New CEN and ISO Standards for Pre-examination Processes

What they mean for us

Lecture Course

Graz, May 16th 2018

Dr. Uwe Oelmüller, SPIDIA4P Coordinator, QIAGEN GmbH

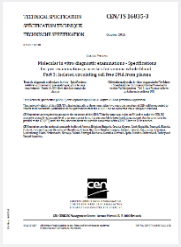
Role of Standards and Technologies

EU IVDR – In-vitro-Diagnostic Device Regulation

Pre-analytical workflow parameters





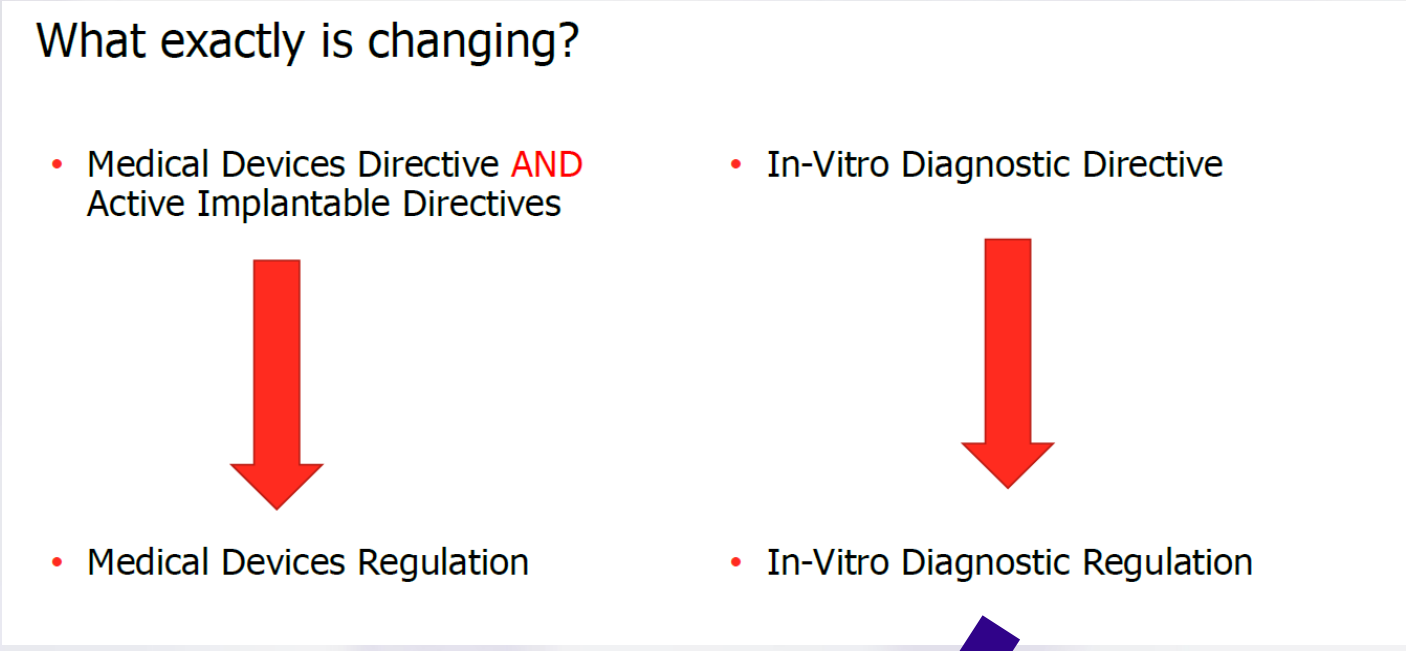


EN ISO & CEN Standards

SOPs

Technologies & Products

New European Medical Device and In Vitro Diagnostic Regulations 2017



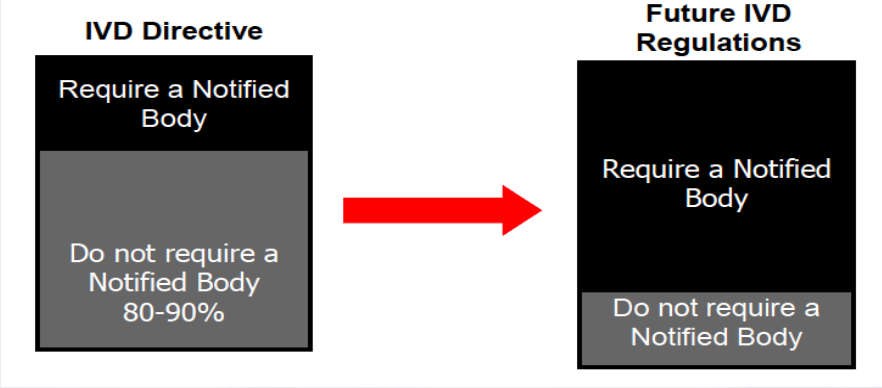
Source: https://www.bsigroup.com

- New European In Vitro Diagnostic Regulation in force since May 2017
  - 5 years transition period ⇨ date of applications: May 2022
  - Grace period for existing CE IVDD: May 2024
  - Warehouse clause: May 2025

New IVDR – Key Changes

Risk Classes

- *from list-based approach to risk-based approach*
- *four risk categories: A (low risk) to D (high risk)*



Conformity Assessment Routes

- *reflect the new classification rules*
- *introduction of pre-examination process parameters*
- *more manufacturers need to use a Notified Body*

Performance Evaluation

- *process of performance evaluation defined*
- *required throughout the lifetime of the device*

Source: https://www.bsigroup.com

New IVDR – Key Changes

Clinical Evidence

- *scientific validity, analytical performance, and clinical performance*

Post Market

- *post market performance follow-up new requirement*
- *incident reporting and trending*

Conformity Assessment Routes

- *reflect the new classification rules*
- *introduction of sampling*
- *more manufacturers need to use a Notified Body*

Scrutiny and Traceability

- *new requirements in technical documentation will mean audit and updates to all technical files*
- *unique Device Identifier (UDI)*

Source: https://www.bsigroup.com

New European Medical Device and In Vitro Diagnostic Regulations 2017

- Also pre-analytical workflow parameters become mandatory (IVDR)

  - REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE (Chapter III, Annex I)
  - (q) conditions for collection, handling, and preparation of the specimen

  - 6. PRODUCT VERIFICATION AND VALIDATION (Annex II)
  - 6.1. Information on analytical performance of the device
  - 6.1.1. Specimen type

    This Section shall describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such as duration, temperature limits and freeze/thaw cycles

SPIDIA4P

Before Designing an Analytical Test: We have to know the Entire Workflow

SPIDIA

European Conference. Standards: Your Innovation Bridge. Brussels (2014). SPIDIA Booth.

CEN CENELEC

European Commission

CEN/TS 16835-3 - Pre-examination Process for Blood ccfDNA

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 16835-3

October 2015

ICS 11.100.30

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus pré-analytiques pour le sang total veineux - Partie 3: ADN libre circulant extrait du plasma

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 3: Aus Plasma isolierte zirkulierende zellfreie DNS

This Technical Specification (CEN/TS) was approved by CEN on 31 August 2015 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. CEN/TS 16835-3:2015 E

ISO/IS Standards expected for 2018

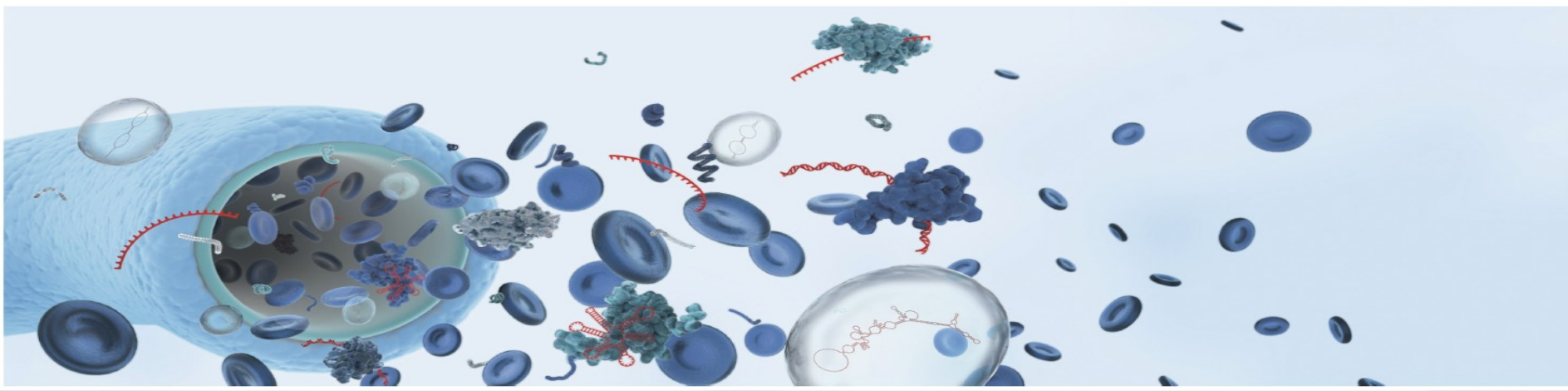
CEN/TS 16835-3 - Pre-examination Process for Blood ccfDNA

ccfDNA Analysis - The Primary Sample is Whole Blood

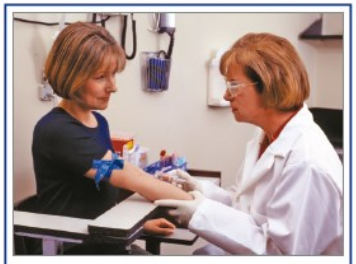
Doctor's Office
Hospital

→ Laboratory

Blood Collection → Storage / Transport → Plasma Separation → ccfDNA isolation → Analytical Test → Data Analysis



Standardized Integrated Sample-to-Insight Workflows



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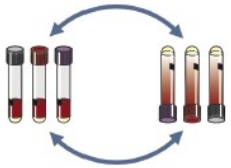

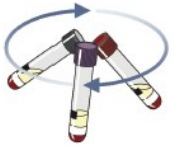

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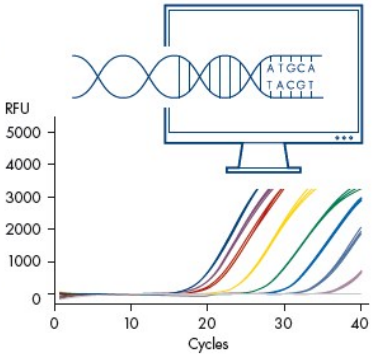
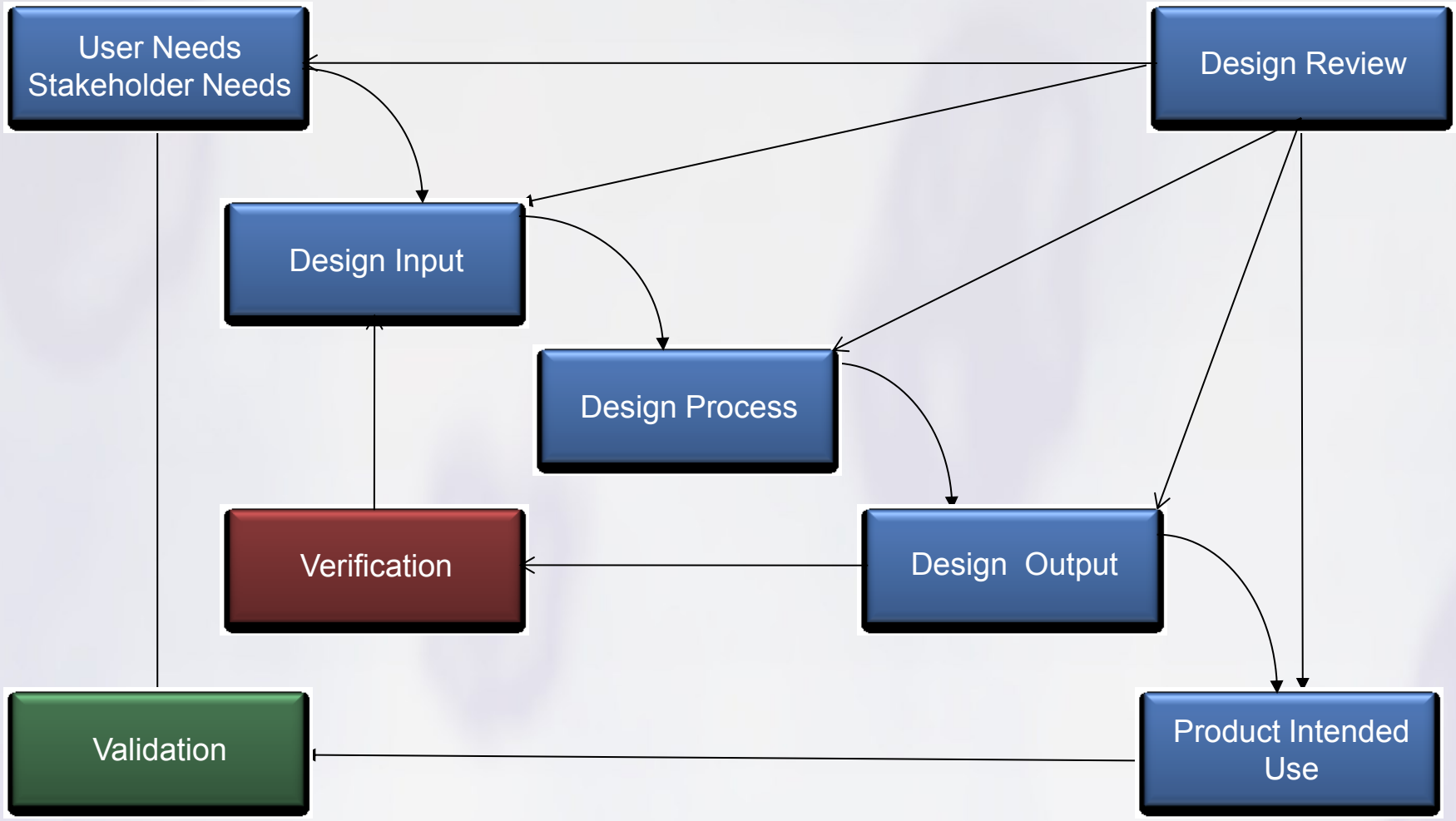


Collection & Stabilization → **Storage Transport** → **Plasma Separation** → **ccfDNA Isolation** → **Analytical Test** → **Data Analysis**

Design Control - What to Verify and Validate



ISO and CEN Standards can always be used

- New ideas, technologies and products benefit from standardization to get into the marketplace and to be successful
  - Build customer confidence that your products are safe and reliable
  - Meet regulation requirements, at a lower cost
  - Reduce costs across all aspects of your business
  - Gain market access across the world

- International Standards help businesses of any size and sector reduce costs, increase productivity and access new markets

- “Standards make market access easier, in particular for SMEs. They can enhance brand recognition and give customers the guarantee that the technology is tested and reliable”

Jens Albens CEO, Nanotron Technologies Ltd, Germany

A big Thank You goes to . . .

- SPIDIA Consortium (EU FP7)
- SPIDIA4P Consortium (EU H2020)
- CEN/TC 140 (Europe)
- ISO/TC 212 (International)
- CD Laboratory for Biospecimen Research & Biobanking Technologies Team (Med. Univ. Graz)
- CBmed Project 1.4 Team (Graz)
- STRATFix UK Consortium (UK)
- CANCER-ID Consortium (EU IMI)
- Barrett Oesophagus m4 Team (Munich)

- . . . and all other international collaboration partners

⇨ ***www.spidia.eu***

Thank you!

Questions ?