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IVD: Definitions & Examples:

- definition of an IVD medical device

IVD: Evaluation of Performance:
- different concepts of analytical performance versus diagnostic (clinical) performance of a test
- meanings of analytical accuracy, trueness, precision, threshold of detection
- explain other parameters characterizing the analytical performance of IVD devices (repeatability, reproducibility)
- diagnostic value, error matrix, decision tree, cut-off levels, ROC,…

IVD: QC in Lab Medicine

- reference interval, reference samples; longitudinal/transversal comparisons;
- sources of variation

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IVD-Regulatory

- You should be able to outline some of the most important elements necessary for a market permission of a product as a medical device (technical documentation, report of analytical performance; assessment of product including verification, validation; clinical trials (if necessary) with report on diagnostic performance; Quality management system; Risk group assignment and effect on the need to involve Notiefied Bodies)

- Difference between verification and validation

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Tumor-IVD

Introduction to tumor biology:

- have a general overview on tumor biology

Tumor Markers:

- aims of TM (diagnostic, prognostic, predictive; early detection/screening?)
- types of tumor markers (genomic, proteomic, cellular, functional, ...)
- Kaplan-Meier curves
- different types of clinical trials?

Tumor Markers – Case Studies:

- explain at least one example of a molecular and a functional tumor marker

Biopsies and Liquid Biopsies:

- be able to explain at least one example of liquid biopsies as a source of tumor marker

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Project CellTEST: Medical&Biological Background

- explain the concept of "personalized (tumor-) medicine"
- explain at least one example of an in vitro tumor model

Project CellTEST: Readout Technologies

- explain how to the quality of an assay (Z- or Z´value)
- explain the principle of at least one readout technology use for functional, predictive testing (ATP-test, electric impedance measurement)