



DIE MEDIZINISCHEN LABORATORIEN DER SCHWEIZ
LES LABORATOIRES MÉDICAUX DE SUISSE
I LABORATORI MEDICI DELLA SVIZZERA
THE MEDICAL LABORATORIES OF SWITZERLAND

FOEDERATIO
ANALYTICORUM
MEDICINALIUM
HELVETICORUM

Generalsekretariat Altenbergstr. 29 031 313 88 30
Secrétariat général Postfach 686 info@famh.ch
Segreteria generale CH-3000 Bern 8 www.famh.ch

Recommendations for the implementation of IvDO in medical laboratories

28.08.2025/v1.0

This publication represents a joint position of the *ad hoc* FAMH IvDV/Odiv Committee on the practical interpretation of Swiss and European requirements for in-house *in vitro* diagnostic devices (IVDs), referred to in this document also as laboratory-developed tests (LDTs).

The primary focus is on the qualification of in-house IVDs—specifically, determining whether a product, examination procedure, or modification to an existing CE-marked device should be considered an in-house IVD. The goal is to support health institutions in identifying which examination procedures and components must comply with the applicable provisions of Regulation (EU) 2017/746 (IVDR) and the Swiss Ordinance on In Vitro Diagnostic Medical Devices (IvDO), and which may be excluded from these requirements. This should enable the development of a streamlined LDT portfolio that can be sustainably managed by laboratories.

In addition, the position paper offers practical solutions to common challenges related to validation, documentation, and demonstrating compliance with the relevant general safety and performance requirements. Considerations related to quality management systems are outside the scope of this paper and are therefore not addressed.

Contents

1	List of Abbreviations	3
2	Introduction	4
3	What is an in-house IVD	4
3.1	In-house IVDs fully developed by the laboratory or using non-CE marked components	4
3.1.1	Qualification	4
3.1.2	Validation and documentation	5
3.2	Substantial modifications to CE-marked IVDs	6
3.2.1	Qualification	6
3.2.2	Validation and documentation	7
3.2.3	Changes to the specimen type	8
4	What is not an in-house IVD	10
4.1	Non-significant changes to CE-marked devices	10
4.1.1	Qualification	10
4.1.2	Validation and documentation	11
4.2	Combination of CE-marked devices used within their specification	12

- 4.3 *Ad hoc* changes to a procedure to answer urgent clinical questions.....12
- 4.4 Products for general laboratory use12
- 4.5 Internal Quality Controls (IQC).....13
- 4.6 Software examples13
- 5 Subcontractors14
- 6 Grouping into examination procedures and workflows.....15
- 7 Grouping and bundling for documentation purposes15
- 8 Information on requirements not fully met.....16
- 9 Conclusions.....16
- 10 Authors and Affiliations17
- 11 Disclaimer17
- 12 References18

1 List of Abbreviations

AWMF	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V.
CE	Conformité Européenne
CLSI	Clinical & Laboratory Standards Institute
EN	European Standard (Europäische Norm)
EQAS	External Quality Assessment Scheme
FAMH	Foederatio Analyticorum Medicinalium Helveticorum, The Medical Laboratories of Switzerland
GSPR	General Safety and Performance Requirement (of the MDR and IVDR)
IFCC	The International Federation of Clinical Chemistry and Laboratory Medicine
IFU	Instruction for Use
ISO	International Organization for Standardization
IQC	Internal Quality Control
IVD	In-Vitro Diagnostic Device
IvDO	(Swiss) In Vitro Diagnostic Medical Ordinance, SR 812.219
IvDV	Verordnung über In-vitro-Diagnostika
ODiv	Ordonnance sur les dispositifs médicaux de diagnostic in vitro
IVDR	(European) In-Vitro Diagnostic Devices Regulation, Regulation (EU) 2017/746
LabV	(Swiss) Ordinance on microbiology laboratories, SR 818.101.32
LC-MS/MS	Liquid Chromatography-Tandem Mass Spectrometry
LDT	Laboratory Developed Test (used interchangeably for in-house IVD)
MDCG	Medical Device Coordination Group
MDSW	Medical Device Software
NGS	Next Generation Sequencing
PCR	Polymerase chain reaction
SOP	Standard Operating Procedure

2 Introduction

The introduction of the European Regulation on *in vitro* diagnostic medical devices [1] has led to significant changes in the regulation of in-house IVDs in Switzerland. These devices must first and foremost comply with the applicable General Safety and Performance Requirements (GSPRs) outlined in the European IVDR [1]. In addition, medical laboratories are required to meet the conditions set out in Article 5(5) of the Regulation.

In Switzerland, health institutions must prepare technical documentation for all in-house IVDs—regardless of their classification—and notify Swissmedic in accordance with Articles 9 and 10 of the Swiss Ordinance on In Vitro Diagnostic Medical Devices (IvDO) [2]. Furthermore, medical microbiology laboratories must adhere to the provisions of the Swiss Laboratory Ordinance (LabV) [3], including the good practice requirements detailed in Annex I.

To clarify the relationship between LabV and IvDO requirements for in-house IVDs, Swissmedic has recently published a factsheet addressing this interplay [4].

Medical laboratories – particularly academic reference centers – often maintain a broad portfolio of in-house IVDs. This includes, for example, tests in medical microbiology for detecting rare or emerging pathogens, flow cytometry-based methods for immunophenotyping in haematology, and next-generation sequencing (NGS) techniques for diagnosing rare diseases in medical genetics.

The validation of these tests, implementation of risk management activities, conformity assessment, documentation, and ongoing maintenance—alongside accreditation requirements—represent a significant effort. This is often disproportionate to the relatively low number of tests performed annually using these LDTs. This recommendation paper reflects a common position of the FAMH IvDO Committee on the practical interpretation of Swiss and European regulatory requirements for in-house IVDs.

3 What is an in-house IVD

3.1 In-house IVDs fully developed by the laboratory or using non-CE marked components

3.1.1 Qualification

Swissmedic, on its IVD notification website [5], provides a non-exhaustive list of examples of in-house IVDs. These may include examination procedures that use non-CE-marked reagents and components, whether fully designed and developed in-house or based on standard or published protocols. The list also includes software and instruments developed and manufactured within the health institution, as well as the use of research-use-only (RUO) products in routine diagnostics. Table 3-1 presents examples of laboratory-developed tests (LDTs) commonly encountered across various laboratory specialties.

Table 3-1. Typical in-house IVD selected examples in laboratory specialist areas**C: Clinical Chemistry****LC-MS/MS analysis of drugs****G: Medical Genetics****NGS-examination procedures including result interpretation software pipelines****H: Haematology****Flow cytometry: Immunophenotypic analysis using flow cytometry for the diagnosis of hematologic and immune diseases****I: Clinical Immunology****Cryoglobulin detection and identification****M: Medical Microbiology****Susceptibility testing of mycobacteria against antitubercular drugs, Nucleic acid amplification technologies for the detection of pathogens or the detection of genes encoding pathogenic factors or providing antibiotic resistance, microscopic detection methods not commercially available**

3.1.2 Validation and documentation

In-house IVDs are required to fulfill applicable general safety and performance requirements according to Annex I, IVDR [1]. In Switzerland, all LDTs, irrespective of their classification, have to have documentation that allows Swissmedic to understand their intended purpose, performance, design and manufacturing as well as conformity with the aforementioned GSPRs. This documentation needs to be provided to authorities upon request [2].

To support laboratories in this effort, the FAMH has provided an abbreviated GSPR checklist alongside this position paper. This tool is designed to help laboratories quickly and efficiently identify the requirements relevant to their in-house IVDs and document conformity with applicable requirements.

For meeting regulatory requirements, the laboratories can refer to several recognized standards for the development, manufacturing, risk management, and verification/validation of in-house IVDs. This includes EN ISO 5649 [6], EN ISO 22367 [7], and various CLSI standards. These documents are widely regarded as state-of-the-art and are generally accepted by regulatory authorities and auditors as viable approaches for meeting requirements. Guidance may also be found in publications from professional organizations such as the IFCC [8] or in peer-reviewed literature, that is more specific for the laboratory field. Selected examples are referenced in this position paper [9][10].

For verification and validation activities, laboratories may, in addition to conducting their own studies, use peer-reviewed literature and data from routine practice – such as internal quality control results (IQC) over time or results from External Quality Assessment Schemes (EQAS). This can be particularly useful in situations where studies are difficult to perform, for example due to low sample numbers in the case of rare diseases. Having an in-house IVD within a legal institution does not exclude the possibility of sharing study data between laboratories. However, the receiving laboratory must be able to verify that the shared data is applicable to its own in-house IVD and that the amount and quality of the data are acceptable.

For documentation purposes, the German AWMF [11] offers useful templates for in-house IVD documentation [6]. The laboratories may also already have method sheets or SOPs that describe their in-house IVDs comprehensively. These can be supplemented with additional information and presented to authorities upon request. Existing verification and validation plans and reports, risk management files and GSPR checklist, can be annexed to this

documentation. Creating tailored templates and reusing existing documentation for other LDTs can significantly reduce time and effort.

The key message is that laboratories are ultimately responsible for ensuring and demonstrating compliance with the IvDO and IVDR GSPRs. It is, in fact, the laboratory's competence as the experts in their field. The general principle is:

- Identify which GSPRs are applicable to the in-house IVD and which are not.
 - Comply with applicable requirements
 - Ensure that the approach is scientifically and statistically sound and represents state-of-the-art/good practice
 - Document the approach and rationale and justify any omissions
- ⇒ **Summary Statement:** All in-house IVDs in Switzerland require a technical file, risk management documentation and verification and validation activities. The IvDV/ODiv committee encourages laboratories to make use of publicly available templates, including the abbreviated GSPR checklist provided by FAMH, as well as relevant standards and guidance documents. Sharing of data between institutions is permitted, provided the data is scientifically sound and applicable.

3.2 Substantial modifications to CE-marked IVDs

3.2.1 Qualification

According to MDCG Guidance 2023-1 [12], when a healthcare institution modifies the intended purpose of a CE-marked device for use within the institution, Article 5(5) of the IVDR applies—meaning the device is considered an in-house IVD. Although MDCG guidance documents are not legally binding, they are widely recognized by Swiss authorities. Therefore, compliance with Articles 9 and 10 of the IvDO [2] will likely be expected when the intended purpose of a CE-IVD is modified.

The intended purpose, as described in Section 20.4.1(c) of Annex I and Section 1.1.1(c) of Annex II of the IVDR [1], includes, where applicable:

- The analyte or marker being detected
- The test function (e.g., aid to diagnosis, monitoring, companion diagnostic)
- The specific disorder, condition, or risk factor
- The nature of the result (qualitative, quantitative, semi-quantitative)
- Whether the test is automated
- The specimen type
- The testing population
- The intended user

Any changes to a CE-marked device that affect one or more of these elements are considered a modification of the intended purpose, thereby rendering the device an in-house IVD.

Examples of such modifications include:

- **Systematic use of a different specimen type** than indicated by the manufacturer (e.g., serum instead of EDTA plasma, or sputum instead of bronchoalveolar lavage material; see also Section 3.2.3)
- **Use in a different clinical condition** than specified (e.g., applying HER2 immunohistochemistry tests intended for breast and ovarian cancer to gastrointestinal cancers)
- **Inclusion of a new patient population** excluded by the manufacturer (e.g., pediatric patients or patients at a different disease stage)
- **Change in test function**, such as using the CE-IVD for blood, tissue, or organ donation screening when this use is explicitly excluded by the manufacturer

The basis for determining whether a laboratory is modifying the intended purpose of a CE-marked device lies in a comparison between the manufacturer's labeling—specifically the intended purpose stated in the instructions for use—and the testing actually offered by the laboratory.

In certain cases, physicians may request off-label testing from the laboratory. This practice falls under the physician's responsibility and duty of care, as defined in Articles 3, 26, and 48 paragraph 2 of the Therapeutic Products Act (TPA). Physicians are legally required to inform patients about the off-label use and discuss associated risks and side effects. Such off-label use by physicians does not render the CE-marked device a laboratory-developed test (LDT) or in-house IVD. The responsibility lies with the treating physician, and the laboratory is not considered to have modified the intended purpose of the device in these cases [13][14]¹

3.2.2 Validation and documentation

Although the change to the *in vitro* diagnostic device may be significant, certain safety and performance aspects already established by the manufacturer may remain unaffected. For example, a change in the device's function or the testing population typically does not impact its stability. Similarly, analytical performance may remain unchanged, although cut-off values and measuring ranges must be carefully considered.

In such cases, the laboratory should conduct a targeted risk assessment of the change, along with an impact analysis of the General Safety and Performance Requirements (GSPRs) applicable to the IVD. The abbreviated GSPR checklist provided by FAMH can be particularly helpful in this context. It enables the laboratory to identify specific points that require further evaluation and the collection of objective evidence—such as internal validation studies—to demonstrate conformity with Annex I of the IVDR [1].

For aspects that remain unaffected by the change, we recommended that the laboratory call on the original CE-marking and conformity assessment performed by the manufacturer.

¹ If the laboratory is aware of an off-label request by a physician for a specific patient, it should consider indicating this fact as well as advise caution in interpreting the result in the final report. Microbiology laboratories should also consider indicating criteria for accepting such samples in their technical handbook [3].

- ⇒ **Summary statement:** For significant changes—particularly those affecting the intended purpose—the laboratory should:
- Assess the impact of the change on the safety and performance of the device, for example by using the abbreviated GSPR checklist.
 - Conduct appropriate risk management activities that specifically address the change.
 - Perform relevant validation activities, such as analytical or clinical performance studies, for parameters that have been affected (e.g., establishing clinical performance for a newly included patient population).
 - Rely on the original CE-marking and conformity assessment for aspects that remain unaffected by the change (e.g., device lifetime).
 - Prepare the necessary technical documentation, issue a public declaration, and carry out notification to Swissmedic in accordance with Articles 9 and 10 of the IvDO.

3.2.3 Changes to the specimen type

Changes to specimen type are a common yet often challenging aspect of routine laboratory practice. Laboratories may choose to use or analyze a different matrix for several reasons, including:

- The healthcare practitioner collected the wrong specimen, but testing is clinically urgent.
- A specific specimen type enables multiplex testing or avoids collecting multiple samples from the same patient.
- The specimen must be taken from a specific site of infection.
- The specimen type indicated by the manufacturer cannot be collected from the patient.

Validating a different specimen type presents several challenges. It may require collecting additional samples from patients or study subjects, which can be difficult—especially in rare conditions. It also raises ethical and logistical concerns.

Figure 1 illustrates a general decision tree for evaluating changes to specimen type. The first key question is whether the change is systematic or ad hoc—i.e., performed for a specific patient to address a clinically urgent need. The latter should not be considered a laboratory-developed test (LDT) (see also Section 4.3).

For systematic changes, the laboratory should first consider whether CE-marked alternatives are available. However, this may not always be practical, as it could limit the benefits for both the laboratory and the patient. Laboratories may also contact the manufacturer to request data on alternative matrices. In some cases, peer-reviewed literature or guidance documents—such as best practices for specimen collection in molecular biology—may provide sufficient evidence to support a matrix change.

The CLSI Guideline EP35A [15] offers a practical framework for validating matrix changes. It covers study design, statistical analysis, sample size considerations, and the use of surrogate samples when sample availability is limited due to the rarity of the condition. The guideline distinguishes between:

- **Similar matrices** (e.g., switching from EDTA plasma to serum): A method comparison study using 20–40 matched samples with duplicate measurements for precision may be sufficient.
- **Dissimilar matrices** (e.g., switching from EDTA plasma to cerebrospinal fluid): These require more extensive risk management, clinical validity assessment, performance verification, and—if performance is impacted—full validation activities.

In the latter case, using a **CE-marked alternative**, such as a specific test kit for detecting *T. pallidum* in CSF, may be a more viable option for the laboratory.

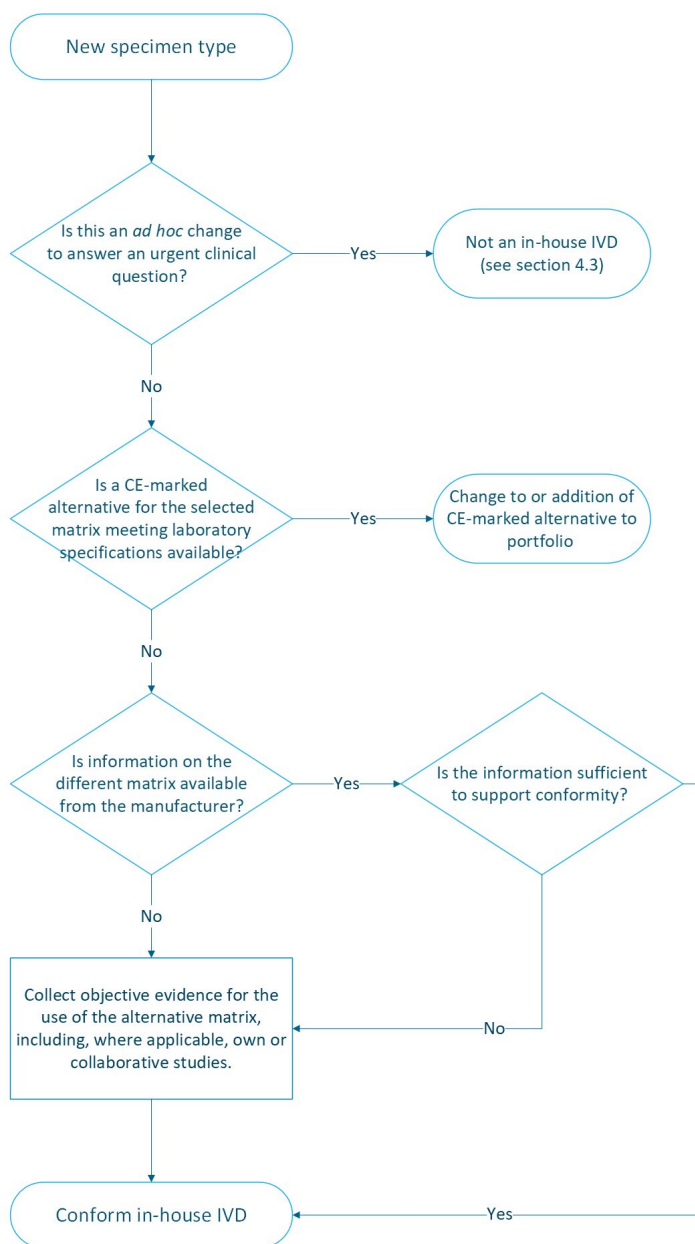


Figure 3-1 Flow-Chart for Specimen Type Change

- ⇒ **Summary statement:** Systematic changes to the specimen type of a CE-marked device offered by a laboratory constitute an in-house IVD. To evaluate such changes, laboratories can refer to available standards and guidance documents, which offer practical approaches for assessing matrix changes – including considerations for rare specimen types and limited sample availability. Laboratories performing similar analyses may also consider collaborating on specimen collection and study execution.

4 What is not an in-house IVD

4.1 Non-significant changes to CE-marked devices.

4.1.1 Qualification

Laboratories may make adaptations to existing CE-marked devices to optimize performance or improve specimen collection, provided these changes do not impact the intended purpose or significantly alter the design of the original product. Based on the principles outlined in MDCG Guidance Document 2022-6 [16], FAMH considers that the following types of modifications do not render a CE-marked device an in-house IVD, as long as they do not negatively affect the device's safety or performance:

- Changes in incubation times and temperatures
- Modifications to processing steps (e.g., adding a washing or enrichment step)
- Introduction of additional sample dilutions (e.g., to extend the assay's measuring range)
- Use of a different instrument, reader, or PCR cycler, provided performance specifications are met
- Change of specimen receptacle to one from a different manufacturer (not to be confused with a change in specimen type)

Verification and validation activities, as described in EN ISO 15189 [17], still apply in these cases. However, as long as the changes do not introduce new risks, impacting safety, and the device's performance remains comparable to or better than that stated by the manufacturer, the device should not be considered an in-house IVD.

Consequently, notification to Swissmedic under Article 10 of the IvDO, as well as the provisions of Article 5(5) of the IVDR and Article 9 of the IvDO [1][2], do not apply.

Please refer to the Figure 4-1 below for guidance on assessing changes to CE-IVD devices:

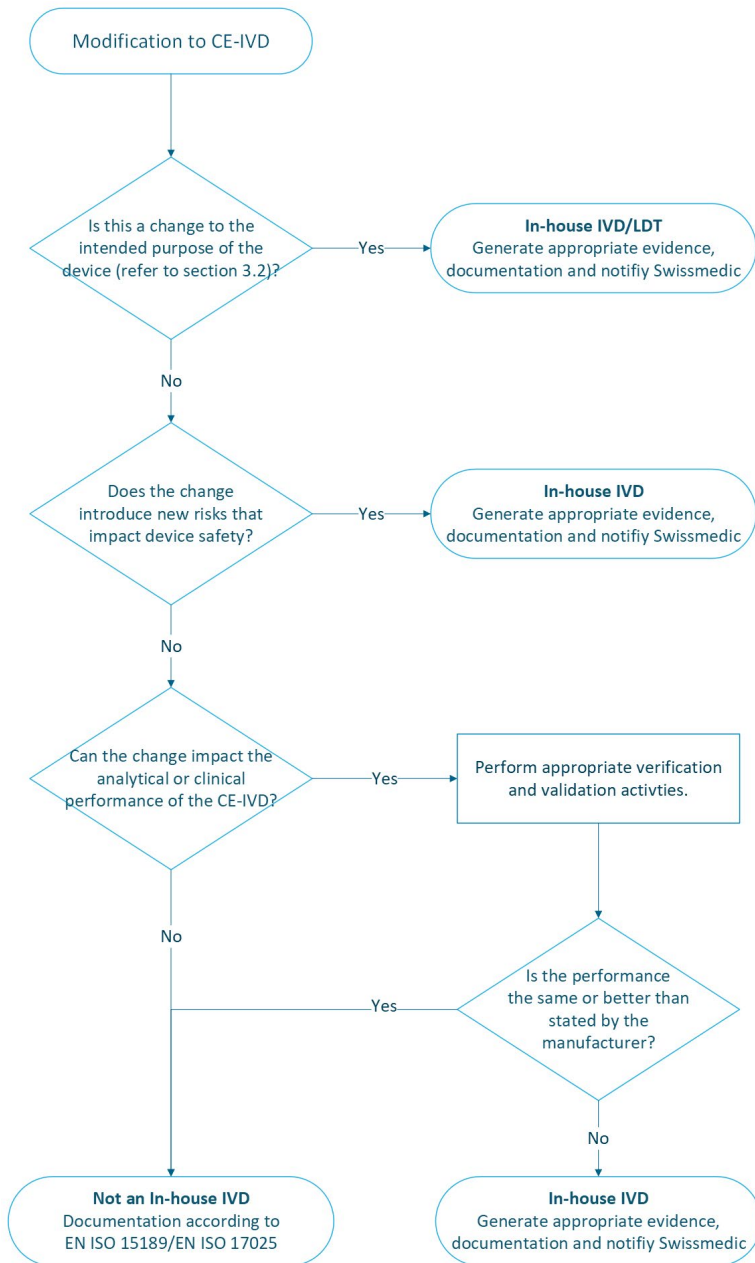


Figure 4-1 Assessing changes for CE -device modifications.

4.1.2 Validation and documentation

For a change to be considered non-significant, it must not introduce new risks that could negatively impact the device’s safety or alter the overall risk–benefit ratio of the analysis. This determination should be supported by a documented risk assessment.

Additionally, the device’s original performance – as stated by the manufacturer in the instructions for use (IFU) – should remain unaffected or be improved. It is the responsibility of the laboratory, based on scientific knowledge and experience, to assess whether any performance characteristics may be impacted (e.g., assay sensitivity due to the addition of a new washing step) and to verify or validate those changes accordingly.

Where appropriate, laboratories may refer to CLSI standards to support their evaluations:

- CLSI EP15 [18]: for verifying whether the change affects precision or introduces bias.
 - CLSI EP17-A2 [19]: for evaluating whether the sensitivity of the examination procedure is impacted.
 - CLSI EP34 [20]: for guidance on assessing extended measuring intervals.
- ⇒ **Summary statement:** Changes that do not affect the intended purpose of a CE-marked device and do not compromise its safety or performance but are made to optimize its use within the laboratory, should not be considered an in-house IVD. However, laboratories should still comply with the verification and validation requirements outlined in EN ISO 15189 and conduct an appropriate risk assessment to ensure that no new safety issues arise.

4.2 Combination of CE-marked devices used within their specification.

Certain examination procedures may require the combination of multiple CE-marked IVD devices. If each device is used within its intended purpose, as specified by the manufacturer, the combination does not constitute an in-house IVD. In such cases, no additional validation or risk management activities are required.

However, if the combination does not align with the manufacturer's original specifications, please refer to Section 4.1 above for guidance on how to proceed.

4.3 *Ad hoc* changes to a procedure to answer urgent clinical questions.

As described in EN ISO 15189:2022 [17], laboratories may accept a compromised, clinically critical, or irreplaceable sample after evaluating the risk to patient safety. Such situations may arise due to:

- Errors during specimen collection by the healthcare practitioner
- Requests to analyze a sample despite the presence of a known interferent
- Use of an alternative specimen type when the recommended one cannot be collected from the patient

In these cases, the medical report should include information about the issue and any limitations regarding result interpretation, as outlined in ISO 15189 [17].

This type of testing, however, does not represent a systematic change to a CE-marked IVD and should therefore not be considered an in-house IVD.

4.4 Products for general laboratory use

As outlined on the Swissmedic website [5] and in MDCG Guidance 2024-11 [21], products intended for general laboratory use—which do not possess characteristics that make them specifically suitable for *in vitro* diagnostic examination procedures—should not be considered in-house IVDs. This includes:

- [1] General laboratory equipment, such as centrifuges, pipettes, flasks, incubators, shakers, scales, balances, and HPLC columns. This category also includes readers and detectors (e.g., ELISA plate readers, fluorimeters, mass spectrometers used in LC-MS/MS and MALDI-TOF procedures), which generate raw data (e.g., peaks, optical densities) that are subsequently interpreted by users.
- [2] General consumables, such as Eppendorf and Falcon tubes, empty ELISA plates, petri dishes, and MALDI-TOF plates. While some manufacturers may label these products as CE-marked, MDCG Guidance 2024-11 [16] clarifies that simply adding the

statement “for *in vitro* diagnostic use” is not sufficient to qualify a product as an IVD or in-house IVD. In such cases, laboratories may disregard the manufacturer’s IVD claims.

- [3] General and standard reagents, including buffers (e.g., PBS), fixation solutions, and standard cell culture or microbial media, provided they do not contain analyte-specific selection agents or chemical indicators.

Note: Particular care must be taken when general buffers or reagents are batch-controlled for use in an in-house IVD. For further guidance, please refer to Section 6..

4.5 Internal Quality Controls (IQC)

Internal quality controls (IQCs) generated by laboratories as part of EN ISO 15189 [17] or ISO 17025 [22] standard requirements—used to monitor the validity of examination results, detect batch-to-batch variability of CE-marked tests, or identify trends indicating instrument or reagent calibration instability—should, in the opinion of the FAMH committee, not be considered in-house *in vitro* diagnostic devices (IVDs). These IQCs are produced to fulfill laboratory quality management system requirements and are not intended to replace manufacturer-provided controls.

This position aligns with the HPRA’s *Guide for Health Institutions that Manufacture and Use In-house In Vitro Diagnostic Medical Devices in Ireland*, which lists “retained patient samples used for internal quality control purposes” as examples that should not qualify as in-house IVDs [23].

However, this does not apply to quality controls that are:

- Manufactured as part of a laboratory-developed test (LDT), which should generally be considered an integral component of the in-house IVD.
- Intended to replace manufacturer-provided controls, particularly when they allow broader result validity criteria or are used as part of a change in the intended purpose of the test (refer to relevant sections for further details).

4.6 Software examples

Medical laboratories may develop their own software, including expert systems, for the interpretation of *in vitro* diagnostic results. Such software may be considered medical device software (MDSW) and therefore qualify as in-house IVDs, in accordance with MDCG Guidance 2019-11 [24]. The FAMH intends to issue a separate position paper addressing the topic of LDT software.

However, the following types of software or algorithms used by laboratories should not be considered in-house IVDs:

- General commercial off-the-shelf software used within its intended application range, such as word processors or spreadsheet programs.
 - Software used solely for viewing, archiving, transmitting/communicating, or simple searching, which does not influence the interpretation of *in vitro* diagnostic results. This includes the basic functionality of Laboratory Information Systems (LIS). However, LIS platforms may include modules that qualify as MDSW; this will be addressed in the upcoming FAMH position paper.
 - Simple arithmetic or plotting functions used to modify the representation of existing IVD data, such as calculating a mean, converting units, plotting results over time, or comparing results to predefined limits or intervals.
- ⇒ **Summary statement:** General laboratory equipment and products, internal quality control (IQC) samples, *ad hoc* changes to CE-marked devices made to address urgent clinical questions, off-label testing requests by physicians, and certain types of software—such as commercial off-the-shelf spreadsheets, software used for viewing, storage, archiving, communication, simple search functions, or for modifying the representation of existing IVD results—**do not need to be considered in-house IVDs.**

5 Subcontractors

Regulations do not prohibit laboratories from engaging subcontractors to develop instruments, software, or reagents according to the laboratory's specifications. This possibility is described in Section 4.3 of EN ISO 5649:2024 [6], which also outlines appropriate supplier control measures.

However, the laboratory remains fully responsible for ensuring that the final in-house IVD complies with the requirements of Article 5(5) of the IVDR [1] and Articles 9 and 10 of the IvDO [2]. The final device must be used within the legal entity of the laboratory.

If the laboratory chooses to outsource development, it is recommended to ensure that subcontractors follow applicable standards. For software development, this may include:

- EN 62304 [25] – Software life cycle processes
- EN 82304-1 [26] – Health software product safety and performance
- IEC 81001-5-1 [27] – Cybersecurity activities in the software life cycle
- IEC 62366-1 [28] – Usability engineering for medical devices

Laboratories should also request technical documentation from the developer to support conformity.

If an instrument is fully developed by the subcontractor and no further modifications are made by the laboratory, the subcontractor should comply with other applicable legislation, such as:

- Electromagnetic Compatibility Directive [29]
- Low Voltage Directive [30]
- Machinery Directive and Regulations [31][32]

The subcontractor must provide appropriate evidence of compliance with these requirements.

- ⇒ **Summary statement:** Subcontractors may be involved in the development of in-house IVDs. However, the laboratory remains responsible for the final product and must ensure that it receives the necessary documentation from its subcontractors. Laboratories should also verify that all applicable safety, performance standards, and legislative requirements are met.

6 Grouping into examination procedures and workflows

The sections above provide detailed examples of products, components, reagents, and software that should or should not be considered in-house IVDs. However, laboratories typically do not view examination procedures as isolated products, but rather as processes and workflows. This perspective may, in fact, be the most appropriate way to define an in-house IVD.

As previously noted by Oberleitner and Gebhard [33], a single examination procedure may involve more than 30 IVD products, including software. Evaluating and validating each element in isolation often makes little practical sense. Like manufacturers, laboratories are afforded a high degree of flexibility in how they group and define the boundaries of their devices.

For example, a medical genetics laboratory may reasonably define its entire NGS pipeline—from specimen collection, DNA extraction, library preparation, sequencing, bioinformatic analysis, to variant calling and annotation—as one system and one in-house IVD. Whether certain components within this system meet the definition of an (in-house) IVD or remain general laboratory components can be documented accordingly. This distinction may allow for the omission of specific General Safety and Performance Requirements (GSPRs) where appropriate.

Nonetheless, validating the system as a whole is often the most practical and scientifically sound approach.

- ⇒ **Summary Statement:** Laboratories are encouraged to manage and validate in-house IVDs not as isolated components or products, but as integrated examination procedures and workflows.

7 Grouping and bundling for documentation purposes

Grouping and bundling of in-house IVDs and technologies is also possible during the creation of technical documentation. The HPRRA also recommends using a common framework file for in-house IVDs that share a common workflow or design [23]. Examples include combinations of immunohistochemical stains or multiplex antibody panels.

A key documentation element is risk management, which is essential but often resource-intensive. When similar technologies are used, laboratories can establish a general template for risk assessment, as initiating events, contributing errors, and control measures are often comparable.

In some cases, multiple in-house IVDs may be grouped into a single risk management activity. For example, genetic panels used at the same stage of a diagnostic work-up may be grouped, provided that the potential patient harm and the probability of harm—such as receiving an incorrect or delayed result—are equivalent across all genes included.

- ⇒ **Summary statement:** Laboratories can use common framework files for in-house IVDs which share a common workflow or design.

8 Information on requirements not fully met

According to Article 5(5)(f)(iii) of the IVDR, health institutions may include in their public declaration “information on which requirements [GSPRs] are not fully met with a reasoned justification; therefor;” [1]. This flexibility is particularly relevant in cases where full compliance is not feasible due to practical limitations.

One example is the inability to collect a sufficient number of samples to establish clinical performance, such as in the case of rare diseases. Another example is the use of a Research Use Only (RUO) instrument that performs signal interpretation in routine diagnostics. In such cases, it may be impossible for the laboratory to retrospectively apply a full software development lifecycle, usability engineering, or comprehensive risk management²

In both scenarios, the laboratory may declare that certain requirements could not be fully fulfilled. To support this declaration and address potential concerns from authorities, it is recommended that laboratories indicate additional measures, such as monitoring of results in routine clinical practice or use of data from clinical experience as evidence of (partial) conformity with requirements. These measures help demonstrate that the device continues to operate safely and effectively, despite the limitations.

- ⇒ **Summary statement:** Under Article 5(5)(f)(iii) of the IVDR, laboratories may justify cases where GSPRs cannot be fully met—such as due to low sample availability for rare diseases or where retrospective application of development standards is not feasible. It is recommended to include information about additional safety measures, such as routine monitoring, and on additional supporting data from clinical experience to compensate for these limitations.

9 Conclusions

The implementation of the IVDR and IvDO has placed a significant regulatory and administrative burden on medical laboratories. Despite these challenges, laboratories remain committed to delivering high-quality diagnostic services, even in the face of discontinuation of CE-marked devices.

To effectively manage this challenge, the *ad hoc* FAMH IvDV/ODiv committee encourages laboratories to:

- Review their in-house procedures
- Consider CE-marked alternatives
- Identify components and products that should not be classified as in-house IVDs
- Group components into workflows, and where appropriate, bundle individual tests into panels to streamline validation and documentation

The flexibility provided under Article 5(5)(f)(iii) of the IVDR allows health institutions to put in-house IVDs into service even when full compliance with all requirements is not feasible—for example, in cases where low sample availability for rare diseases prevents comprehensive validation.

The use of available resources—such as documentation templates, standards, guidelines, and recommendations—can support laboratories in meeting regulatory requirements. To

² The RUO instrument must in any case be conform with other applicable legislation such as EMC, LVD and machinery directives and regulations [29][30][31][32]. Evidence of conformity should be requested from the manufacturer.

facilitate efficient verification of compliance with Annex I of the IVDR [1], FAMH provides an abbreviated GSPR checklist (template available from FAMH). This tool also assists in evaluating changes to existing LDTs or modifications to the intended purpose of CE-marked IVDs.

Ultimately it is the laboratories' experience and expertise that will enable a scientifically sound approach to meeting requirements and providing patients with quality services.

10 Authors and Affiliations

Dr. med. Martin Risch, Kantonsspital Graubünden, Dr. Risch
Executive Board FAMH

Dr. med. Dieter Burki, Sonic Suisse,
Executive Board FAMH

MSc Claudia Anderegg, Kantonsspital Aarau,
Representative of Swiss Cytometry Society, Member FAMH

Dr. sc. ETH Livia Berlinger, Luzerner Kantonsspital,
Representative of the Coordination Commission for Clinical Microbiology (CCCM) of the
Swiss Society of Microbiology (SSM), Member FAMH

Dr. Luca Bernasconi, Kantonsspital Aarau,
Representative of Swiss Society of Allergology and Immunology, Member FAMH

Dr. Thierry Nospikel, MD, PhD., Hôpitaux universitaires de Genève,
President of Swiss Society of Medical Genetics, Member FAMH

Dr. med. Maurice Redondo, Viollier
Representative of Swiss Society of Hematology, Member FAMH

Prof. Dr. Katharina Rentsch Savoca, Universitätsspital Basel
Representative of Swiss Society of Clinical Chemistry, Member FAMH

MSc Kaspar Gerber, ISS AG, Integrated Scientific Services

Dr. Alicja Ritz, ISS AG, Integrated Scientific Services

11 Disclaimer

The contents of this publication and the recommendations expressed herein have been developed by the authors as part of the ad hoc FAMH IvDV/ODiv Committee. They are based on applicable regulations, available guidance documents issued by the Medical Device Coordination Group, Swissmedic, and EU competent authorities, as well as relevant publications on the topic of in-house IVDs.

Where no formal interpretation of the applicable regulations was available, the recommendations were derived from analogous guidance documents for IVD devices and interpretation proposals from comparable organizations, such as the Dutch IVDR Task Force [34].

The contents of this publication are intended to be applicable across various fields of laboratory medicine, including medical microbiology, clinical chemistry, immunology, medical genetics, flow cytometry and haematology. As a result, specific considerations or field-specific guidance documents may not be exhaustively covered in this recommendation paper.

All information in this document has been compiled and assessed with great care, and the sources used are considered reliable. Nevertheless, the content is provided without liability and is non-binding. No responsibility is accepted for any errors, omissions, or outdated information.

For questions, please contact: info@famh.ch

Please include: "IvDV/ODiv" in e-mail header.

12 References

- [1] [Regulation \(EU\) 2017/746](#) on *in vitro* diagnostic medical devices (IVDR) (EUR-Lex, consolidated version: 10.01.2025)
- [2] [SR 812.219](#) Ordinance on In Vitro Diagnostic Medical Devices (IvDO) (Fedlex, status as of 01.01.2025)
- [3] [SR 818.101.32](#) Verordnung über mikrobiologische Laboratorien (LabV) (Fedlex, status as of 01.09.2023)
- [4] [Swissmedic Factsheet](#), Selbst-entwickelte und modifizierte Analysensysteme im Vorgabenkontext der Verordnung über mikrobiologische Laboratorien (version of 19.08.2024)
- [5] Swissmedic website on IVD notification, <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/meldung-ivd.html>
- [6] EN ISO 5649:2024, Medical laboratories - Concepts and specifications for the design, development, implementation, and use of laboratory-developed tests
- [7] EN ISO 22367:2020, Medical laboratories – Application of risk management to medical laboratories
- [8] IFCC website for IFCC Publications / Documents / Webinars: <https://ifcc.org/ifcc-communications-publications-division-cpd/ifcc-publications/>
- [9] Yusuf E, et al. How to verify and validate a clinical microbiology test before it can be used in routine diagnostics: a practical guide. *Clin Microbiol Infect.* 2024 Oct;30(10):1261-1269.
- [10] Rabenau et al. The new In Vitro Diagnostics Regulation (IVDR): assistance in the validation/verification of methods used or developed and applied in diagnostic laboratories for the detection of infectious agents. *GMS Z Forder Qualitatssich Med Lab* 2022
- [11] AWMF work aids and forms, <https://www.awmf.org/service/arbeitshilfen-und-formulare>
- [12] [MDCG 2023-1](#), Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- [13] [SR 812.21](#) Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) (Fedlex, status as of 01.01.2025)
- [14] [SAMW-Guideline](#), Rechtliche Grundlagen im medizinischen Alltag (2020)
- [15] CLSI EP35, Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 2nd Edition
- [16] [MDCG 2022-6](#), Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR

- [17] EN ISO 15189:2022, Medical laboratories - Requirements for quality and competence
- [18] CLSI EP15, User Verification of Precision and Estimation of Bias, 3rd Edition
- [19] CLSI EP17, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition
- [20] CLSI EP34, Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition
- [21] [MDCG 2024-11](#), Guidance on qualification of *in vitro* diagnostic medical devices
- [22] EN ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories
- [23] [SUR-G0052-1](#), Guide for Health Institutions that Manufacture and Use In-house *in vitro* Diagnostic Medical Devices in Ireland, 24 May 2024
- [24] [MDCG 2019-11](#), Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
- [25] EN 62304:2006 + A1:2015, Medical device software - Software life-cycle processes
- [26] EN 82304-1:2017, Health Software - Part 1: General requirements for product safety
- [27] IEC 81001-5-1:2021, Health software and health IT systems safety, effectiveness and security, Part 5-1: Security — Activities in the product life cycle
- [28] IEC 62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices
- [29] [Directive 2014/30/EU](#) on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (EMC) (EUR-Lex, consolidated version: 11.09.2018)
- [30] [Directive 2014/35/EU](#) on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (LVD) (EUR-Lex, consolidated version: 29.03.2014)
- [31] [Regulation \(EU\) 2023/1230](#) on machinery (EUR-Lex, consolidated version: 29.06.2023)
- [32] [Directive 2006/42/EC](#) on machinery (EUR-Lex, consolidated version: 26.07.2019)
- [33] Oberleitner A. and C. Gebhard, The European *In vitro* Diagnostics Regulation (IVDR) and the Swiss IvDV – challenges and recent developments. Labmed 2024/4
- [34] Bank PCD et al. The end of the laboratory developed test as we know it? Recommendations from a national multidisciplinary taskforce of laboratory specialists on the interpretation of the IVDR and its complications. Clin Chem Lab Med. 2020 Nov 23;cclm-2020-1384.