Guidance on the Provision of Testing Services in Pharmacies

Pharmaceutical Society of Ireland

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Contents

1. Introduction

The purpose of this guidance is to support pharmacy owners and pharmacists in the provision of safe and effective testing services to patients and the public. Pharmacists and pharmacies should not provide testing services unless they are satisfied that the requirements of this guidance can be met.

Technological advances in medical tests and associated medical devices have facilitated the increased provision of testing services in pharmacy for patient diagnosis, monitoring and screening. The appropriate use of such tests and medical devices by pharmacists has the capacity to increase patient access to these services, to allow for patient screening, to improve public health and to enhance inter-professional collaboration. Earlier detection, prevention and improved management of patients' medical conditions can also be achieved through the responsible use of such tests. However, in order to maximise patient outcomes and ensure patient safety, the provision of such services and any related information must be in accordance with best practice standards.

One of the duties that the Pharmacy Act 2007 imposes on the PSI is, the *duty to take suitable action to improve the profession of pharmacy*. The guidance also sets out the standards that must be met if testing services are to be offered in pharmacies.

In the provision of these services, it is essential that patients' expectations of the standard of care provided by their pharmacist are met and that they can be assured of the quality, accuracy and reliability of such testing.

2. Regulatory Requirements

Pharmacists and pharmacy owners must be satisfied that the provision of testing services is in full compliance with all relevant requirements of pharmacy legislation and any other pertinent legislation e.g. Safety, Health and Welfare at Work Act 2005 and the Data Protection Acts, 1988 & 2003.

In addition, pharmacists must ensure that their practice is in compliance with the statutory Code of Conduct for pharmacists and the requirements and guidance of the PSI.

Pharmacists should comply with the *Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care* produced by the Health Products Regulatory Authority (formally called the Irish Medicines Board) and approved by the PSI Council. These guidelines are available on the PSI website www.thepsi.ie.

3. Implementation of Testing Services within a Retail Pharmacy Business

Principle one of the PSI Code of Conduct states that *the practice by a pharmacist of his/her profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient*. Principle two states that, *a pharmacist must employ his/her professional competence, skills and standing in a manner that brings health gain and value to the community and the society in which he/she lives and works*. Therefore, members of the public should expect that the quality of services and products supplied in pharmacies are appropriately assured.

In addition, under principle three, prior to the provision of a test, patients should receive honest, relevant, accurate, current and appropriate information on the nature, cost, value and benefit of the service(s) provided. Pharmacists should also ensure that their professional judgement is not impaired by personal or commercial interests including incentives, targets or similar measures when evaluating the appropriateness of test(s).

3.1 Clinical Governance

3.1.1 Professional Management

Superintendent pharmacists hold overall responsibility and accountability for the selection, provision and supervision of the testing service(s) provided in the pharmacy or pharmacies that are under their control. This includes ensuring the quality and appropriateness of the testing service(s) provided. A system for the professional management and clinical governance of the testing service(s) must be established by the superintendent pharmacist for each pharmacy under their control. It is also the responsibility of the pharmacy owner and superintendent pharmacist to ensure that all aspects of the testing service(s) provided are covered by professional indemnity arrangements.

Pharmacy owners are responsible for ensuring that, in any of their pharmacies where testing services are being provided, their superintendent pharmacists are facilitated and supported in ensuring that the necessary equipment, facilities and training are made available so as to enable them to effectively discharge their roles and responsibilities.

Supervising pharmacists, under the personal control of the superintendent pharmacists, are responsible for the operation of any testing service(s) provided in the pharmacy under their personal charge and each individual pharmacist is responsible for any testing services that they may provide.

3.1.2 Policies and Procedures

Superintendent and supervising pharmacists should ensure that appropriate and robust, documented policies and standard operating procedures (SOPs) are incorporated into the pharmacy's professional management system, for all aspects of each testing service provided. These policies and SOPs should be reviewed and updated, at least on an annual basis, to ensure that they are in accordance with current best practice. Policies and SOPs should take into account and comply with relevant legislation and guidance, patient needs, best practice and health and safety requirements. These documents should clearly designate staff duties and responsibilities.

Appropriate components of such policies and SOPs include: patient inclusion and exclusion criteria, patient information, consent, interpretation of results, follow up and referral, performance of the test(s), recordkeeping, staff training, the storage and maintenance of equipment and consumables, the management of incidents, safety notices and complaints, waste management, infection control and quality assurance.

Procedures should be put in place for the recording, reporting and investigating of errors, 'near misses' and relevant incidents (including sharps injuries); such procedures should detail the actions to be taken in the event of an incident occurring.

Superintendent pharmacists should ensure that a complaint handling policy is in place and that all staff are familiar with the appropriate procedure for dealing with complaints or concerns of patients and the public.

3.1.3 Clinical Appropriateness

Tests should only be offered or performed by pharmacists where there is an established clinical and scientific evidence base and for which the validity, accuracy and reliability of the test(s) can be assured. The purpose, health benefit and clinical need for the use of a particular test must be established prior to its introduction and re-evaluated at regular intervals.

Where available, relevant national healthcare strategy, health promotion campaigns, clinical guidelines and best practice should be observed in the provision of testing services.

Patient inclusion/exclusion criteria should be established for each test, which considers not only the test's safety and efficacy but also the clinical need and benefit of providing the test to particular patient cohorts. Prior to the provision of a test to a patient, the appropriateness of the test should be established by the pharmacist with the patient, and in all instances on an individual patient basis.

3.1.4 Patient Consultations

Due to the potential significant health implications for patients, all tests should be performed by a registered pharmacist or by a recognised registered healthcare professional acting within the scope of their practice.[1]

Consultations should take place at a suitable time e.g. to ensure fasting status. Consultations should also be of a suitable duration e.g. to provide adequate counselling or allow for incident management. An appointment system may therefore be appropriate.

At the outset of the consultation, a relevant clinical history should be established to determine which (if any) tests are indicated for each patient.

1 The PSI may review this requirement should other members of the pharmacy team become members of a registered and regulated profession e.g. pharmacy technicians.

Pharmacy policies and SOPs should outline how the pharmacy will protect patient confidentiality and also protect vulnerable groups of patients e.g. older people, children, people with disabilities or patients for whom the pharmacist develops reasonable concerns for their safety and welfare. In particular, it is possible that in the provision of services, such as pregnancy or sexually transmitted infection testing, that concern for patient safety and welfare may arise. Where such services are provided, having regard to the age and circumstances of the individual patient and any child protection issues arising, pharmacists should consider whether referral to a medical practitioner, other healthcare professional, or other agency or authority, is appropriate.

3.1.5 Information and Consent

In line with principle three of the Code of Conduct, prior to the administration of a test the patient should receive honest, relevant, accurate, current and appropriate information on the nature, purpose and limitations of the test being carried out. They should be advised of the risks of having or not having the test performed and the testing process should be outlined. Information should be provided in a clear and comprehensible manner.

The test should only be carried out once the patient has given their consent to the performance and the recording of the test.[2] Consent should be documented for all tests involving the use of blood or bodily fluids and any tests whose results may have significant health implications for the patient. This record of consent should include the patient's signature (or that of a parent or guardian in the case of a child under the age of 16) and should be securely retained in the pharmacy in hard copy or electronic format. Where patients are attending the pharmacy for an on-going testing service, although consent must be obtained on each testing occasion, it may be sufficient to document consent to on-going testing at the commencement of this service.

Patients should be encouraged to consent to the sharing of their results with their general practitioner, if the patient attends one. Consent regarding the sharing of results should be discussed and, where possible, obtained prior to testing. Where patients do not agree to the sharing of their results, they should be advised regarding the consequences of withholding this information and counselled to seek medical advice where appropriate.

3.1.6 Interpretation of Results, Follow up and Referral

Results should be interpreted in the context of the patient's medical history, family history, age, gender, current medical status, use of medications and previous results, where appropriate. Interpretation should be in accordance with current best practice and any national guidelines. Patients should be provided with suitable, evidence based lifestyle advice.

At the conclusion of the consultation, patients should have received all the necessary information and counselling about their results, the significance of their results and any further action advised. Written information should also be provided and results should be provided using stated recognised units of measurement.

Appropriate referral criteria and clear and appropriate referral pathways, reflecting current best practice and any national guidelines, should be in place. Pharmacists should, where appropriate and prior to the establishment of testing services, advise other local healthcare providers regarding the testing services that will be provided and the referral mechanisms that will be used.

Referral criteria should be established taking cognisance of both patient safety and the appropriate utilisation of health resources. These should ensure that patients are referred for further medical attention, asked to return to the pharmacy and/or directed to sources of further information and support, as necessary.

2 *Consent: A guide for health and social care professionals*, produced by the HSE Quality and Patient Safety Directorate, is a useful reference for pharmacists concerning the common issues, relating to consent, that may arise in practice e.g. issues regarding capacity, consent for the treatment of a child. It can be found at: www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Advisory_Group/guidehealhsocialcareprof.pdf

In addition, pharmacists should ensure that any results that are unexpected in the context of the patient being tested are referred, as appropriate, for further investigation. Referrals should be made in a manner that does not unduly alarm or inappropriately reassure patients.

Procedures for the management of any medical emergency, which could be identified as a result of testing, should also be established.

Patients should be given the contact details for the pharmacy, and the name of the pharmacist who performed the test, should they have anything further that they wish to discuss with the pharmacist after they leave the consultation.

3.1.7 Recordkeeping

Adequate and appropriate records of the patient consultation and test results should be kept with the patient's full knowledge and consent. It may be appropriate to keep such records with the patient's medication record.

These records should include:

- The date of the test
- The patient's name, address, contact details and date of birth
- The name of the pharmacist/healthcare professional who carried out the test
- The test results including units of measurement
- The test batch numbers, where appropriate
- The relevant details of the consultation including any referral or recommendations made and, where pertinent, the patient history and test indication.

In addition, records should allow the identification of the name and any serial number of the equipment used for each patient test.

Records of patient consent should be retained in the pharmacy in hard copy or electronic format. The management of any data or information recorded, collected or retained must be in accordance with relevant legislative provisions, including those of the Data Protection Acts 1988 and 2003. Records should be kept securely for an appropriate period of time that is both in keeping with data protection legislation and in the interests of patient safety. Access to such data may be required for legal, insurance or other purposes at some time in the future.

3.2 Pharmacy Staff

Where testing services are provided in pharmacies there must be adequate pharmacist personnel to allow for the service to be appropriately delivered while facilitating the supervision of all other professional activities being undertaken within the pharmacy.

3.2.1 Training, Competence and Continuing Professional Development

For each testing service provided, the pharmacy owner must be satisfied that the needs of the superintendent pharmacist are fully met in regard to the training needs of the pharmacist staff providing the testing service. They must also be satisfied that each pharmacist has successfully completed the appropriate training for the conduct of the test and that he or she has acquired, and continues to possess, the requisite competence, knowledge and skills.

Pharmacists should complete accredited training, where available for the provision of the relevant service. They should be capable of demonstrating any competencies identified as required for the provision of the testing service. In line with principle five of the Code of Conduct, pharmacists should maintain their own competence in the services provided and continue to update their knowledge and

skills as necessary as part of their on-going continuing professional development.

All pharmacy staff should be familiar with the testing services provided in the pharmacy and be trained according to their level of involvement. Staff training should be on going and ensure familiarity with all relevant policies and SOPs. Records of staff training should be kept on the premises.

3.3 Pharmacy Facilities and Equipment

3.3.1 Testing Service Delivery Area

Testing should take place in an area of the pharmacy designated for the provision of the testing service(s). The requirements for an area to be used for most testing services exceed those specified in the PSI's Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses, particularly in relation to the size of the area required, the degree of privacy required, and the equipment requirements.

The area provided for testing service delivery should ensure the dignity and privacy of the patient e.g. there may be visual privacy requirements. The area should be of a sufficient size and appropriate layout to allow for a comfortable and safe workflow in the performance of the test and comfortably accommodate the patient, their carer or chaperone and the pharmacist. Space should be available to accommodate the equipment, consumables and documentation required; it may be appropriate to install a sink in this area to facilitate the provision of professional services and to ensure hand hygiene. There should be adequate space for dealing with potential adverse events, such as a patient fainting. If consumables, sharps or records are to be stored in this area, there should be sufficient space to accommodate these. Sharps, clinical waste and records should be kept secure when not in use. A second separate area within the pharmacy may be required and designated solely for the analysis of patient samples. This area should be of an appropriate layout and finish and should be designed to safeguard patient confidentiality and eliminate any risk of contamination or cross contamination.

The dispensary, storage areas or any area where food or drink is consumed are not appropriate places for the collection of samples or the performance of tests.

Where the patient consultation area is used for testing, pharmacists should consider the expected volume of activity that the service will generate and the potential impact on the availability of the patient consultation area for counselling patients about their medicines.

3.3.2 Equipment and Consumables

Equipment for the provision of testing services will vary depending on the test(s) being undertaken and may include: blood pressure monitors, weighing scales, blood glucose monitors, carbon monoxide monitors and other point of care testing equipment. Consumables may include: lancets, test strips, control solutions, capillary tubes and disposable mouthpieces. (These lists are neither indicative nor exhaustive.)

When selecting equipment, pharmacists should assure themselves of its accuracy and validity in the context of its intended use e.g. screening or disease management. Where possible the accuracy, reliability and validity of the equipment should have been evaluated by an independent body. The analytical and clinical performance of the device and any device limits or interferences should be considered. Pharmacists should also establish the equipment and consumables' safety and practicality of use within the pharmacy setting e.g. appropriateness of sample size and contamination risks. Where a piece of equipment is being considered for multi-patient use, the pharmacist should assess its suitability for such use e.g. they should consider the potential for cross contamination, and the durability of measurement accuracy.

Equipment should only be used in accordance with the manufacturer's instructions for use, should be maintained in good order and should be serviced, cleaned and calibrated in accordance with the manufacturer's directions. Records of maintenance and repair should be kept in the pharmacy. To facilitate equipment traceability and recall, the serial number of any equipment purchased should be registered with the supplier, should the supplier offer such a service.

An adequate stock of any equipment or consumables required for the provision of the service should be maintained. Consumables should have their expiry dates frequently checked, where applicable, and be stored according to the manufacturer's instructions. Consumables that require refrigeration should be clearly labelled and kept in a designated area of a pharmaceutical grade refrigerator, appropriately segregated from medicinal products. The temperature range recommended for the storage of such products should be maintained, as per manufacturer's instructions, and appropriate records should be in place to demonstrate this.

For the testing of blood or bodily fluids, appropriate personal protective equipment should be provided and worn. Gloves, plasters and tapes should be latex free. When a capillary blood sample is required and appropriate, single use safety lancets suitable for the patient should be used. Where test strips are used, an assessment should consider the most appropriate method for reading the strips.

Devices which fulfil the definition of an in-vitro diagnostic medical device (e.g. blood glucose meters) must comply with the In-vitro Diagnostic Medical Devices Directive 98/79/EC and related SI 304 of 2001. General medical devices (e.g. blood pressure monitors) must comply with the Medical Devices Directive 93/42/EEC and related SI 252 of 1994. All selected medical devices must display the CE mark, which indicates that the device satisfies the relevant legislation. This means that a medical device must achieve the performance criteria specified by the manufacturer and in doing so must not compromise the health and safety of patients, service providers and any other persons. However, the presence of a CE mark does not negate the need for pharmacists to establish the suitability of equipment for its intended use.

The Health Products Regulatory Authority publishes notices relating to the safety and/or quality of medical devices. Pharmacists participating in the delivery of testing services should keep aware of these notices. In the event of a recall or safety alert, all necessary steps must be taken to ensure patient safety e.g. contacting and following up with the affected patients, suspending the performance of the test.

3.3.3 Incident Management

Any incident with a medical device that causes, or has the potential to cause, unexpected or unwanted effects is an adverse incident. Pharmacists participating in the delivery of testing services should be aware of the correct management of medical device safety notices and medical device incidents, including patient follow up.

Any suspected adverse incident should be reported to the manufacturer and/or the Health Products Regulatory Authority (HPRA) using the HPRA Incident User report form available from www.hpra.ie. Reports should be as detailed as possible. Where any incident causes injury or poses a risk to the health of a patient/staff member, pharmacists must communicate this risk to both the patient/staff member and, where appropriate and with the persons consent, to their medical practitioner. Risks include inappropriate treatment or a delay in seeking treatment.

3.3.4 Waste Management

Waste products such as sharps and clinical waste should be placed in specialised waste bins in a timely manner. Waste bins should be of an adequate capacity and should not be overfilled. When not in use, they should be stored securely in the testing area or removed and stored in an area inaccessible to the public. Bins should be securely sealed when

filled to the manufacturer's fill line or, if no fill line is present, when three-quarters full. They should then be appropriately secured pending prompt removal from the pharmacy by an appropriately authorised waste management company.

Further information on how to safely dispose of waste should be obtained from the pharmacy's waste management company. Detailed records of the disposal of sharps and other clinical waste should be retained in every pharmacy.

3.3.5 Health and Safety

Prior to the introduction of a testing service, a health and safety risk assessment should be carried out, and appropriate risk reduction measures implemented, to safeguard the health and safety of staff, patients and the public. The results of the risk assessment should be written into the pharmacy's safety statement.

Appropriate, infection control measures should be in place and the current principles of infection prevention and control should be followed when testing bodily fluids. Occupational health advice should be provided to staff; staff should be trained in and observe hand hygiene and adopt universal precautions (whereby all blood and bodily fluids are treated as if infectious).

All pharmacists testing blood or bodily fluids, and all other pharmacy staff, as appropriate, should be offered and encouraged to avail of vaccination against Hepatitis B, and the receipt or refusal of the vaccination, and the completion of vaccination regimes, appropriately documented.

3.4 Quality Assurance

In order to ensure that the results generated by tests are reliable and accurate and to protect patient safety, robust quality assurance systems, including self-audit, should be put in place. Such systems should ensure the on-going monitoring of quality and accuracy and outline the corrective measures to be taken should a quality assurance deficit, or the potential for quality improvement, be identified.

Pharmacists should consider liaising with an accredited clinical laboratory as a source of advice and support when establishing and carrying out tests using blood or bodily fluids. Participation in peer review may also be a useful quality assurance tool. Records of all quality assurance measures should be retained in the pharmacy.

3.4.1 Internal Quality Control

Manufacturers' instructions regarding internal quality control (IQC) procedures should be followed at all times. This may include testing control solutions, calibration etc. IQC testing should take place at appropriate intervals and test results should be documented. If results are outside specification, pharmacists should ensure that appropriate corrective measures are taken.

3.4.2 External Quality Assurance

Pharmacists engaging in the testing of blood or bodily fluids should participate in external quality assurance (EQA) schemes, where available. External quality assurance involves the testing of an unknown sample provided by an independent EQA provider such as the Irish External Quality Assessment Scheme (www.ieqas.ie). If EQA is not available, the appropriateness of the provision of the service should be examined. If a decision is made to provide a service where EQA is unavailable, pharmacists should ensure that additional measures are introduced to ensure quality and patient safety e.g. liaising with a laboratory, additional IQC measures.

The instructions for the EQA scheme should be complied with fully e.g. all pharmacists carrying out tests should be evaluated. Where external quality assurance results identify quality concerns, appropriate corrective measures should be taken.

3.5 Public Information and Awareness

The provision of public information on pharmacy testing services should be consistent with the professional role of the pharmacist. Any clinical claims should be supported by robust evidence. All information should be accurate and factual in nature. Where possible it should be aligned with national healthcare strategy. Information regarding the cost of the testing service should be available to patients. Any such information should not create an invidious distinction between the pharmacy or pharmacist in question and any other pharmacy or pharmacist.

3.6 Samples for Analysis outside the Retail Pharmacy Business

Where samples are collected in the pharmacy for analysis outside of the pharmacy, pharmacists should ensure that the service provided conforms to the quality, safety and confidentiality standards outlined in this guidance. Best practice should be ensured in the storage and stabilisation of samples and in the transport of any samples to hospital laboratories. Results, together with the appropriate information, should be provided to patients within a suitable timeframe.

3.7 Tests Carried Out by Pharmacists outside a Retail Pharmacy Business

When considering the provision of testing services other than in a retail pharmacy business (e.g. for the purposes of health promotion) pharmacists must ensure that patients receive the same standard of professional care as those patients who attend personally at the pharmacy practice. Patients should be given the contact details for the pharmacy where their consultation record(s) will be kept, and the name of the pharmacist who performed the test, should they have anything further that they wish to discuss with the pharmacist after they leave the consultation.

3.8 Tests Carried Out by an Independent Practitioner

It is important to note that any service carried out within a retail pharmacy business is carried out under the responsibility and supervision of the superintendent and supervising pharmacist(s). This includes engaging another recognised healthcare professional to carry out the service within the pharmacy.

If a recognised independent healthcare practitioner is providing an independent service and the service is not being provided as part of the retail pharmacy business, a clear contract should be in place to provide clarity for this. It must be clear to the patient that this service is not being provided by the pharmacy or pharmacist; it must also be clear to the patient who the service provider is.

4. Home Use Tests Sold or Supplied in a Retail Pharmacy Business

This section provides guidance on the sale or supply of tests and testing equipment in pharmacies for use by patients in their homes. Patients and members of the public have a right to expect that the quality, safety, efficacy, reliability and validity of any such products supplied in pharmacies have been appropriately established. Under principle one of the Code of Conduct, pharmacists should not supply any product where there is reason to doubt its safety, efficacy or quality or where a product may impose a hazard to a patient's health or wellbeing. Pharmacists should

therefore only sell or supply test(s) for which the appropriateness of the test or of such supply has been established.

Superintendent and supervising pharmacists should consider the appropriateness of the stocking of each such test on an individual basis. This should be in the context of their roles and responsibilities, with regard to the Code of Conduct and the requirement that they direct their professional activity in the best interests of patients and the public.

When establishing the appropriateness of a test to be sold or supplied in the pharmacy, pharmacists should assess the following criteria:

- **Clinical benefit:** Do the results of the test provide valuable clinical information to the patient? Is the provision of the test in the best interest of the patient and in accordance with best clinical practice? Are tests provided in line with relevant national healthcare strategy or health promotion campaigns, where available?
- **Usability:** Can the test be performed in the recommended manner by the patient? Are the instructions for use adequate, appropriate and easy to read and understand? Are there health and safety issues raised in the performance of the test?
- **Validity:** Will the test provide consistent, reliable and accurate results?
- **Specificity:** Is the test non-specific i.e. may it indicate a variety of conditions or no condition at all?
- **Accuracy of claims made and supplementary information:** Are the claims made in the promotion of the product valid and is the information supplied with the product accurate? Will this information help the patient to correctly interpret their results and to take any necessary further actions?
- **Potential consequences of incorrect results:** If the patient receives a false positive, false negative or incorrect result, what are the consequences and can these be negated?

Pharmacists should only sell or supply tests for which the appropriateness of such supply can be assured in light of the criteria above.

Medical testing devices supplied in pharmacies should be CE marked, however the presence of a CE mark does not negate the need for pharmacists to establish the suitability of the testing device for its intended use. Pharmacists should also consider the need for and ease of their servicing, calibration and maintenance. Those obtaining tests or testing equipment from a pharmacy should be advised to report any problems they experience with tests or devices to the pharmacy.

Pharmacists should be able to advise and answer questions on the use and maintenance of any tests or medical testing devices supplied in their pharmacy. Pharmacists should also be able to advise and answer questions on the interpretation of the results obtained and on the management of any medical conditions being monitored. Information provided should include advice regarding when those acquiring tests should seek further medical help, where further medical help should be sought and/or advice regarding appropriate lifestyle interventions.

Where patients have been supplied with medical testing devices for the on-going self-monitoring of a medical condition, pharmacists should only supply replacement devices where it is in the best interests of the patient e.g. in the event of a patient with diabetes losing their blood glucose monitor. In such cases, pharmacists should advise and answer questions on the use and maintenance of the medical testing device and on the interpretation of the results obtained. Results should be generated in the same units of measurement previously used by the patient. Patients should be advised to inform their healthcare team regarding the change of device and pharmacists should advise patients regarding any on-going consumable requirements.

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5. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Are all pharmacists familiar with the *PSI Guidance on the Provision of Testing Services in Pharmacies* and is a copy readily available in the pharmacy?				
Are all testing services covered by appropriate professional indemnity arrangements?				
Are all tests performed and/or home use tests sold or supplied accurate, valid and reliable? Have the purpose, benefit, clinical need and evidence base for their use been established?				
Are documented policies and SOPs relating to all aspects of the provision of testing services available in the pharmacy?				
Do these policies and SOPs address: • Patient inclusion and exclusion criteria • Patient information, consent, interpretation of results, follow up and referral • Performance of the test • Recordkeeping • Staff training • The storage and maintenance of equipment and consumables • The management of incidents, safety notices and complaints • Waste management • Infection control • Quality assurance				
Are all relevant staff aware of, and trained in, the pharmacy's testing service policies and SOPs?				
Do all policies and SOPs contain an implementation and review date and are these documents reviewed regularly, in accordance with best practice, when any element of the process changes, or at a minimum annually?				
Are hard/electronic copies of patient consent records maintained in the pharmacy for all tests involving blood/bodily fluids?				
Are adequate and appropriate records of the patient consultation and the test results kept?				