The conditions of the evaluation should be closely allied to the 'users' working environment, using staff (e.g.
nurses) with skills similar to those of potential users under routine conditions in the intended location of the equipment. Henceforth, these staff will be referred to as 'user-evaluators'.

2. The operational evaluation should be designed to highlight possible sources of error or calibration drift. Moreover, the evaluation should be tailored to the type of equipment and materials under assessment. For example, the evaluation of an automated blood counter would be different to that of a simple haemoglobinometer. A capillary Prothrombin Time analyser, for oral anticoagulant control, would be evaluated in a different environment to an instrument using venous or arterial blood for heparin control during, for example, cardiac bypass surgery.

Before the evaluation

**Documentation**

Ensure that there is appropriate documentation and a record is kept of:

(a) Down-time and reason for breakdown.
(b) Maintenance schedules.
(c) Reagent usage (batch number, expiry dates, storage conditions etc).
(d) Use of appropriate control materials.

**Training**

The training should be provided by the central haematology laboratory organizing the evaluation and/or the equipment supplier.

Trainee 'user-evaluators' should be nurses or junior doctors, etc. of similar experience to those staff who could potentially use the equipment, if approved and introduced following the evaluation.

The training should centre around the principle that 'user-evaluators' are given basic tuition about the equipment followed by a period of familiarization with the equipment. These staff should then be given SOPs and be allowed to follow these procedures through to the production of patient results. Training should also be planned on the assumption that operators have little or no knowledge of sources of systematic and random errors, such as the effects of high cell counts, background counts and the possibility of clots reducing platelet counts.

Trainees should be awarded a certificate of competence by the central laboratory, after appropriate training and prior to the commencement of the evaluation. An assessment of the adequacy and effectiveness of training should be made during the evaluation. A register of competent staff should be kept by the organizing laboratory.

**The evaluation should assess:**

**Equipment location**

Physical requirements (equipment dimensions, weight, free standing/bench-top, size of bench, flat surface, stability of bench, floor area, ease of access, power supply, noise and heat generation, air conditioning, waste disposal).

**Safety**

A COSHH, microbiological, electrical and mechanical assessment will normally have been undertaken during the National MDA evaluation.

It is important to ensure that staff using the equipment can adhere to appropriate control of infection standards. An assessment should be made of microbiological risks arising from, for example, contamination of equipment/surfaces by patient specimens, together with an assessment of appropriate decontamination and waste disposal procedures.

A risk assessment of any potential mechanical and fire hazards (e.g. is the equipment continuously powered) should also be made.

**Operational aspects**

These aspects should be assessed by completion of questionnaires. One questionnaire should be compiled for ‘user-evaluators’ and a separate questionnaire for central laboratory staff (MLSOs etc).

Sample questionnaire are detailed in Appendices 1 and 2.

**Random and systematic errors**

Imprecision, inaccuracy and drift, etc. will have been assessed during the national MDA Evaluation. The purpose of this section is to assess imprecision under routine conditions. These performance characteristics should be assessed in accordance with 'Protocol for evaluation of automated blood cell counters' (ICSH 1994).

**Blood count analysers**

Comparison of Imprecision. Twenty to thirty patients’ specimens, covering the expected clinical range (normal, high, low), should be analysed in triplicate by a ‘user-evaluator’, and by a competent Medical Laboratory Scientific Officer.
These experiments will provide estimates of optimal (MLSO) and achievable (NPT user) levels of precision (mean, SD and CV). If these data are not significantly (clinically) different the equipment should be judged appropriate for use in the operational evaluation (ICSH 1994).

**Between-batch imprecision** During the trial period (over a period of days), several "user-evaluators" should analyse patients' samples in triplicate, from different batches, to achieve a total of 20-30 patients' samples. The samples must cover the expected clinical range (normal, high, low). This much be undertaken under routine conditions to provide an estimate of routine between-batch variance (ICSH 1994).

**Assessment of comparability** During the trial period, a minimum of 40 samples (ICSH 1978) should be analysed by the NPT instrument and be analysed by the central laboratory instrument in the hospital laboratory and comparisons made in accordance with the protocol from the ICSH (1994). This should be repeated—comparing a "user-evaluator" and MLSO on the NPT equipment alone, to provide an estimate of achievable levels of comparability in a near-patient location.

**Carry-over/interfering substances** These aspects will have been fully assessed during the National MDA Evaluation. During this Operational Evaluation the assessment should be limited to determining whether staff are aware of carry-over from, for example, high white cell counts and the effects of interfering substances such as lipids or cold agglutinins. During the course of the evaluation a few samples of these types should be included in each evaluator's assessment and their ability to take appropriate action should be assessed.

**Dilution procedures** Modern analysers sample 'whole blood' and NPT should not involve dilutions—hence this aspect is not included.

**Coagulation analysers**

**Comparison of imprecision** At least twelve samples from patients, with a range of clotting times from normal values to just above the therapeutic range for anticoagulant control, should be analysed by a user-evaluator and by a qualified MLSO. This will provide an estimate of the achievable level of precision (median, SD and CV). If these data are not significantly different, the equipment should be judged appropriate for clinical use. If there are statistically significant differences between the data obtained by the MLSO and the user-evaluator, then it must be considered whether these differences would alter the clinical management of the patient, before the instrument is judged appropriate for clinical use.

**Within-batch imprecision** For instruments using anticoagulated blood or plasma, imprecision should be checked by performing 10 replicate tests from the same blood sample. Blood should be collected from a healthy normal subject, a patient with a mildly prolonged coagulation time (at the lower end of the therapeutic range for warfarin or heparin), and a patient with a moderately prolonged coagulation time (middle of the therapeutic range).

For instruments requiring finger-prick samples, precision should be checked by sampling from six separate finger-pricks from the same volunteer, within a period of 2 h. This should be carried out with at least one healthy normal subject and at least one patient with a moderately prolonged coagulation time (e.g. for PT and APTT, in the mid-point of the therapeutic range for warfarin and heparin respectively).

Some manufacturers provide lyophilized whole blood quality control samples for their instruments, and where available these should also be used for precision exercises.

**Between-batch imprecision** With instruments that can use anticoagulated blood or plasma, lyophilized or frozen plasma with normal and prolonged clotting times should be run twice daily throughout the trial period. Where a lyophilized commercial whole blood sample is available, this should be used as an additional quality control/precision sample.

For instruments which will only use non-anticoagulated whole blood, true between-batch precision cannot be tested. Useful information may be obtained by comparing the median, SD, and CV obtained with each batch of NPT samples with the data obtained in the reference method in the hospital laboratory.

**Assessment of comparability** A minimum of 50 blood samples should be tested and citrated blood specimens sent to the hospital laboratory for comparative analysis.

Where an instrument is evaluated for use in oral anticoagulant control, at least 40 samples with International Normalized Ratios (INRs) spread evenly over the therapeutic range (INR 2.5-4.0), as well as at least 10 samples from over-anticoagulated patients (INR > 4.5) and 10 from healthy normal subjects, should be tested. The hospital laboratory should test the citrated plasma with their routine prothrombin time method. Some reagents do not give comparable results with individual NPT instruments.
If this is the case, the hospital laboratory may wish to use a more appropriate prothrombin time method and reagent. It is recommended that the additional reagent is selected from those in common use in the U.K. with an International Sensitivity Index (ISI) assigned by the manufacturer for the particular method used. If there is any discrepancy over the therapeutic range, it may be necessary to perform larger numbers of tests.

Where an instrument is evaluated for use in an operating theatre, intensive care unit, or renal dialysis unit for control of heparin, the 50 samples should cover the full range of heparin levels encountered in normal use. The NFT instrument APTT should be compared to an APTT, and if possible an anti-Xa assay for heparin in the hospital laboratory using citrated plasma. The local routine reagent and method for APTT should be used, provided that it is suitable for heparin monitoring. The APTT ratio must be calculated using the mid-point of the locally derived reference range, or the geometric mean-normal APTT, derived from at least 20 fresh samples from healthy normal subjects. The anti-Xa assay for heparin may act as a useful reference point for comparing heparin levels, since the APTT is influenced by numerous variables, and there is wide variation in heparin sensitivity between reagents. If an MDA operational evaluation has been performed, then the above protocol must be used to ensure good precision and comparability, before the introduction of the NFT instrument into clinical practice.

There is no routinely used counterpart for the activated clotting time (ACT) in the hospital coagulation laboratory. The only meaningful comparison may therefore be with the anti-Xa assay for heparin.

Some NFT instruments perform a thrombin time (TT) with and without protamine sulphate, for the detection of haemostatic abnormalities and heparin control. A comparison should be made with a TT on citrated plasma, with the thrombin reagent diluted appropriately to be sufficiently sensitive for the purpose for which the TT is being performed.

Appendix 1

Sample Questionnaire: User-Evaluators

Instrument name (model):
Manufacturer:
Evaluator’s name:
Start date of evaluation:
End date of evaluation:
Number of patient samples analysed:

Grades
0 Poor 1 Unsatisfactory 2 Acceptable
3 Good 4 Excellent NA Not applicable

GRADING
Were the SOPs easy to follow?
Was the instruction manual documentation easy to follow?
Was the equipment easy to start-up?
Was the start-up rapid?
Was the equipment easy to shut-down?
Was the shut-down rapid?
Was the equipment easy to use?
Was the equipment easy to maintain?
Did you understand the training?
Are there too many steps in the analysis?
Was the instrument generally reliable?
Did too many faults occur with the instrument?
Were faults easily rectified?
How did you find the presentation of results?
How would you grade the total analysis time?
Were reagents easy to use?
Was reagent packaging satisfactory?
Comments

Appendix 2

Sample Questionnaire: Haematology Staff Assessment

Instrument name (model):
Manufacturer:
Evaluator’s name:
Start date of evaluation:
End date of evaluation:
Number of patient samples analysed:

Grades
0 Poor 1 Unsatisfactory 2 Acceptable
3 Good 4 Excellent NA Not applicable

GRADING
Is the equipment in a secure environment?
Is the instrument ‘tamper-proof’?
Were patient results treated with appropriate confidentiality?
Were the SOPs used appropriately?
Was the rate of sample throughput satisfactory?
Were manufacturers’ manuals satisfactory?
Were reagents used appropriately?
Were reagents stable during the evaluation?
Were reagents stored appropriately?
Were failure alarms noted?
Were ‘out of control’ alarms noted?
How would you grade ‘user maintenance’?
How would you grade ‘equipment cleaning’ by users?
How would you grade the use of quality control samples?
Was Internal Quality Control appropriate?

Did IQC samples cover the appropriate clinical range? [ ]
Was quality maintained in small batches of patient samples? [ ]
Is there an appropriate EQA scheme available? Yes/No
Would users register with an appropriate EQA scheme? Yes/No/NA
Were specimens collected properly? [ ]
Were specimens in the correct container? [ ]
Were samples identified properly? [ ]
Were samples of appropriate quality? [ ]
Was the volume of blood appropriate (90–110% of nominal volume)? [ ]
Were specimens stored properly? [ ]
Were sample mixing conditions appropriate? [ ]
Were any samples analysed that contained clots? Yes/No
Were any haemolysed samples analysed? Yes/No
Were request forms appropriate? [ ]
Were request forms stored appropriately? [ ]
Was the method of reporting results appropriate? [ ]
Were result reports integrated into the hospital? Case-notes
Were historical results stored properly? [ ]
Were samples disposed of properly? Yes/No

Joint Working Group (JWG) on External Quality Assessment (EQA) in Pathology (1992) Guide-lines on the control of Near-Patient tests (NPT) and procedures performed on patients by non-pathology staff. Available from D. Xiaishow. Secretary, JWG/EQA, c/o Med House. Derby Road. Liverpool. L20 1EA.