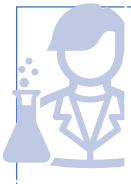
Biomedical Alliance in Europe

Info sheet: essential role of in-house devices in the IVD Sector

What are in house devices used for?

Fulfil unmet diagnostic needs & provide personalised care

Support the diagnosis and care for rare diseases

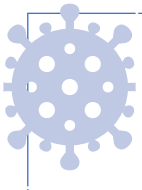


Facilitate better access to innovation & new research outcomes

- Improve uptake of new research results, and provide a path to market

Meet interoperability needs with existing systems in the lab

Provide access to Research Use Only devices that are not yet available as CE marked devices



Health emergency preparedness

- In house devices play an important role in health emergency responses, for instance: during the COVID-19 pandemic, the first tests were in house devices

Facts

In House devices play an important role in health institutions

- In UZ Leuven, currently 25% of 2200 IVD tests in their portfolio are in house devices. In more specialised labs this number can be higher (up to 75-80%[1]).

They are less frequently used than CE-marked devices and fairly complex

- 98% of UZ Leuven results are obtained using CE-IVD–certified methods

Often there is no CE-marked alternative available

- In 2020, Leuven Hospital noted that there was no CE-marked alternative available for 71.9% of their in house devices[2]

There are strong quality management systems in place

- Labs adhere to strong ISO 15189 accreditation requirements in place[1]
- They participate in internal and external quality management systems
- They undergo both internal and external audits

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Perspective of diagnostic laboratories on the changes to IVDR article 5.5

Proposed amendments to IVDR Article 5.5 encourage innovation, reduce the additional administrative burden that health institutions face, and facilitate the transfer of in house devices from one health institution to another (under conditions mentioned)

Changed wording 5.5a for in house IVDs allows innovative tests to reach a broader group of patients (including during health emergencies), and helps meet their specific unmet needs

Removal of 5.5d reduces heavy administrative requirements for laboratories

It is not their intention to compete with CE-marked devices, but to alleviate the high administrative burden. It is already stated in article 5.5 that devices manufacturered on an 'industrial scale' are already outside the scope of the provisions.

Quality in the diagnostic sector is already guaranteed, partly through existing quality systems (such as ISO 15189) and highly integrated internal and external quality assessment in these areas

For more information: find the BioMed Alliance position on the Revision Proposal of MDR & IVDR here

Sources:

[1] Lubbers BR, Schilhabel A, Cobbaert CM, Gonzalez D, Dombrink I, Brüggemann M, Bitter WM, van Dongen JJM. The New EU Regulation on In Vitro Diagnostic Medical Devices: Implications and Preparatory Actions for Diagnostic Laboratories. Hemasphere. 2021 Apr 21;5(5):e568

[2] Vermeersch P, Van Aelst T, Dequeker EMC. The new IVD Regulation 2017/746: a case study at a large university hospital laboratory in Belgium demonstrates the need for clarification on the degrees of freedom laboratories have to use lab-developed tests to improve patient care. Clin Chem Lab Med. 2020 Jul 21;59(1):101-106.

[3] For more information and examples of IH-IVDs, see: EFLM position statement on the proposed 2025/0404(COD) IVDR Amendment of Article 5.5 https://pubmed.ncbi.nlm.nih.gov/42089505/