

Guidelines for
Safe and Effective Management
and Use of
Point of Care Testing
in Primary and Community Care



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Chairman's Foreword

Point of care testing involves the performance of a test in the immediate vicinity to a patient to provide a rapid result outside the conventional laboratory environment. Recent advances in diagnostic technology and the delivery of healthcare services has resulted in an increase in the demand for and provision of point of care testing (POCT) in Primary and Community Care environments. GP surgeries, community pharmacies, community clinics, health centres, industrial medical centres and anticoagulation clinics all represent Primary and Community Care locations. While the concept of POCT in Primary and Community Care is not new, the complexity and variety of tests and instruments available and in use has evolved significantly.

The capacity to provide a rapid test result which can be acted upon directly permits increased clinical effectiveness and improved outcome for patients. However this is only true if the result delivered is accurate and reliable. These Guidelines extend the principles outlined in the Guidelines for Safe and Effective Management and Use of Point of Care Testing, published by the IMB in 2007, from hospital to community settings.

There are three different aspects to POCT testing; Diagnosis, Monitoring and Screening. Where POC testing is being used primarily for screening purposes as is usually the case in a pharmacy setting, then a robust system of patient consent, follow-up and referral should be put in place. POCT is not a replacement for conventional laboratory testing but rather a supplement to it. POC test results which are used for diagnosis or critical patient management decisions, or which give unexpected results should be confirmed by hospital laboratories to ensure accurate diagnosis and to facilitate correct patient management decisions.

It is recommended that these guidelines be adopted by those responsible for POCT in Primary and Community Care settings in Ireland to ensure that POCT is performed in a well structured and controlled manner to minimise the risk to public health and to ensure patient safety. A well-managed and properly governed system for the provision of POCT services has the potential to deliver considerable benefits to the Irish health service and to patients.

I am grateful for the time and contributions of the Working Group on

Point of Care Testing in Primary and Community Care settings, which I had the privilege to chair, and in particular the energy and patience of the IMB staff who co-ordinated our efforts on behalf of the Advisory Committee for Medical Devices (ACMD).

DR GEOFF CHADWICK

Chairman, Working Group on Point of Care Testing in Primary and Community Care Settings and member of the Advisory Committee for Medical Devices

Membership of the Working Group on Point of Care Testing in Primary and Community Care

Ms. Damhnait Gaughan	<i>Pharmaceutical Society of Ireland</i>
Dr. Joe Clarke	<i>Health Service Executive</i>
Dr. Deirdre Mulholland	<i>Health Information and Quality Authority</i>
Dr. Gerard Boran	<i>RCPI Faculty of Pathology</i>
Dr. Sean Cunningham	<i>Association of Clinical Biochemists in Ireland</i>
Dr. Nuala McCarrroll	<i>Association of Clinical Biochemists in Ireland</i>
Mr. John Collier	<i>Academy of Medical Laboratory Science</i>
Mr. Tadhg Hurley	<i>Academy of Medical Laboratory Science</i>
Dr. Judith Martin	<i>Irish Medicines Board</i>
Ms. Ann O'Connor	<i>Irish Medicines Board</i>
Dr. Geoff Chadwick	<i>Advisory Committee for Medical Devices</i>

Executive Summary

Recent advances in diagnostic technology and the delivery of health-care services has resulted in an increase in the demand for and provision of point of care testing (POCT) in Primary and Community Care environments. Point of care testing involves the performance of a test in the immediate vicinity to a patient to provide a rapid result outside the conventional laboratory environment. GP surgeries, community pharmacies, community clinics, health centres, industrial medical centres and anticoagulation clinics all represent Primary and Community Care locations. While the concept of POCT in Primary and Community Care is not new, considering that urinalysis and blood glucose testing has been done for many years in GP surgeries, the complexity and variety of tests and instruments available and in use has evolved significantly. Point of care testing has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result near a patient which can be acted upon directly. This can lead to increased clinical effectiveness and improved outcome for patients. However this is only true if the result delivered is accurate and reliable. POCT is not a replacement for conventional laboratory testing but rather a supplement to it.

There are three different aspects to POCT; Diagnosis, Monitoring and Screening. Where POC testing is being used primarily for screening purposes as is usually the case in a pharmacy setting, then a robust system of patient consent, follow-up and referral should be put in place; refer to Appendix 7.3 (GP referral letter template). POC test results which are used for diagnosis or critical patient management decisions, or which give unexpected results should be confirmed by hospital laboratories to ensure accurate diagnosis and to facilitate correct patient management decisions. It is therefore imperative that POCT in Primary and Community Care settings is performed in a well structured and controlled manner to minimise the risk to public health and ensure patient safety and quality of care.

The majority of problems that arise with POCT are due to incorrect sampling technique, poor operator experience and training, inappropriate interpretation of results and absence of appropriate quality control which

can lead to inaccurate and unreliable results which in turn may have serious implications for patients.

The aim of this document is therefore to provide guidelines to Primary and Community Care settings on the implementation and management of a POCT service with a specific focus on the safe use of Point of Care (POC) tests. It is intended to provide recommendations for best practice for POCT in the Primary and Community Care environment to ensure accurate and reliable patient results. Practitioners carrying out any POC service should be cognisant of the regulatory and professional requirements and standards specified by regulatory and professional bodies governing such testing and their profession e.g. statutory code of conduct.

The majority of tests used at POC (for example pregnancy tests and blood glucose meters) fulfil the definition of an *in-vitro* diagnostic medical device (IVD) and hence must comply with the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC. Other commonly used POC devices such as blood pressure monitors, pulse oximeters and thermometers are regarded as general medical devices (GMDs). These medical devices are governed by the Medical Devices directive 93/42/EEC. The Irish Medicines Board (IMB) is designated as the Competent Authority for medical devices in Ireland, including IVDs. Its role is to ensure that all medical devices sold into the Irish market comply with the relevant legislation. There is a legal requirement on manufacturers to notify the IMB of all adverse incidents involving medical devices including those used for POCT. All adverse incidents (refer to section 2.6) that occur with POCT devices must be reported to the manufacturer and/or the Irish Medicines Board (IMB) using the appropriate form located on the IMB website (www.imb.ie). Direct user reporting of adverse incidents to the IMB is not mandatory but is encouraged by the IMB. A user adverse incident report form is included in appendix 7.1.

Key Recommendations

The following list summarises the key recommendations in these guidelines, which are necessary for the safe use and management of POCT in Primary and Community Care.

- Where POCT services are provided, a system for clinical and managerial governance of the service should be established including a person designated as responsible and accountable for the service.
- It is advisable that providers of POCT are aware of other laboratory services in their locality which can provide specialist advice and expertise if required and be cognisant of utilising them as appropriate. It is recommended to consult the Guidelines for Safe and Effective Management and Use of Point of Care Testing which recommends communication between the hospital and Primary and Community Care sectors.
- Only trained and fully competent staff should perform POCT.
- Standard operating procedures should be developed and implemented for all aspects of the POCT service, including the performance of the POC test, record keeping, interpretation of results, patient referral criteria, quality assurance, patient and staff safety and health.
- Quality assurance is key to assuring the accuracy and reliability of a POCT service and quality control testing should be performed for POC tests in accordance with manufacturer's instructions. It is further recommended that POCT providers should participate in External Quality Assurance (EQA) schemes, where available.
- Patient results should only be interpreted and reviewed by appropriately trained personnel.
- All patient and quality control results should be recorded appropriately either via paper or electronic format in accordance with defined procedures and the Data Protection Act.
- Appropriate referral criteria should be in place to ensure that confirmatory testing is performed and patients are referred for further medical attention as necessary.

- All adverse incidents that occur with POCT devices must be reported to the manufacturer and/or the Irish Medicines Board (IMB) using the appropriate form located on the IMB website (www.imb.ie) and/or the appropriate professional regulatory body, if necessary.
- POCT should be reviewed and monitored on an ongoing basis and a test should be withdrawn or suspended in the event of a safety related issue e.g. a recall.
- POCT devices should be CE marked as this is an indication that the device meets the requirements of the relevant legislation.
- It is the responsibility of the service provider to ensure that appropriate occupational health advice is provided to staff performing POCT.
- Records should be kept of staff who have been trained in carrying out and/or interpreting test results.

The implementation of these guidelines should provide the framework to facilitate the safe use of POCT in Primary and Community Care settings which in turn will deliver healthcare benefits for patients.

1.0 INTRODUCTION

1.1 What is Point of Care testing?

Point of care testing (POCT) involves the performance of a test in the immediate vicinity of a patient to provide a rapid result outside the conventional laboratory environment. Recent advances in diagnostic technology and in the provision of healthcare services have resulted in an increased demand for POCT in the Primary and Community Care environments such as GP surgeries, community pharmacies, community clinics, health centres, industrial medical centres and anticoagulation clinics. While the concept of POCT in Primary and Community Care is not new, considering that urinalysis and blood glucose testing has been done for many years in GP surgeries, the complexity and variety of tests and instruments available and in use has evolved significantly. Pharmacies have also moved into the area of POCT through the provision of health screening services. Currently the level of POCT in Primary and Community Care can range from simple tests such as urinalysis or pregnancy tests to more complex analysis such as cardiovascular risk monitoring and prothrombin time / INR monitoring. There are a number of advantages to the provision of a POCT service in Primary and Community Care including patient convenience, availability of rapid results to facilitate patient management and the screening of patients for early identification of certain diseases. However this is only true if the test result that is provided by the POCT service is accurate and reliable. It is therefore imperative that POCT in Primary and Community Care settings is performed in a well structured and controlled manner to minimise the risk to public health and to ensure patient safety.

1.2 Scope

The aim of this document is to provide guidelines to Primary and Community Care settings for the implementation and management of a POCT service with a specific focus on the safe use of POC tests. It is intended to provide recommendations for best practice for POCT in Primary and Community Care environments to ensure accurate and reliable patient results.

1.3 Point of care (POC) tests used in Primary and Community Care settings

There is a wide variety of tests available and in use for POCT in Primary

and Community Care, examples of which are outlined in Table 1. These include test kits operated alone or with an instrument which can provide either a qualitative or quantitative result.

TABLE 1:
Examples of POC tests used in Primary and Community Care settings
(not an exhaustive list)

Medical Device	Medical Device category
Blood glucose (includes self-testing devices)	IVD
Urinalysis (with or without a reader)	IVD
Cholesterol, Triglyceride and HDL	IVD
Anticoagulant therapy monitoring (includes self-testing devices)	IVD
Pregnancy and ovulation tests (includes self-testing devices)	IVD
Prostate Specific Antigen test	IVD
Haemoglobin	IVD
<i>Chlamydia trachomatis</i> kits	IVD
Faecal occult blood tests	IVD
<i>Helicobacter pylori</i> tests	IVD
Blood Pressure Monitor	GMD*
Pulse Oximeter	GMD*
Thermometer	GMD*

* *General Medical Devices (GMDs) differ greatly from IVDs in relation to their mode of action, quality control procedures and quality assurance structures. Advice relating to these devices should be sought from a source with relevant expertise such as the manufacturer or their authorised representative.*

2.0 REGULATORY REQUIREMENTS FOR POC TESTS

2.1 What is a medical device?

As defined in the Medical Devices Directive (93/42/EEC), a medical device means any instrument, apparatus, appliance, material or other

article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

2.2 What is an *in-vitro* diagnostic medical device (IVD)?

As defined in the IVD Directive 98/79/EC, an IVD is any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures

The majority of test kits and instruments which are used for POCT in Primary and Community Care (see examples listed in Table 1) are defined as *in-vitro* diagnostic medical devices (IVDs). Broadly, an IVD can be a reagent, a test kit, an instrument or a blood collection receptacle which is intended by a manufacturer for the *in-vitro* examination of specimens derived from the human body (for example blood, urine, saliva or faeces) to provide information regarding a physiological, pathological or therapeutic state.

Note: Devices intended to be used only in the course of law enforcement or other non-medical purposes, for example paternity tests or tests for detecting drugs of abuse or alcohol, are not considered IVDs. If however the *in vitro* examination of human specimens with a medical purpose is one of the intended uses of a specific product then the IVD legislation applies.

2.3 What legislation applies?

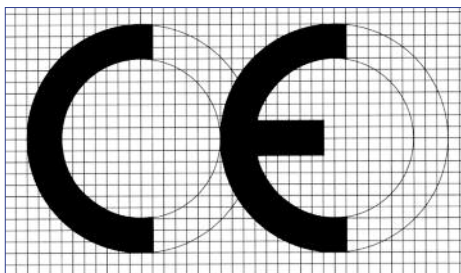
General Medical devices are regulated by the Medical Devices Directive 93/42/EEC and related Irish Regulations. The Medical Devices Directive (93/42/EEC) has been mandatory since June 1998 and has been implemented in Ireland via the Statutory Instrument S.I. No. 252 of 1994, European Communities (Medical Devices) Regulations, 1994.

IVDs are regulated by the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC and related Irish Regulations. The IVD Directive has been mandatory since December 2003 and has been implemented in Ireland via the Statutory Instrument S.I. No. 304 of 2001, European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001.

2.4 Compliance with the legislation

All manufacturers must ensure that any medical device placed and used on the Irish Market complies with the relevant legislation. Compliance with this legislation is demonstrated by displaying a CE mark on the device. The CE mark is represented in Figure 1 below.

FIGURE 1:
Representation of the CE mark that should be displayed on a medical device.



2.5 The Irish Medicines Board (IMB)

The IMB is designated as the Competent Authority for medical devices in Ireland. Its role is to ensure that all medical devices sold into the Irish market comply with 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.

2.6 Adverse Incident Reporting

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects. In a POCT environment the health and safety of patients, service providers or other persons may be impacted. For example, an incorrect result could lead to a delay or inappropriate treatment, a life-threatening illness or injury or a serious deterioration in the state of health, or even death. Any adverse incident involving a POC medical device should be reported to the manufacturer. The manufacturer in turn has a legal requirement to report all adverse incidents that occur with medical devices on the Irish Market to the IMB. The role of the IMB is to ensure that all adverse incidents which occur in Ireland are investigated by manufacturers and that appropriate corrective action is implemented to prevent recurrence.

Direct user reporting of adverse incidents to the IMB is not mandatory but is encouraged by the IMB. A user adverse incident report form is included in appendix 7.1. It is important that POCT service providers understand the meaning of an adverse incident and report it to the manufacturer and / or IMB on occurrence. It may also be necessary in exceptional cases to notify other appropriate regulatory bodies of an adverse incident. POCT service providers have an important role to play in ensuring that any incidents that occur with POCT devices on the Irish Market are reported in order for the manufacturer to conduct an appropriate investigation.

2.7 Implications of the legislation for POCT service providers

- Check with the manufacturer / supplier that the device is CE marked and complies with the relevant legislation prior to purchase and use.
- Ensure that the manufacturer's instructions for use (IFU) are followed

and that the device is only used for the purpose intended by the manufacturer.

- Ensure that all staff are appropriately trained and are familiar with the IFU and the interferences and limitations of the device.
- Ensure that staff understand the meaning of an adverse incident and know what to do on discovery of an adverse incident.
- Establish service and maintenance programmes for medical devices in accordance with manufacturer's instructions.
- Cooperate with corrective actions conducted by the manufacturer, for example the recall of an affected batch of test strips

3.0 IMPLEMENTATION OF POCT IN PRIMARY AND COMMUNITY CARE

It is important that Primary and Community Care settings have a clearly defined and well-structured approach to POCT to ensure that it is performed in a safe and appropriate manner and that the results generated are accurate and reliable. The following outlines key elements that should be considered as best practice for implementation and use of POCT.

Where POC testing is being used primarily for screening purposes as is usually the case in a pharmacy setting, then a robust system of patient consent, follow-up and referral should be put in place; refer to Appendix 7.3 (GP referral letter template).

Prior to the implementation of a POCT service for a specific test, in particular in a GP surgery, careful consideration should be given to the ability of the local hospital laboratory to provide this service in a timely manner. On consultation with the laboratory it may be agreed that the provision of a regular reliable courier service and / or electronic result reporting can provide a turn around time for patient results by the laboratory which meets the requirements of the practice. This in turn may negate the need for a particular POC test to be established in Primary and Community Care settings.

The following points should be considered for the evaluation and approval of a POC test prior to its implementation for diagnostic purposes.

- Ensure the test is CE marked and in compliance with the relevant legislation.

- Ensure that the test is suitable for its intended use and is clinically effective. A business case or cost benefit analysis may be performed. Clinical effectiveness should also be based on evidence based medicine, published guidelines etc.
- Ensure that the POC test achieves the performance specified by the manufacturer.

3.1 Clinical and managerial governance of POCT

Where POCT services are provided, a system for clinical and managerial governance of the service should be established including a person designated as responsible and accountable for the service.

Directors, managers and POCT service providers in Primary and Community Care environments are responsible for ensuring that POCT is carried out in accordance with relevant national regulations, standard operating procedures, agreed quality assurance programmes and health and safety regulations. POCT managers should keep abreast of developments in the POCT area. Managers of Primary and Community Care settings should also ensure they have the appropriate level of professional indemnity insurance cover. Responsibility and accountability for the service should include overall responsibility for quality, training, interpretation and delivery of the service.

3.2 Standard operating procedures

Protocols should be developed and implemented for all POCT services within the Primary and Community Care setting and should include the following elements:

- The manufacturer's instructions for performing the test (IFU)
- Instructions for performing calibration and quality control, the material to be used and the defined acceptable limits
- Guidelines on interpretation of instrument error codes
- Guidelines on interpretation of test results
- Instructions on patient result reporting and comprehensive record keeping ensuring patient data confidentiality is respected at all times
- Reference to the current version of ISO 22870 - a new set of standards for POCT (or equivalent)
- Guidelines for reporting of adverse incidents

- Instructions for co-operation with field safety corrective actions / recalls etc

SOPs for Primary and Community Care environments other than GP practices should also include the referral procedure for patients to a GP or the local hospital based on defined test criteria for all POC tests offered as part of the health screening service. In addition, only appropriately trained personnel should interpret test results, discuss test results with patients and refer them for further medical attention. A template GP Referral letter is included in Appendix 7.3.

The SOP for GP practices should also include referral criteria for POC tests to the local hospital laboratory if the results are outside defined acceptable limits prior to taking patient management decisions.

3.3 Training of POC testing staff

It is imperative that all staff performing POCT are trained and competent in the use of the test. This training may be conducted by the manufacturer or authorised representative. Relevant professional organisations may also provide training on certain tests. It is important to agree the detail and level of training to be provided by the manufacturer or his representative at the time of purchase of the POC test and to ensure that this training is completed and recorded prior to implementation of the POCT service. Training records should be kept in each testing location. Where appropriate, trainers should be designated and such individuals should receive extra training. A training record template is included in Appendix 7.5. The competency of the individual performing POCT should be assessed on an ongoing basis and supplementary training provided if required.

A training programme should be put in place and should include the following elements.

- Instructions on safe working practices
- Principles of operation of the device
- Review of the manufacturer's instructions for use (IFU), limitations of the device, interferences
- Review and understanding of error messages, interpretation, and appropriate responses

- Calibration and quality control requirements, including acceptable limits, appropriate record keeping and required actions for failed results
- Patient preparation, sample collection and handling according to the manufacturer's stated requirements and health and safety regulations
- Interpretation and recording of patient results and appropriate patient referral and follow-up
- Training of new recruits and periodic refresher training for service providers

3.4 Quality Assurance

Quality assurance is key to the delivery of POCT as it ensures that the results generated are accurate and reliable. Internal quality control is where a control sample is tested to ensure that the device is performing within certain defined specifications on a daily basis. The quality control sample may be included with the test kit or may need to be purchased from the manufacturer or authorised representative. It is also recommended that controls from a third party supplier be used where possible. The quality control limits should be defined by the manufacturer and may vary between different batch numbers for each POC test. Quality control testing should also be performed between new batches of test kits. Performing the quality control provides confidence that the POC test is working correctly at a specified time and that the patient test results are reliable before they are acted upon. If the quality control is not performed on a POC test in accordance with the manufacturer's instructions, then the accuracy of the test result generated cannot be guaranteed which in turn may result in serious implications for patients. It is imperative therefore that all POCT service providers adhere to defined quality control procedures and understand what action to take when the quality control sample is out of specification. Advice should be sought from the manufacturer or their authorised representative with regard to the appropriate action to take in such instances.

It is further recommended that POCT providers should participate in External Quality Assurance (EQA) schemes, where available. External quality control involves the testing of an unknown test sample as part of an external quality assurance scheme, for example WEQAS (the largest

provider of EQA services for the Point of Care testing market) or IEQAS (the Irish EQA scheme). This process enables POCT service providers to determine how their POCT device is performing compared to similar devices across other Primary and Community Care sites. Advice should be sought from a source with relevant expertise and quality assurance structures such as the manufacturer, their authorised representative or the local hospital laboratory. It is recommended that, where sought, external accreditation should be performed in line with ISO 22870 or equivalent.

It is advisable for POCT service providers to conduct a self-audit on a regular basis to ensure that the POCT service being provided is accurate and reliable. The Pharmacy Practice Guidance Manual – a self-audit tool for pharmacists and pharmacy owners issued by the Pharmaceutical Society of Ireland Standards and Practice Unit is a useful guide for this activity. Additionally, the checklist included in Appendix 7.4 is a useful guide to ensure the POCT service being provided is optimal.

It is highly recommended to consult the Guidelines for Safe and Effective Management and Use of Point of Care Testing in relation to liaising with designated hospital based POCT committees.¹ This document recommends communication between the hospital and Primary and Community Care sectors to facilitate continued development in this area. Additionally, the Primary and Community Care sector could benefit from the extensive experience of hospital staff in this area. This could take the form of participation in the networking of POCT centres, management of EQA schemes and / or provision of advice on request.

3.5 Interpretation and recording of results

Patient results should only be interpreted and reviewed by appropriately trained personnel and the operator identity should be recorded in all cases. All patient and quality control results should be recorded appropriately either via paper or electronic format in accordance with defined procedures and the Data Protection Act. This should also include specific test batch numbers as appropriate and operator identification. A sample Patient Evaluation form is included in Appendix 7.2.

1. These guidelines will be revised in light of any developments in laboratory medicine that may impact POCT.

3.6 Maintenance and service of POC Instruments

In order for POC instruments to continue to perform accurately and reliably they must be serviced and maintained in accordance with manufacturer's instructions. This should be defined by the manufacturer or his representative at the time of purchase of the instrument. A maintenance and service log book should be available for each POC instrument to record details of all services, maintenance, faults and corrective actions.

3.7 Health and Safety

It is important that a procedure is in place for the safe disposal of biological waste and/or sharps in accordance with the appropriate health and safety and/or infection control legislation. It is the responsibility of the service provider to ensure that appropriate occupational Health advice is provided to staff implementing POCT. For example, all staff involved in POC testing must be appropriately vaccinated e.g. against Hepatitis B.

3.8 Premises

It is necessary to ensure that a designated area is available for the provision of a POCT service. This should have suitable facilities for sample collection, POC test execution, instrument storage, safe disposal of sharps and clinical waste and storage of consumables under the appropriate conditions as defined by the manufacturer. The area shall also ensure dignity and privacy for the patient. A refrigerator may also be required for storage of certain POC reagents. In addition, consideration should be given to the environmental conditions in which the POC test and/or instrument is stored and operated, as incorrect temperature and/or power supply conditions may impact the performance of the POC test and hence the test result.

4.0 CONCLUSIONS

Point of care testing has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result near a patient which can be acted upon directly. This can lead to increased clinical effectiveness and improved outcome for patients. However this is only true if the result delivered is accurate and reliable. POCT is not a replacement for conventional laboratory testing but rather a supplement to it. POC test results which are used for diagnosis or critical patient management decisions, or which give unexpected results should be confirmed by hospital laboratories to ensure accurate diagnosis and to facilitate correct patient management decisions.

These guidelines have been approved by the Pharmaceutical Society of Ireland (PSI), the Health Service Executive (HSE), the Faculty of Pathology (RCPI), the Association of Clinical Biochemists in Ireland (ACBI), the Academy of Medical Laboratory Science (AMLS) and the regulatory agency for medical devices in Ireland, the Irish Medicines Board (IMB). The guidelines are also supported by the Health Information and Quality Authority (HIQA). It is recommended that these guidelines be adopted by those responsible for POCT in Primary and Community Care settings in Ireland to ensure that POCT is performed in a well structured and controlled manner to minimise the risk to public health and to ensure patient safety. These guidelines will be reviewed and updated in light of further developments in the area of POCT.

The implementation of these guidelines should facilitate a well-managed and properly governed system for the provision of POCT services in Primary and Community Care settings, which in turn will deliver considerable benefits to the Irish health service and to patients.

5.0 GLOSSARY AND ABBREVIATIONS

Medical Device

According to the Medical Devices Directive (93/42/EEC), a medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

In-vitro Diagnostic Medical Device (IVD)

As defined in the IVD Directive 98/79/EC, an IVD is any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures

CE Mark

The CE mark that appears on an medical device or on its packaging means that the device satisfies the relevant legislation and is fit for its intended purpose as specified by the manufacturer.

Competent Authority

The Competent Authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the Medical Devices Directives are carried out in that particular Member State.

ISO

The International Organization for Standardization (ISO) is the world's largest developer and publisher of International Standards.

Quantitative Test Result: A test result expressed in numerical terms in order to determine the specific quantity of a substance present in a sample.

Qualitative Test Result: A test result expressed in non-numerical terms in order to determine the presence or absence of a substance in a sample.

Adverse incident: An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects.

Quality assurance (QA) refers to planned and systematic processes that provide confidence of a product's or service's effectiveness.

External quality assurance (EQA) is a program that allows testing sites to assess the quality of their performance by comparing their results with those of other laboratories.

WEQAS: The largest provider of EQA services for the Point of Care Testing (POCT) market (UK based).

IEQAS: The Irish External Quality Assessment Scheme.

6.0 KEY REFERENCES

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5. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.
6. S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994.
7. S.I. No. 304 of 2001 European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001.
8. IMB Guide to the *In-vitro* Diagnostic Medical Devices Legislation
9. IMB Guide to Incident Reporting for *In-vitro* Diagnostic Medical Devices
10. ISO 22870: 2006 Point-of-care testing (POCT) – Requirements of quality and competence.

11. **Pharmacy Act 2007:**
http://www.pharmaceuticalsociety.ie/Publications/upload/File/Legislation/Pharmacy_Act_2007.pdf
12. **Pharmacy Practice Guidance Manual:**
<http://www.pharmaceuticalsociety.ie/Standards/upload/File/S&P%20Guidance%20Manual%20ckeogh%20240708.pdf>
13. **World Health Organisation Guidelines for Point of Care Testing:**
http://whqlibdoc.who.int/php/WHO_PHP_34.pdf
14. **Australian General Practice POCT Study:**
<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pathology-poctt-index.htm>
15. **HSE Report on Laboratory Medicine Services:**
http://www.hse.ie/eng/Publications/services/Hospitals/Teamwork_report_Implementing_a_new_system_of_service_delivery_for_laboratory_medicine_services.html
16. **Irish Heart Foundation (IHF) Report:**
<http://www.irishheart.ie/iopen24/pub/strokereports/inascclinicalauditapril2008.pdf>

7.0 APPENDICES

Appendix 7.1 Medical Device Incident User Report Form

	IRISH MEDICINES BOARD MEDICAL DEVICE INCIDENT USER REPORT FORM
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If you have experienced problems with a medical device, please complete this form and send it to the Irish Medicines Board, Medical Devices Department, Earlsfort Centre, Earlsfort Terrace, Dublin 2 or contact us by telephone at 01-6764971 or by email vigilance@imb.ie

SECTION 1: CONTACT DETAILS OF REPORTING ORGANISATION	
Name of Organisation:	Fax Number:
Address of Organisation:	Contact Name:
	Position:
Telephone Number:	Email Address:
Can the Irish Medicines Board provide your contact details to the manufacturer, as they may need to contact you in order to carry out an investigation <input type="checkbox"/> Yes <input type="checkbox"/> No	

SECTION 2: DEVICE DETAILS	
Name of device and model number:	
Kind of device (e.g. pacemaker):	
Serial number / batch number / lot number:	
Where did you get the device?	Name of the person who supplied the device:
Name and address of the manufacturer:	Name and address of the distributor:

SECTION 3: INCIDENT DETAILS
What went wrong with the device?

Was an injury suffered? Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, specify who and what injuries were suffered?
Have you contacted the manufacturer? Yes <input type="checkbox"/> No <input type="checkbox"/>

Signature:	Date of Report:
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The Irish Medicines Board investigates all incidents reported to us in order to identify any faults with medical devices and to prevent similar incidents happening again. Please note that the Irish Medicines Board may contact the manufacturer of this medical device to request they carry out an investigation.

Appendix 7.2 Patient Evaluation Form Template (for non-GP based POCT settings).

Title:				
First Name:				
Surname:				
Date of Birth:				
Address:				
GP Name and Address:				
Date of assessment:				
Test performed	Result	Units	Within acceptable limits (Yes/No/N/A)	Additional Information (Test Batch number / N/A etc)
Are you aware of the significance of the test being performed and the consequences of an abnormal result?				
Is there any relevant medical history you would like to disclose?				
Is there any relevant medication history you would like to disclose?				
Referral to be made (Yes/No). If yes include reason for referral				
POCT service provider (Print Sign & Date):				
POCT service provider position:				
Do you consent to a referral?				
Patient (Print, Sign & Date):				

Appendix 7.3 GP Referral Letter template (for non-GP based POCT settings).

Dear Dr. _____

Please be advised that _____ (Patient's name) presented at _____ (POCT location) on _____ (date) and received the following test _____ (test name).

The result of this test was as follows: XXXXX

The following information was also provided by the patient: XXXXX

Other comments: XXXXX

The patient was informed that this referral letter would be written and was advised to contact their own GP for follow-up.

Referee:

Signed:

Referee Position:

Date:

Appendix 7.4 Point of Care testing checklist

The following is a useful checklist for POCT providers and POCT SOP authors:-

Points to consider		Yes	No	N/A
1	Is the premises appropriate for the POC test being performed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Is the POC test carried out in a private dedicated area suitable for patient counselling?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Is a shredder provided for disposal of waste paper containing confidential patient information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Is access to patient records and confidential information controlled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Are Information leaflets available to patients?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Is the necessary testing equipment available and of appropriate quality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Is the equipment maintained regularly to ensure it is operating correctly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Is there suitable storage space for consumables and reagent components requiring specialised storage e.g Quality Assurance samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Are all materials stored in a manner which minimises risk and is legislatively compliant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Are the relevant safety data sheets available (if required)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Are suitable bins provided and is the disposal mechanism for POCT waste in compliance with environmental provisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Is a Sharps container available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Is a written procedure available and are staff trained in the management of possible contaminated spillages?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Are suitable procedures in place for transportation of patient samples if required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Is there a structured quality assurance programme in place and is it reviewed regularly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Is a self-audit regularly carried out by the manager to review all aspects of the POC service?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	Is personal protective equipment available (e.g gloves)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	Are all products checked on receipt for quality, quantity and expiry date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Are the POC tests CE marked and in compliance with the relevant legislation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

continued overleaf ►

Points to consider	Yes	No	N/A
20 Are the devices maintained, calibrated and within expiry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 Is the POCT service provider trained and adequately competent to perform all aspects of the POC test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22 Are patients advised of the requirements in advance of a POC test e.g. in the case of a blood pressure test to avoid strenuous exercise, smoking or caffeine within 30 mins of testing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23 Has the patient completed an evaluation form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24 Is the significance of the test result explained in a clear and understandable manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25 Are written procedures (SOPs) in place for the execution of each POC test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26 Is the current version of the manufacturer's instructions for use (IFU) available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27 Is the test procedure quality assured?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28 Are instructions available for performing calibration and quality control, including details of the material to be used and the defined acceptable limits?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29 Are guidelines available on interpretation of instrument error codes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30 Are guidelines available for interpretation of test results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31 Is there a process for documenting adverse incidents and reporting of adverse events to the IMB and/or other appropriate regulatory body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32 Are results provided to the patient in a documented format?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33 Is there a procedure in place to inform staff of the requirements in respect of patient referral?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34 Are appropriate patient result records maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35 Is there a process for co-operation with field safety corrective actions and product recalls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36 Is a documented staff training record maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37 Is an ongoing training programme provided for all staff?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38 Does ongoing evaluation and monitoring of POCT service provider performance occur?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39 Does the training assess current and future requirements and developments in the area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40 Do newly appointed staff members receive adequate training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41 Are all staff aware of their professional role, the associated boundaries and accountabilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

continued overleaf ►

Appendix 7.5 Training Record template

Title of Training:	
Internal or External Training?	
SOP Edition/Revision No:	
Session Date(s):	
Training Duration: hrs/mins):	
Training Method: Instructor Led / Self-Train / Other	
Has the Trainee reviewed the relevant SOPs?	
Is the Trainee fully trained and adequately competent to perform all aspects of the test including interpretation?	
Is the Trainee sufficiently competent to execute the test unsupervised?	
Trainee's Name (Print):	
Trainee's Signature/Date:	
Instructor's Name (Print):	
Instructor's Signature/Date:	
Periodic refresher training:	