

Management of In Vitro Diagnostic Medical Devices

January 2021

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Revision history

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1 Executive summary

This publication addresses aspects that are important in the procurement of in vitro diagnostic medical devices (IVDs) and in their safety, quality and performance. Specific purchasing and supply guidance is outside the scope of this document (see section 3).

A number of the decisions involved in the management of IVDs can affect the quality of the results produced and their usefulness in the clinical management of patients. This document particularly considers the importance of:

- obtaining meaningful performance evaluation data prior to making a decision to purchase
- adequate, in-house validation before a new testing system is introduced into routine use.

Reports received by the MHRA demonstrate that these two areas continue to produce problems.

This document is focused on IVDs which, in the main, do not come into direct contact with patients but may nevertheless cause indirect harm to patients if they do not perform as intended. IVDs used in point of care testing (POCT) are outside the scope of this document and are dealt with in a separate MHRA publication [1].

1.1 Who this document is for

This publication provides advice on the safe and effective management of in vitro diagnostic medical devices (IVDs). It builds on and provides additional information to our publication 'Managing Medical Devices' [2] but can also be used as a stand-alone document.

This document is aimed at all professional staff who are responsible for purchasing, supplying, using, maintaining and replacing IVDs. This includes staff such as:

- pathology managers
- scientists, technical and clinical staff in all disciplines of pathology laboratories
- purchasers.

1.2 Key points

The user organisation should ensure that:

- users of IVDs and healthcare providers who use test results have appropriate input into purchasing decisions.
- the performance claims, maintenance, servicing arrangements, and software compatibility are considered at the stage of selection.
- adequate levels of staff training are maintained.
- appropriate user validation to determine that the test is suitable for your intended purpose is undertaken prior to introduction for routine use.
- the instructions for use are applicable to the user's situation.
- there is a system in place to manage device repair and maintenance.
- adverse incidents are reported promptly to the MHRA.

In the management of IVDs the following aspects are critical:

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- Choice of the IVD including critical assessment of the adequacy of performance data provided by the supplier.
- Appropriate use of the device, including:
 - > adequate user verification to demonstrate that the device meets the requirements in your specification prior to installation into routine use (see section 6.3)
 - > strict adherence to the instructions for use
 - > adequate training
 - > appropriate maintenance.
- Timely reporting of adverse incidents to the MHRA and the supplier.
- Recognition of legal liabilities.

Inadequate performance validation by the manufacturer has, on occasion, resulted in users finding themselves validating the product prior to being able to use it for routine testing. This may make unanticipated demands on the laboratory. Failure to report adverse incidents to the MHRA in a timely manner may give rise to wider continuing use of an inappropriate product.

2 Introduction

In vitro diagnostic (IVD) medical devices are test kits and instrumentation used to test human samples to assist clinical diagnosis or decisions concerning clinical management. The UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) gives definitions for: a medical device; an in vitro diagnostic medical device (see appendix); and manufacturer and supplier, which are used throughout this document.

The following are some characteristics of IVDs that are pertinent to their management:

- The term IVD covers a diverse range of products from individual reagents to testing systems that consist of reagents, instrumentation and software. Also included are accessories such as dedicated software, and control and calibration materials. IVDs differ from most general medical devices in that many do not come into direct contact with patients. Therefore they cannot cause direct harm to the patient if they fail to perform as intended. However, if the results that are produced from testing are incorrect and are not recognised to be so, indirect harm can occur to patients through incorrect diagnosis or inappropriate treatment.
- Where IVDs are used within a testing system, changing one component of the system may affect the performance of other parts of the system. Such a change therefore requires reconsideration of whether it is appropriate to continue to use all the other components of the testing system. For example, when testing kits are changed do the swabs for patient sample collection also need to be changed? Is the laboratory information system (LIS) still fully compatible after analyser software upgrades have been obtained?

2.1 Best practice

Several principles of best practice should be applied in the use of IVDs.

Suitability for the intended purpose

IVD manufacturers are required by law to state the performance characteristics of their device within the instructions for use. In addition, it is important to be aware that, even with CE/CE UKNI/UKCA marked devices, there is no requirement that clinical utility is demonstrated as a condition of placing an IVD on the market. This means that the onus is on the customer to assess whether the product is suitable for the use to which the results will be put in the clinical management of patients. These aspects are covered further in sections 3, 4, 5 and 6.

Maintenance in a safe and reliable condition

Device management includes not only strategies for the routine maintenance carried out by users and on behalf of the manufacturer but also monitoring and replacement of devices and appropriate training of all users. This is covered in more detail in section 7.

Reporting of adverse incidents that arise during use is covered in more detail in section 8.

3 IVD procurement – safety, quality and performance

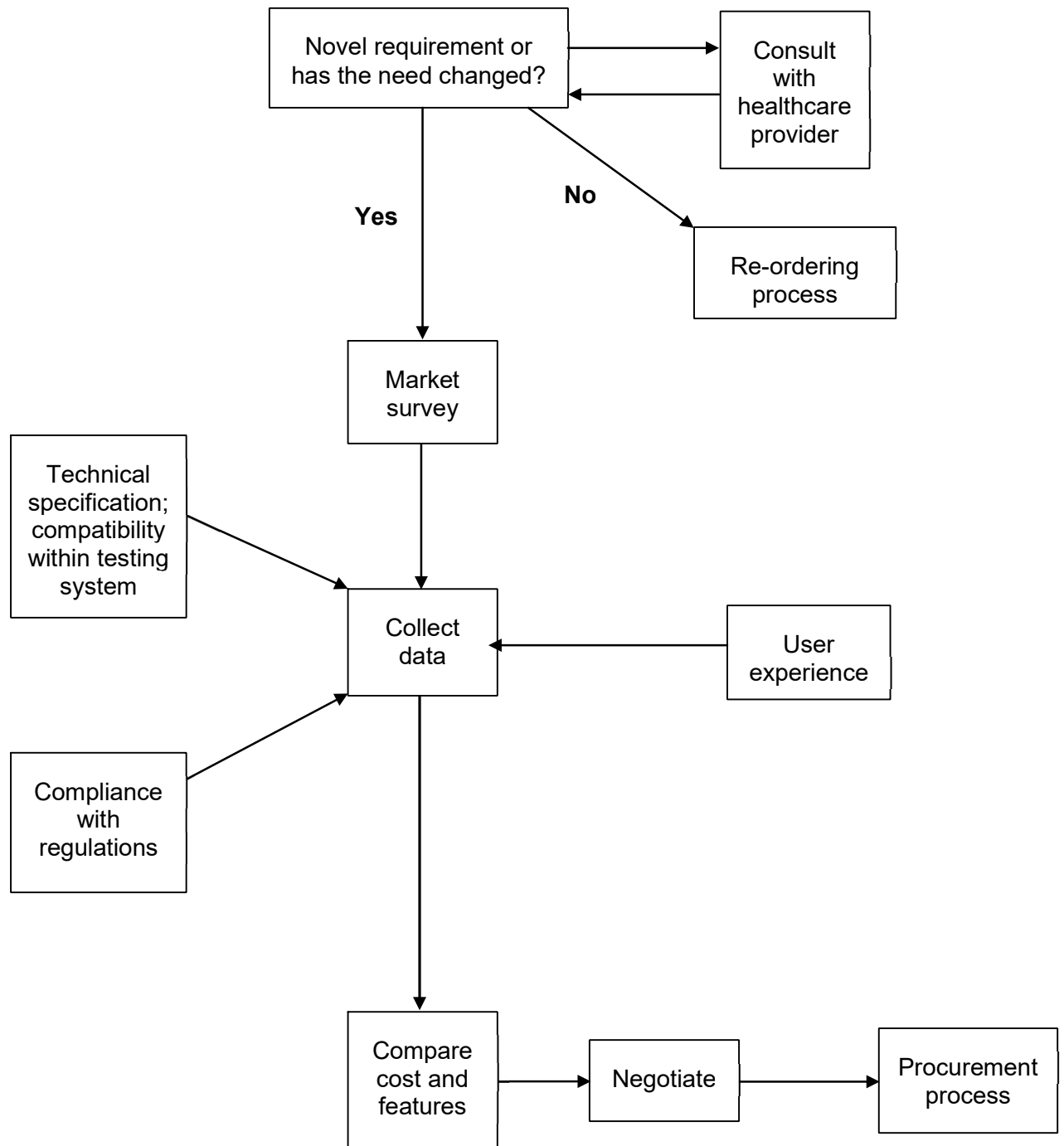
This section addresses aspects of the selection process during procurement decision-making that may have an impact on the safety, quality and performance of the devices. It does not attempt to address wider issues of best procurement practice such as regulations implementing EU purchasing requirements, financial evaluations and purchasing specifications. Evaluation reports originally published by the Centre for Evidence-based Purchasing were [archived by the Department of Health](#) (available at time of writing). Procurement or acquisition may be by, for example, purchasing, reagent rental (where the analyser is loaned free of charge provided reagents are purchased from the manufacturer) or leasing.

3.1 Factors to be considered in the decision making process

3.1.1 Collecting data

The flow chart in Figure 1 shows the decision-making process of relevance to the safety, quality and performance of IVDs.

Figure 1 The decision-making process of relevance to safety, quality and performance of IVDs.



3.1.2 User experience

It is important to ensure that the people who make purchasing decisions take account of the implications of all the relevant technical information.

This may be particularly relevant where devices such as swabs or specimen receptacles are purchased centrally e.g. within a trust, because they may be:

- used by a large number of different healthcare professionals for different purposes
- used with patients having different clinical conditions.

In addition, their performance characteristics may contribute to:

- their safe handling
- the reliability of results of diagnostic testing.

See examples 1 and 2.

Example 1 Leaking specimen receptacles

A central purchasing group introduced into the hospital specimen receptacles with which the laboratory had previously experienced leakages. The purchasing group, which did not include a laboratory representative, was resistant to the laboratory's requests to change supplier despite the laboratory reporting an unacceptable level of specimen leakages with use. The laboratory's perspective was not influential in the purchasing decision despite health and safety implications to laboratory staff of the use of unsatisfactory products.

Healthcare providers who request testing for their patients should also be consulted to ascertain whether there are particular formats or tests that they require that may not otherwise be catered for.

3.1.3 Technical specification

The desired technical specification in terms of sensitivity and specificity should be drawn up and compared with the performance claims made by the manufacturer. It may also be helpful to compare the manufacturer's claims with the actual data from which the claims have been derived. A record of the claimed performance at the time of the purchasing agreement should be kept (see section 4, example 4).

It is also important to assess the instructions for use prior to purchasing to ensure that the method advised, and therefore validated by the manufacturer, is appropriate to the intended use of the device in the laboratory (see example 2). Further detail is provided in section 4 on instructions for use.

Additionally, the US organisation the Clinical and Laboratory Standards Institute (CLSI) produces standards and guidelines that may also prove helpful (<http://www.clsi.org>).

Example 2 Open system analyser with test kit designed for manual use A supplier provided a laboratory on a reagent rental scheme with an open system analyser, designed by its manufacturer to automate enzyme immunoassay (EIA) testing, and an EIA test kit manufactured by a different company for manual testing. The supplier did not have instructions for automated use of the kit nor validation data demonstrating the performance characteristics of the kit using an automated protocol. The laboratory thought they were buying a testing system that could be put straight into use to test patient's samples. Instead they inadvertently spent many months themselves developing and validating an appropriate automated protocol.

During the procurement process, it is important to consider carefully the implications of the servicing and response times on offer, the implications of this to the testing service, and whether there are alternative ways in which the testing service can be provided during unavoidable down-time.

Where an IVD has a software component, it is important to ensure that it is compatible with other software with which it may be required to interface, such as laboratory information system (LIS) or hospital information systems (HIS). The costs of such interfacing also need to be considered during the initial tendering process. See example 3.

Example 3

An incident was reported which related to the interface between a LIS and an analyser, where data travelling along the interface had become corrupted and had blocked the interface. This resulted in delays in recognising clinically significant results. The incident was found to be connected with a recent software modification in the interface. The LIS manufacturer had not validated the modification for use with the analyser.

3.1.4 Commercial advice

Specific purchasing and supply guidance is outside the scope of this document. Figure 1 represents a decision making process before consideration of the next stages of procurement and the development of collecting data.

3.1.5 Compliance with product-specific regulations

IVDs must comply with the UK MDR 2002. .

3.1.6 Lease-purchase

Many of the pre-purchase processes are equally applicable to the operating lease of IVDs or to reagent rental.

4 Instructions for use

Good, clear instructions have a crucial role in the safe and effective use of IVDs.

4.1 Legal requirements

All IVD devices supplied within the UK market must be CE, CE UKNI or UKCA marked and the UK MDR 2002 [3] place clear requirements on the manufacturer in respect of supplying appropriate instructions for use and labelling.

Under the UK MDR 2002 [3], if a user reassigns the intended use of a CE, CE UKNI or UKCA marked IVD or modifies the instructions for use without the agreement of the manufacturer, they themselves become liable for any resultant performance failure that arises from such use of the device.

It is, therefore, essential that any standard operating procedures (SOPs) that give instructions for use, exactly reproduce the manufacturer's instructions for how the device should be used and that all existing copies are updated as appropriate. Clear responsibilities should exist for ensuring that essential information is given to all users (see example 4). Situations where it may be particularly important to ensure that the users are aware of the current instructions for use include:

- where the device is used by individuals who may not routinely have access to the instructions for use;
- on-call staff.

In the event of litigation by a patient or their representative, user organisations may need to be able to call upon evidence that instructions were given to users in respect of equipment and upon documentary evidence that crucial steps in the process were, in practice, carried out (see example 4).

Example 4

A laboratory entered into a contract with a supplier to provide a particular test kit. After some time, the performance characteristics of the test kit were found to have shifted, giving rise to false negative results that were issued to patients. The manufacturer had made no specific claims for the performance of the product in the instructions for use. The laboratory could not find the evaluation data that they had used in the purchasing decision. In addition, although the laboratory believed it had followed the manufacturer's instructions for use, there was no clear laboratory record documenting crucial stages in the testing process. If legal action had been taken, the laboratory could have been in a vulnerable position.

4.2 Suitability of manufacturer's information

Information that must be supplied by the manufacturer is addressed in the essential requirements within Part IV of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002).

Users are entitled to instructions that are comprehensible in their national language. It is unsatisfactory for instructions to be provided in a poor translation which may obscure the meaning (see example 5).

Example 5 Poor translation of instruction manual into English

An analyser that was made by a non-UK manufacturer was distributed in the UK by four different companies.

Although the instrument was sold under different names by the distributors, in each case it was supplied with the manufacturer's own translation of the manual. This was poorly translated into English and none of the distributors had obtained an improved translation. In a number of places the manual was very difficult to comprehend. When contacted by MHRA the original manufacturer appeared unaware of the deficiencies in the translation and agreed to have the manual re-translated.

4.3 Manufacturer's revisions to instructions

It is important to:

- ensure that manufacturers have the correct contact details for users of the device. Users should automatically be sent copies of revised instructions.
- check with the manufacturer that revised instructions are appropriate to the products in service – there may have been software upgrades or changes.
- have a procedure for keeping track of all the sets of instructions in use, and for replacing them with revised versions when necessary
- ensure that all instructions deemed necessary by the manufacturer are provided in written form by the manufacturer using a formalised mechanism.

It is increasingly common for manufacturers of automated systems to provide revised instructions on their website. As with any revised instructions it is important to ensure that all users are fully conversant with the revision.

Revised instructions may arise out of problems with the previous instructions or changes to the product. It may be necessary to ensure that not only are the revised instructions sound and adequately validated but that the possible implications of any problems in respect of test results previously obtained have also been assessed.

Possible implications for training needs in relation to instructions for use are considered in section 5.

4.4 Storage

Inappropriate storage conditions can render devices unserviceable – inappropriate physical conditions (such as temperature, humidity, and presence of sunlight for some reagents) and stock rotation failures are some examples. Apart from possible dangers to the end users of the equipment, poor storage conditions also put the organisation at legal risk. Manufacturer's information and instructions both on storage conditions and shelf life should be followed.

5 Training

The effects of training in relation to the overall laboratory performance are outside the scope of this document. However, the role of training in the safety, quality and performance of IVDs themselves is considered.

The obligation to provide appropriate training lies with the manufacturer. Part IV of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002) states that the instructions for use should indicate whether any particular training is required (Section B, 8.7 h).

However, the following aspects also require consideration:

- which individuals within the laboratory (out of the total number of individuals who will be working with the IVD) should receive the training offered by the manufacturer or supplier
- how the remaining individuals will be trained, by whom and the timescale
- when retraining is indicated
- training of temporary or locum staff
- training of on-call staff
- future training needs in the event that those trained directly by the manufacturer/supplier change jobs
- training updates in the event of instrument/software upgrades.
- training records / documentation

There is a separate MHRA publication that deals with IVDs used in a point of care setting [1].

If samples for which the method of collection is critical to IVD performance are collected by ward staff, it is important to ensure that ward staff are adequately trained and that retraining follows significant changes in the ward staff. Users of IVDs should also be trained in the local system for identifying and reporting adverse incidents to the MHRA (see section 8).

6 Acceptance testing and user verification

Tests that need to be applied on delivery of a new product fall into three categories:

- acceptance testing
- commissioning
- user verification.

6.1 Acceptance testing

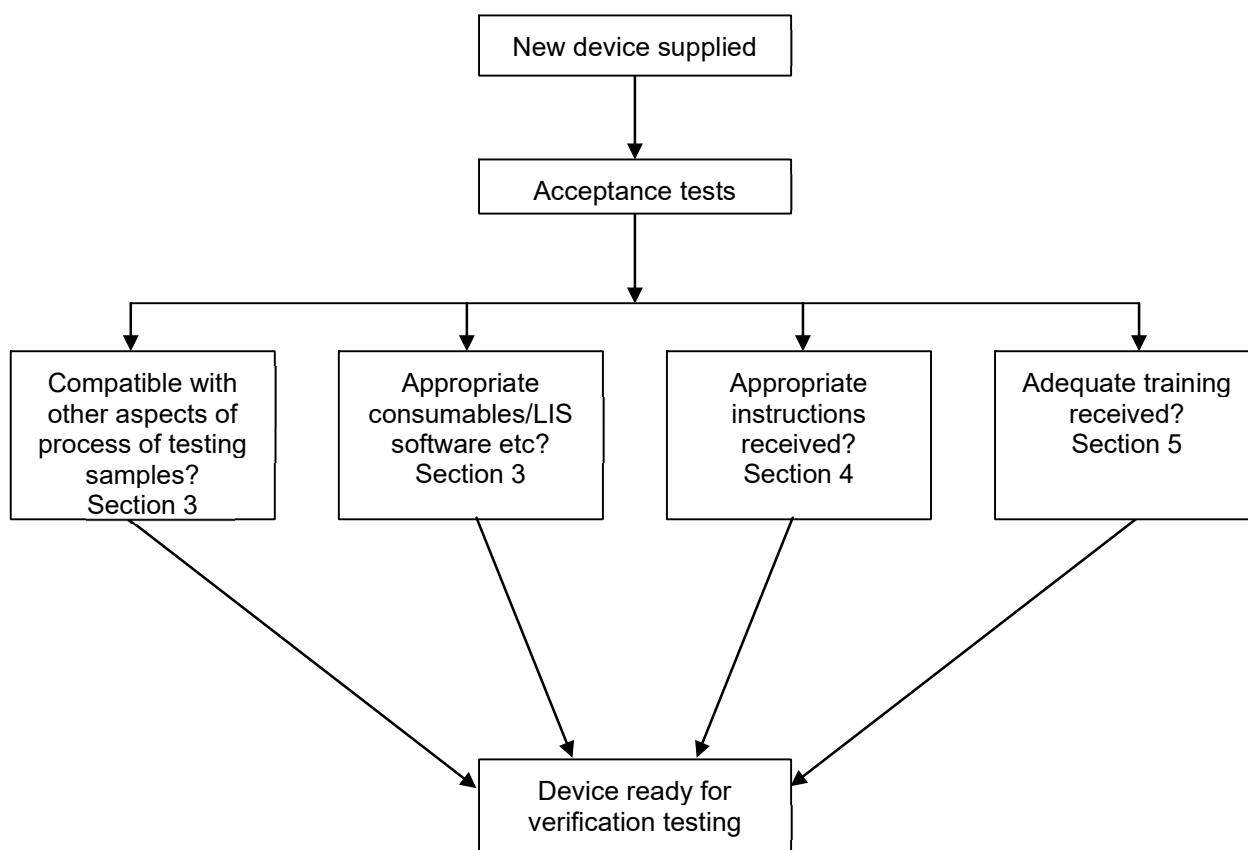
This can weed out faulty product items which may have slipped through the manufacturer's quality assurance process, or which may have been damaged in transport or storage. They do not aim to test whether a given device model is suitable for its intended use – this must be done before purchase (section 3).

Laboratory instrumentation, such as analysers, which need to be installed and commissioned, should have a comprehensive set of prescribed acceptance tests. Manufacturers may recommend certain forms of acceptance testing in the device manual. Electrical testing will also be necessary.

All equipment new to an organisation (on loan as well as newly purchased) should be checked before it is put into use for producing results on patient samples that will be issued to the attending clinician.

Figure 2 outlines the main aspects of acceptance testing, the main purposes of which are:

- to ascertain whether the device that was intended to be purchased is the same as the device that has been delivered
- whether all the appropriate components have been delivered
- whether in practice it is compatible with other aspects of the testing process
- whether the instructions are adequate
- whether any training that was given was adequate.

Figure 2 Acceptance tests

6.2 Commissioning

For complex instrumentation such as laboratory analysers this is usually carried out by the manufacturer, supplier or their representatives. In some instances the trust's medical engineering department or pathology laboratory may be involved. The purpose of commissioning is to set up the instrument so that it is in good and safe working order to put into service. Checks to ensure recommended practice in the installation of the device and to ensure electrical safety should be covered.

6.3 User verification

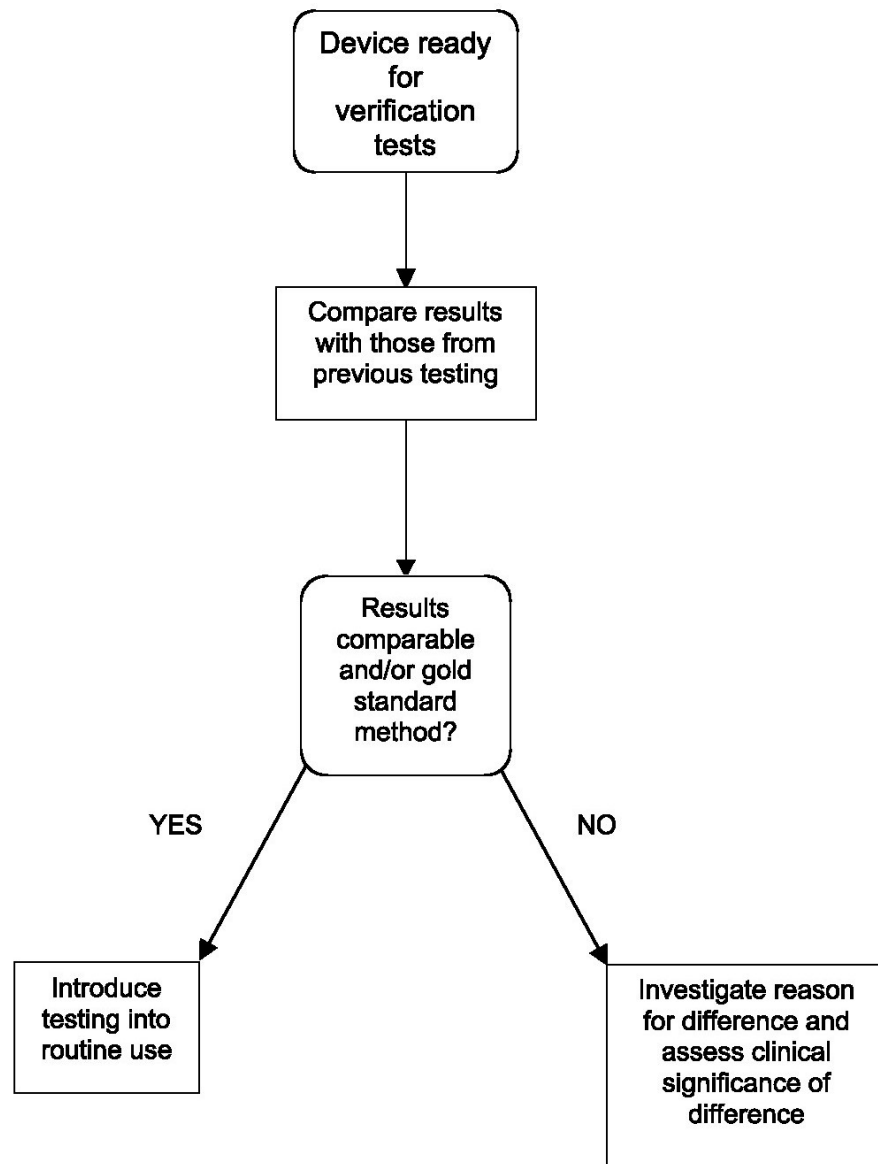
This process is described in Figure 3. It is the stage during which the user verifies that the performance of the device in their hands is comparable with the manufacturer's claims. This also includes verifying the performance of devices used in combination (see DB 2008(04) [6] for more details). This stage also provides the opportunity for comparing the performance of the newly delivered device with that of the testing system that has previously been in use to ensure that appropriate and reliable results are achieved with the new product. It provides the opportunity to assign quality control (QC) ranges, assess training, write SOPs and determine consumable requirements. It is essential that this stage is carried out prior to introducing the new testing system for use in reportable patient sample testing. The new system can be compared with the previous system whether this previously involved in-house testing, using a different method, or sending samples away to another laboratory. Ideally, this should involve comparison with a recognised gold standard. Investing resources at this stage can minimise costly blunders in the future.

For example, if the new system contains flaws that have not yet been identified and it is used for testing patient samples, results may be issued before the problem is recognised. This may necessitate retesting patient samples that were stored or recalling patients (see example 6).

Example 6 False results on introduction of a new testing system for rubella A laboratory changed from a manual method for testing for antibody to rubella, to an automated system. They ordered the new system to be delivered before they had used up all the manual test kits so that the two testing systems could be compared. However, there were unanticipated delays in the delivery of the new testing system and the old product ran out just as the new product arrived. The laboratory switched from one system to the other without any period of assessing the performance of the new system against the performance of the old system. Within one month they had obtained 12 false negative results out of 48 patient samples, some of which had been issued to patients. Parallel testing of the new system with the previous one would have prevented these false results from being issued and would have allowed the teething problems with the new system to be sorted out without patient results being affected.

Similarly, software needs to be tested to ascertain whether in the local situation it behaves as intended by the manufacturer. With software there is the possibility that issues may not come to light immediately. The device software may interface with other software (such as LIS or HIS) and these may have been modified locally. The designers of either software may not have fully anticipated all the implications to other software with which communication is made. The supplier may also not have anticipated the full extent of validation testing required under these particular circumstances. This may hold for initial releases and for upgrades.

Figure 3 Verification testing



Laboratories should ensure that a formal record of all strategic actions is kept. This is particularly important because of inevitable changes of personnel.

Some of the strategic actions that should be recorded include:

- introduction/modification of device
- training
- acceptance testing • connecting systems.

Such records can be important if there is a need subsequently to understand modifications that have been made in the past that may impact on IVD performance. For example, incorrect patient results may arise where software designed by its manufacturer for a defined use is locally modified to broaden its application. Responsibility lies with the user to rigorously validate the performance of the software (including subsequent updates) in respect of use beyond that of its manufacturer's intended purpose, see MDA/2010/001. Where modifications have been made locally, the trust will bear any liability issues.

7 Maintenance and repair

Planned preventative maintenance should follow manufacturer's guidance on procedures and staff training. If this is not practicable for some reason, the manufacturer should approve changes, preferably before purchase.

Equipment that has been used for testing patient samples and which needs maintenance work must be cleaned and, where relevant, decontaminated before release. A failure to have effective procedures in place will put staff at risk and create a danger of legal liability being incurred. Any departure from the manufacturer's recommendations will inevitably carry a risk of increased liability in the event of an adverse incident.

Where manufacturers or distributors themselves subcontract maintenance and servicing operations to a third party, it may be useful to clarify whether the subcontracted organisation is contractually obliged to report instrument failings to the distributor or manufacturer. If not, it may be possible for repeated problems to escape the attention of the manufacturer's design team.

Similarly, any contract with a third party servicing organisation should specifically address compliance with the manufacturer's recommendations by:

- the third party agreeing to follow the manufacturer's recommendations
- including evidence that the manufacturer approves the recommendations
- the third party accepting full liability for inadequate maintenance and maintenance induced faults.

A strategy is needed to help identify when to replace IVD instrumentation. Criteria suggested include:

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- unacceptable levels of wear and damage
- chronic unreliability
- obsolescence
- consumables no longer available.

7.2 Breakdowns

An efficient servicing organisation aims for rapid recovery from breakdowns. The simplest method is often to substitute a similar device in working order, although this is not always possible. However, increased stock levels can be set against the likely costs of, for instance, paying a third party servicing organisation for 24-hour fast response cover or manufacturer's call-out fees for engineers.

Prior consideration can be given to the provision of an alternative verified testing service for periods of time when instrumentation may be out of action. This will help to safeguard against a backlog of untested specimens arising in the unexpected event of instrument failure. Alternative testing strategies to consider include outsourcing, the use of a familiar and verified manual test, and the use of alternative instrumentation including that held in a different local pathology discipline. Appropriate verification testing should, however, be carried out prior to introduction into service.

8 Adverse incident and vigilance reporting

8.1 Reporting adverse incidents

With IVDs, it may not be immediately obvious to those observing an unusual result that the problem is with the device. The problem may only become apparent when several different laboratories are found to be experiencing the same phenomenon. For this reason it is important to bear in mind that the prompt reporting of incidents may be very important in preventing large-scale problems, and that other laboratories may have similar findings. The MHRA therefore strongly encourages all IVD users to report problems as they come to light even if the cause has not been clearly identified, so that the MHRA is aware of potential problems that may have nationwide implications.

The [Yellow Card portal](#) is our preferred method of receiving reports.

In addition to voluntary user reporting, which covers all types of adverse incidents related to medical devices, the UK MDR 2002 [3] contains reporting requirements for incidents that fall under the criteria of 'vigilance'. If a manufacturer is aware of an incident involving an IVD that has the potential to cause death or serious injury (whether to a patient, user or third party), there is a legal requirement for the manufacturer to report such an incident to the MHRA.

Some differences between the user reporting system and the vigilance reporting system are listed below:

User reporting system	Vigilance reporting system for manufacturers
<ul style="list-style-type: none"> • Voluntary. • Broad scope. • No time limit on reporting. 	<ul style="list-style-type: none"> • Required by law. • Limited to cases where death or serious injury or the potential for these. • Legal requirement for 'immediate' reporting.

9 Glossary

CE, CE UKNI or UKCA mark

The CE, CE UKNI or UKCA mark means that a manufacturer is satisfied that their product conforms to the relevant essential requirements of the UK MDR 2002 [3] and that it is fit for its intended purpose. Note that the UKCA mark is valid in Great Britain only.

In vitro diagnostic medical device (IVD)

The term 'in vitro diagnostic medical device' means '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 of donations, including blood and tissue donations, with potential recipients, or
- to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.'

Manufacturer

An organisation with responsibility for the design, manufacture, packaging and labelling of a device. (A more detailed definition can be found in the UK MDR 2002).

Medical device

The term 'medical device' means: 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is 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

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- 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, even if it is assisted in its function by such means and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.'

Laboratory information system (LIS)

A database application used for managing laboratory information.

Supplier

The manufacturer or their authorised representative.

10 References

1. Medicines and Healthcare products Regulatory Agency. Management and Use of IVD Point of Care Test Devices, DB 2010(02), 2010.
<https://www.gov.uk/government/publications/in-vitro-diagnostic-point-of-care-test-devices>
2. Medicines and Healthcare products Regulatory Agency. Managing Medical Devices, DB 2006(05), 2006.
<https://www.gov.uk/government/publications/managing-medical-devices>
3. The Medical Devices Regulations 2002 (SI 2002, No 618, as amended) ISBN 0110423178. <https://www.legislation.gov.uk/uksi/2002/618/contents/made>

Website links correct at time of publication.

Appendix Categories of in vitro diagnostic medical devices

Taken from Part IV of the UK MDR 2002, Annex II (as modified by Schedule 2A to the UK MDR 2002):

List A

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell.
- Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV1 and 2), HTLV I and II and hepatitis B, C and D.

List B

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd.
- Reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies.
- Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis.
- Reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria.
- Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia.
- Reagents and reagent products, including related calibrators and control materials for determining the following HLA tissue groups: DR, A, B.
- Reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA.
- Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21.
- The following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.