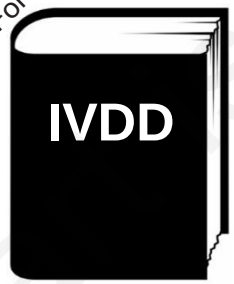
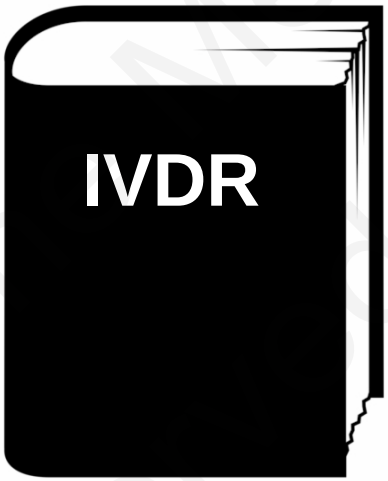
What impact for health care professionals & laboratories?

- IVD**D** regulates commercial IVDs (CE-IVDs)
- IVD**R** regulates CE-IVDs and LDTs/IH devices





CE-IVDs

LDTs

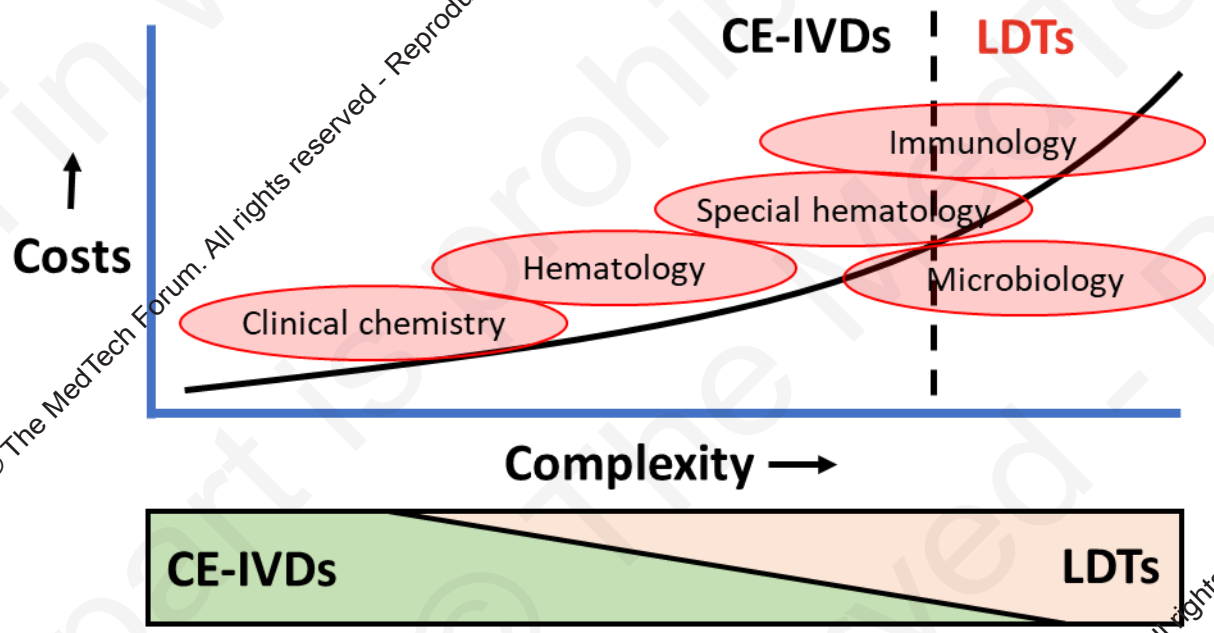
Laboratory-developed tests / In-house devices

1998 - 2022

Entry into force: 2017

Date of application: May 26th, 2022

High complexity assays are frequently LDTs/In-House

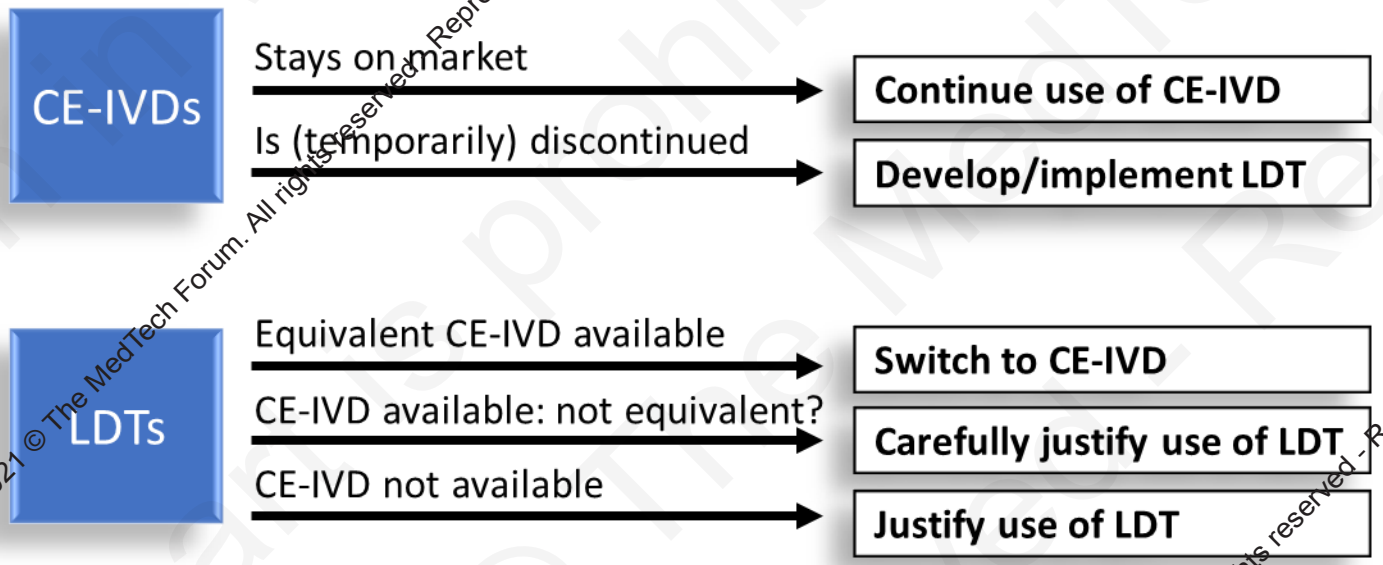


Cellular, Protein and Molecular

- Assays with higher complexity are more difficult to commercialize
- To provide optimal healthcare, diagnostic laboratories depend on development of LDTs for many (complex) applications
- This dependence significantly differs per diagnostic field

Slide from Van Dongen, 9th ESLHO Symposium, Zoom webinar, 5 November 2020

IVDs under the IVDR: 5 different scenarios



RISK

Missing tests

Monopolies

Work load

Work load

Increased diagnostic costs

Offset by other benefits ?

Biomedical Alliance in Europe

ESLHO european scientific foundation laboratory hemato oncology

EHASWG SCIENTIFIC WORKING GROUPS

EHA

Take home messages

- LDTs will continue to be critical for high quality health care under the IVDR
- IVDR will restrict LDT use, and LDT use will become more burdensome
- Member state independence for LDT validation will increase this tendency
- European networks such as ESLHO can help concerted validation of rare tests
- This will contribute to disseminating equal access to optimized rare IVD tests in Europe and should be encouraged and supported

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