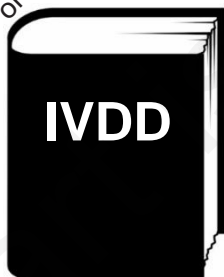
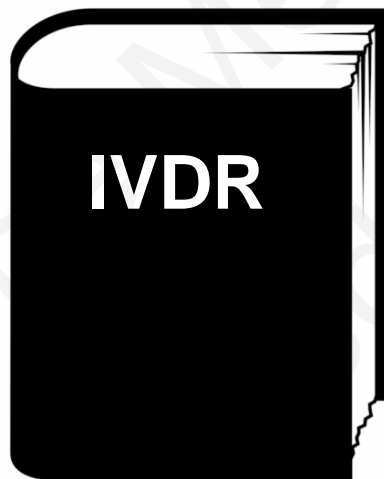


## What impact for health care professionals & laboratories?

- IVDD regulates commercial IVDs (CE-IVDs)
- IVDR regulates CE-IVDs and LDTs/IH devices



1998 - 2022



Entry into force: 2017

Date of application: May 26<sup>th</sup>, 2022



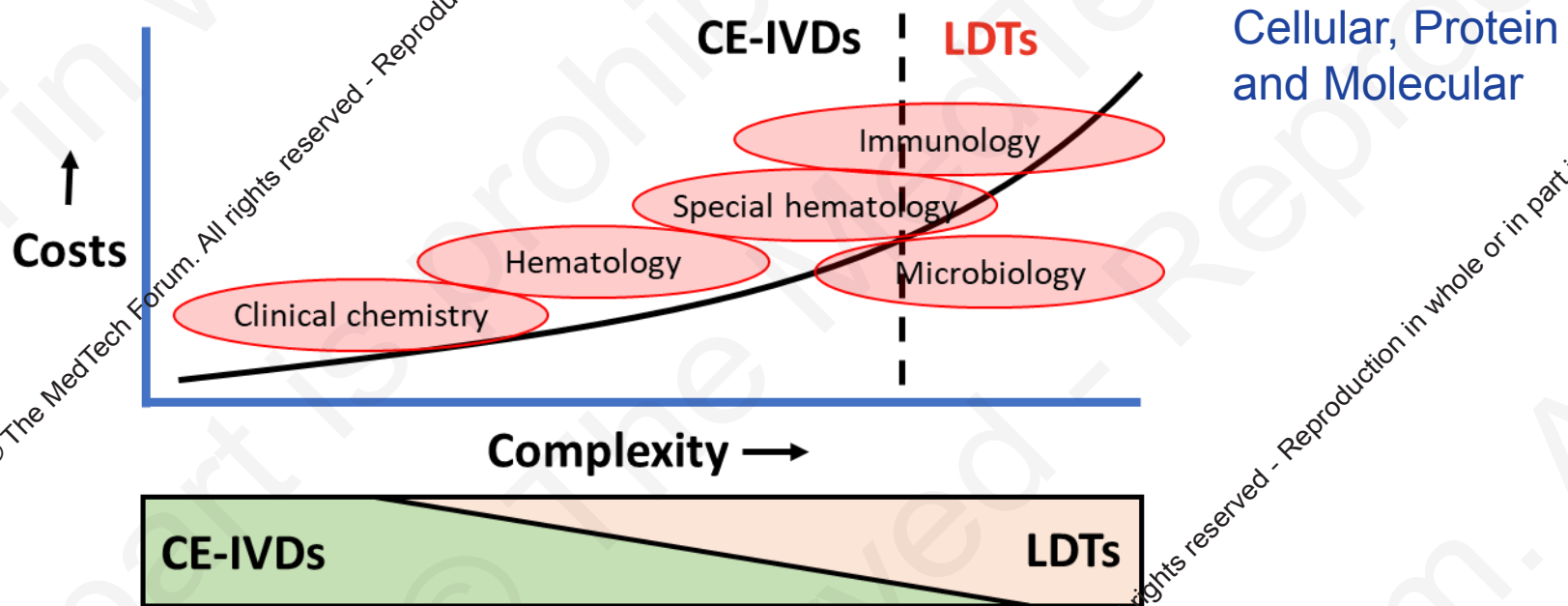
CE-IVDs



LDTs

*Laboratory-developed tests /  
In-house devices*

# High complexity assays are frequently LDTs/In-House



- 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

# IVDs under the IVDR: 5 different scenarios

**CE-IVDs**

Stays on market

Is (temporarily) discontinued

**Continue use of CE-IVD**

**Develop/implement LDT**

**LDTs**

Equivalent CE-IVD available

CE-IVD available: not equivalent?

CE-IVD not available

**Switch to CE-IVD**

**Carefully justify use of LDT**

**Justify use of LDT**

**RISK**

**Missing tests**

**Monopolies**

**Work load**

**Work load**

**Increased diagnostic costs**

**Offset by other benefits ?**



Biomedical Alliance in Europe



## 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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