SPIDIA4P & BBMRI-ERIC: What Solutions can we provide to improve in vitro Diagnostics?

EU Parliament

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Deficiencies in Routine Healthcare and Research demand for Improvements

- Diagnostic errors cause about 10% of all patient deaths and about 17% of adverse events

  Institute of Medicine (IOM) Report Sept. 2015

- Pre-analytical phase accounts for 46% to 68% of clinical laboratory errors

  Medical Laboratory Observer, May 2014

- Irreproducible preclinical research exceeds 50%, US $28B / year spent on preclinical research that is not reproducible - in the US

  Freedman LP, Cockburn IM, Simcoe TS (2015) PLoS Biol 13(6): e1002165.doi:10.1371/journal.pbio.1002165

An Analytical Test Result is the Result of an entire Workflow

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

Major Efforts for Improvements

- **Technologies**
- **International CEN & ISO Standards**
- **External Quality Assessment (EQA) Schemes**
- **Implementation** - healthcare, biobanking, research

. . . . many more

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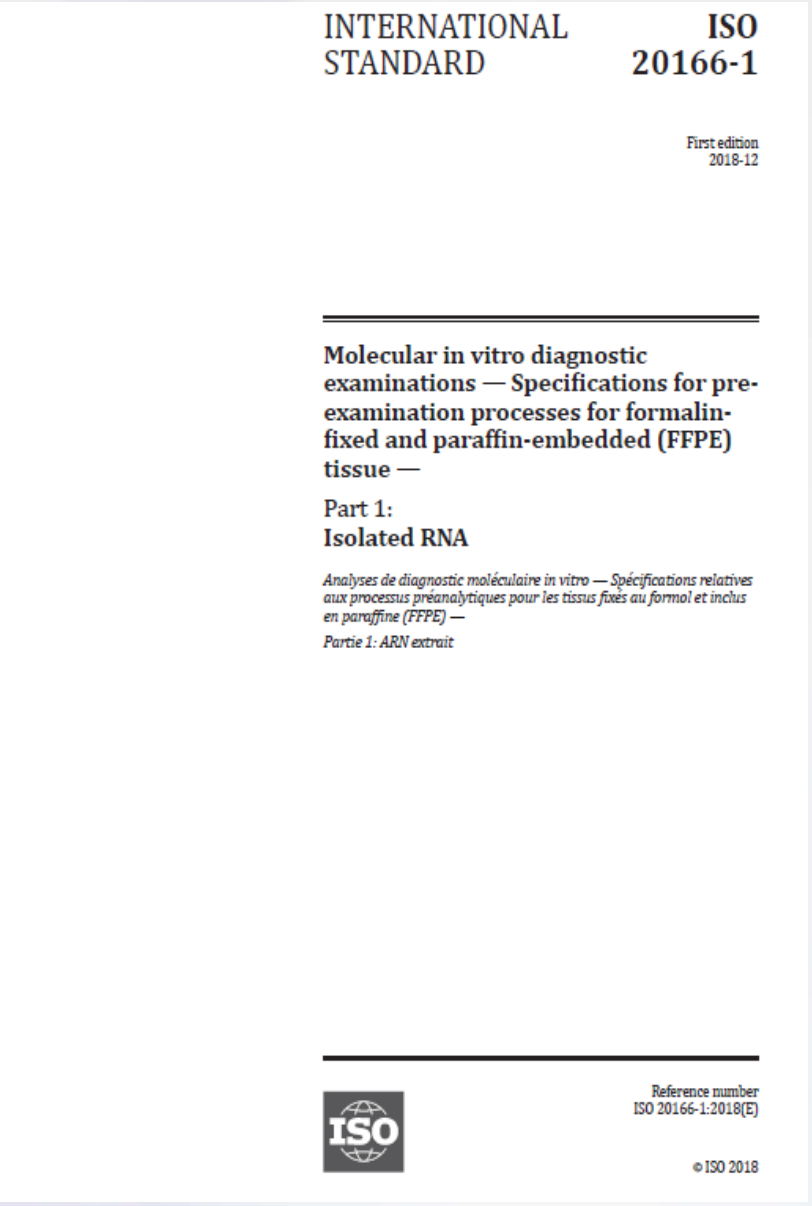
22 CEN & ISO Standard Documents and EQAs by 2020



INTERNATIONAL STANDARD

ISO 20166-1

First edition
2018-12

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue —

Part 1:
Isolated RNA

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) —

Partie 1: ARN extrait

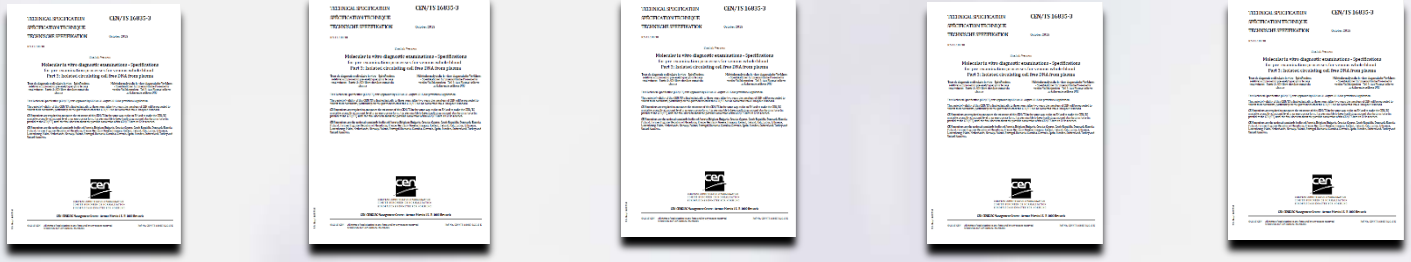
Reference number
ISO 20166-1:2018(E)

- Molecular in-vitro diagnostic examinations - Specifications for **pre-examination processes** for
  - **Blood** — Cellular RNA, gDNA, ccfDNA, ccfRNA
  - **Blood** - Exosomes
  - **Tumor Cells** in Blood – DNA, RNA, staining
  - **Tissue** (FFPE & Frozen) — DNA, RNA, Proteins
  - **Tissue** (FFPE) - staining
  - **Fine Needle Aspirates** – DNA, RNA, Proteins
  - **Saliva** – DNA
  - **Urine & Body Fluids** – cfDNA
  - **Metabolomics** – Urine, Serum, Plasma
  - **Microbiome** – Stool, Saliva etc.

Role of Standards and Technologies

EU IVDR – In-vitro-Diagnostic Device Regulation

Pre-analytical workflow parameters



EN ISO & CEN Standards

SOPs

Technologies & Products

Pre-analytical Workflow - Same Standards for all Segments

- **Biobanks**
  - Source for high quality samples
  - ⇨ BBMRI-ERIC plays a central role

- **Biomedical & Translational Research**
  - Academia
  - Pharma industry
  - Diagnostic Industry

- **Diagnostics**
  - High sample quality is the safe way
  - Analytical assay might tolerate lower quality or not ⇨ Validation studies

Future Perspective beyond SPIDIA4P

- Patients sample qualities stay key for healthcare & innovation
  - ⇨ new diagnostic targets
  - ⇨ new electronic patient data modelling & integration, electronic patient records, new links between applications by digitalization etc.

- Continue standards initiative

- Continue implementation

- Health economics

- Clinical demonstrations / trials

SPIDIA4P

Thank you for Your Attention!

Questions ?

www.spidia.eu **- New website coming soon**

Back Up Slides

SPIDIA's Road to Standardization

Vienna Agreement 1991

– **2018:** Progressing to ISO/FDIS

– **2014:** 8 new projects for ISO Standards approved in ISO/TC 212 „*Clinical laboratory testing and in vitro diagnostic test systems*"

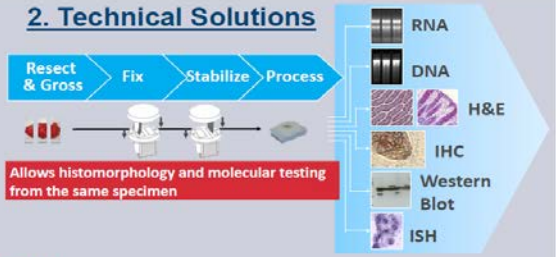
– **2015:** 9 CEN Technical Specifications published

– **2013:** 9 new projects approved in CEN/TC 140 „*In vitro diagnostic medical devices*"

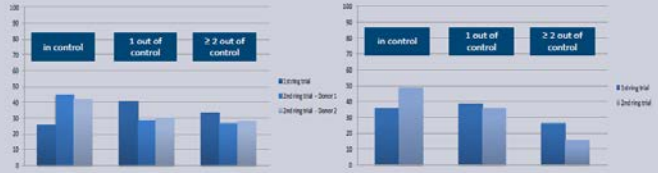
– **2010:** Start of standardization work

1. Problem - Errors in Diagnostics

2. Technical Solutions



3. Ring-Trials – Blood RNA (l.) and DNA (r.)



SEVENTH FRAMEWORK PROGRAMME