The Laboratory Services Reform Programme

ADVICE NOTE

Declaration of use of ‘In House’ In Vitro Diagnostic Devices (IVDs)

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Clinical Practice Guidance Document Cover Sheet

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The Laboratory Services Reform Programme offers the following advice:

1.1 Advice for Laboratories

1. The IVD Regulations permit Health Institutions to use 'In House' IVDs (IHIVD) but require that those Health Institutions using IHIVDs prepare a declaration outlining
   - the device identification,
   - the class of device (A-D) as per Annex VIII [1]
   - the intended purpose
   - and either confirm compliance with the conditions laid down in Article 5.5 General Safety and Performance Requirement as itemised in Annex 1 of the Directive or provide justification for non-compliance[1].

   As most IVD use in public hospitals is within the laboratory services, the laboratory service usually leads on the work of compliance with this requirement. Laboratories are advised to confirm with the Health Institution within which they function that they should prepare this declaration on behalf of the Health Institution. The regulations require that the declaration be publicly declared on the institution's web page. This can be as a stand-alone document or incorporated into the publicly available User Manual.

   A template declaration to assist in complying with this requirement is provided as an appendix to this advice note.

2. The Regulations require that Health Institutions using IHIVDs inform the relevant authority (in Ireland this is the Health Products Regulatory Authority (HPRA) that they are using IHIVDs. See S.I no 365/2022 In vitro Diagnostic Medical Devices (registration) Regulation (IVDR).
   This can be done on line at Health Institution: In-house Manufacturer Notification

   To inform the HPRA you will need
   - Name, Address, Eircode and Email address of Institution
   - Name, Email, Contact No, Role and Department of Contact person.
   - Location of public declaration
   - Confirmation of acceptance of terms and conditions

   Additional contact persons may be added if desired. One registration per Health Institution is sufficient therefore, it is appropriate to compile relevant information from all Laboratory Departments.

3. In considering whether you are using an IHIVD:

   In relation to tests performed using integrated commercial systems (kits) you should look at the instructions for use (IFU) provided by the manufacturer.

   Do they :
   - specify use in specific clinical contexts (for example in symptomatic patients, or a specific age range)
   - limit use to one to one or a number of specimen types or matrices
   - specify the reagent diluent and dilution
   - the requirements for incubation times
   - the equipment to be used (e.g. analyser) specified.

If you are deviating from the IFU consider if this is required to provide a safe service to your specific patient population (justification). If the clinical decision is that there is a clinical justification to deviate from the IFU to sustain patients services, then, as above, regulation requires that the Health Institution Publish a Declaration and inform the HPRA in accordance with Article 5.5 of the EU Regulation.

If you are using a series of individually sourced products/components to perform an analytic process that provide clinical information consider if that process may represent an IHIVD.

Note steps involved in preparing the specimen for analysis but which do not generate clinical information need not be considered as components of the IHIVD.

4. In house IVDs may not be transferred to another institution which is not part of the same legal entity. This stipulation does not prevent specimens being referred from one Health Institution to another for analysis in the receiving institution using an IHIVD

5. Software used to process data from an IVD for a specific medical purpose is considered an IVD.

6. Changes from the stated intended purpose of a CE marked IVD may be easy to identify. Some changes may not be immediately apparent.
   The Laboratory Services Programme acknowledges that it may take some time to identify all IHIVDs
   Health Institutions are advised to identify and declare their most critical 'In House' IVDs (Classes C and D) and inform the HPRA before the end of 2025. Declarations and notification can be updated as additional issues are identified

2 Background

Health institutions that manufacture and use in-house IVDs within that institution are required under the national law S.I. No. 365/2022 *In Vitro* Diagnostic Medical Devices (Registration) Regulations 2022, to identify themselves to the HPRA and supply any information about the in-house MD/IVD on request.

Definition

'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software 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 on one or more of the following:

- Concerning a physiological or pathological process or state.
- Concerning congenital physical or mental impairments.
- Concerning the predisposition to a medical condition or a disease.
- To determine the safety and compatibility with potential recipients.
- To predict treatment response or reactions.
- To define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be IVDs.

'In House' IVD

Where a health institution alters or changes the intended purpose of a CE marked IVD, it could qualify as an IHIVD.

Examples of IHIVDs include, but are not confined to,

1. Manufacturing an IVD from raw materials parts or components
    - Using primers and associated reagents to create a genetic test.
2. Use of products which are not CE marked IVDs or are 'research use only' (RUO) for a medical purpose
    - Using RUO antibodies to determine the presence/absence of a clinically relevant marker.
    - Using non-CE marked immunohistochemical stains for a medical purpose
3. Use of a non-CE marked software to process data derived from IVDs for a specific medical purpose.
4. Using a CE marked IVD for a purpose, different to that intended by the manufacturer or modifying a CE marked IVD to create a new IVD. This could include:
    - Using on a different specimen type not intended by the manufacturer,
    - Changing volumes or concentrations of reagents where the manufacturer has specified set conditions.
    - Using the CE marked product on a platform other than that intended by the manufacturer

Note: Some IVDs are intended by the manufacturer to be optimised by a laboratory. These may include recommended conditions with a statement that the laboratory should define optimal conditions. In these circumstances, optimisation activities are considered within the intended purpose, and do not fall within the scope of an in-house IVD.

5. Combining IVDs or products for a medical purpose, which may include:
    - Products which do not bear CE marking,
    - Products which are labelled as RUO (research use only),
    - CE marked IVDs. where the products are not CE marked or where the combination of CE marked IVDs, and other IVDs/products is not in line with their original intended purpose.

3 References

1. Regulation (EU) 2017/746
2. S.I. No. 365/2022 *In Vitro* Diagnostic Medical Devices (Registration) Regulations 2022
3. sur-g0052-guide-for-health-institutions-who-manufacture-and-use-in-house-ivds-in-ie-v1.pdf
4. Health Institution: In-house Manufacturer Notification
5. mdcg_2023-1_en.pdf

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Declaration Regarding the Manufacture and Use of In-house Devices

Name of Health institution:

Address:

The health institution declares that the devices described in the accompanying table are only manufactured and used in …..
They meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices regulation (EU 2017/746).
A reasoned justification is provided where applicable general safety and performance requirements are not fully met.

Declaration completed by responsible person(s):

Name:	
Role:	Clinical Director/Associated Clinical Director/Laboratory Manager/Quality Manager/Other
Signature	
Date:	

If the Health Institution wishes to have the document signed by two or more responsible persons insert additional signature boxes as required

Name:	
Role:	Clinical Director/Associated Clinical Director/Laboratory Manager/Quality Manager/Other
Signature	
Date:	

Laboratory Department…… **Device Type (IVD/MD)** …….

Device Identification (e.g. Name, description)	Risk Class of Device	Manufacturer Intended Use as per CE Mark (if applicable)	Intended Use in the Health Institution	Applicable GSPR fully met? Y/N	Information on, and justification for, application GSPR that are not fully met

[Insert additional rows as required. Use one table per department]

Column on Manufacturer Intended Use as per CE Mark (if applicable) may be deleted if desired

Examples for consideration [Delete this page before saving the document for publication on the Health Institution website]

Device Identification (e.g. Name, description)	Risk Class of Device	Manufacturer Intended Use as per CE Mark (if applicable)	Intended Use in the Health Institution	Applicable GSPR fully met? Y/N	Information on, and justification for, application GSPR that are not fully met
Acme Monoclonal Antibody X10 Lab developed test	C	E/IVD marked antibody to Mib-1 is intended for use with the Acme Instrument to assist in diagnosis or prognosis of certain cancers.	E/IVD marked antibody to Mib-1 is used with the Rivendell Instrument to assist in diagnosis or prognosis of certain cancers Essential for patient care. Not practical to maintain service with multiple different manufacturers.	Yes	Yes
Reagent X Lab developed test	B	No applicable. No CE marked kit available.	Use for diagnosis of sickle cell disease (in house developed test) Essential test for patient care no practical CE marked alternative.	No	20.2 not practicable
Acme Cartridge for detection of M. tuberculosis DNA Lab developed test	C	Detection of *M. tuberculosis* DNA in respiratory secretions	Detection of *M. tuberculosis* DNA in specimens other than respiratory secretions Essential test for patient care. No practical CE marked alternative.	Yes	
Acme Precision Assay on the Acme Brand Instrument Assay Research Use Only	C	NA	The Acme Precision assay is a panel run on the Acme Brand ™ instrument. It includes relevant targets for precision medicine; this 25 gene panel covers oncogenes and other changes This test is essential for patient care. There is no practical CE marked alternative to use of this RUO product.	Yes	
Acme Software for Reporting			Utilising a source file generated from the Acme assay the Acme Software for Reporting matches genetic variant	Yes	

Device Identification (e.g. Name, description)	Risk Class of Device	Manufacturer Intended Use as per CE Mark (if applicable)	Intended Use in the Health Institution	Applicable GSPR fully met? Y/N	Information on, and justification for, application GSPR that are not fully met
			information with relevant data . The software is used to prepare a report that presents a sample-specific view of data. This test is essential for patient care. There is no practical CE marked alternative to use of this RUO product. .		

Sickle Cell Screen (IQC) IVD B None CE marked kit, IQC for sickle cell kit used in detection of sickle cell disease.

Note as above the column on Manufacturer Intended Use as per CE Mark (if applicable) may be deleted if desired