SELF-ASSESSMENT TOOL FOR MOLECULAR PATHOLOGY TO CHECK PRE-ANALYTICAL WORKFLOWS

BACKGROUND & AIM

A series of the CEN Technical Specification (CEN/TS) and ISO Standards for “In-Vitro Diagnostic examinations - Specifications for Pre-examination Processes” have been published and are in development.

The standards define requirements along the entire pre-analytical clinical workflow of samples. They are applicable to diagnostics, molecular pathology and classical in situ detection methods.

RESULTS

**BBMRI Self-Assessment Survey Tool (SAS)**

for assessing compliance of pre-analytical workflows of pathology samples with CEN/TS & ISO Standards

1. **What is the BBMRI SAS**

   The Self Assessment Tool set of IT-based questionnaires based on CEN and (upcoming) ISO standards for pre-analytical procedures:

   - FFPE tissue - RNA (CEN/TS 16827-1:2015)
   - FFPE tissue - DNA (CEN/TS 16827-3:2015)
   - Snap frozen tissue - RNA (CEN/TS 16826-1:2015)
   - Snap frozen tissue - proteins (CEN/TS 16826-2:2015)
   - Venous whole blood - RNA (CEN/TS 16835-1:2015)
   - Venous whole blood - DNA (CEN/TS 16835-2:2015)
   - Venous whole blood - cfDNA (CEN/TS 16835-3)
   - Metabolomics in serum, plasma, urine (CEN/TS 16945:2016)

2. **How to get access and use the BBMRI SAS**

   Access
   - Go to: [www.bbmri-eric.eu](http://www.bbmri-eric.eu)
   - Fill out request form & fulfill pre-conditions
   - Get started: receive link to SAS

   Evaluation
   - Complete SAS survey
   - Print report
   - Submit report to BBMRI-ERIC

   Quality Label
   - Receive BBMRI-ERIC quality label for a sample collection
   - Enhance visibility of your sample collection in the BBMRI-ERIC Directory

3. **Look inside the BBMRI SAS**

   Inside the laboratory
   - Primary tissue collection
   - Transport conditions

   Outside the laboratory
   - Primary tissue sample receipt at laboratory
   - Evaluation of pathology of specimen and selection of sample
   - Post-fixation of frozen samples
   - Storage conditions

   Isolation of total RNA
   - General information for RNA
   - Using a commercial kit / a laboratory
   - RNA quantity & quality assessment
   - Storage of isolated RNA


SUMMARY

The Self-Assessment Survey Tool

- is a supportive tool to be used in combination with CEN & ISO standards
- provides an interactive electronic check-list on pre-analytical quality requirements
- helps laboratories in implementation of standards
- enables structured evaluation of established pre-analytical processes and SOPs
- reveals deviations from standard requirements
- shows were optimization measures are needed
- allows pathology biobanks to display their quality-labeled collections in the BBMRI-ERIC Biobank Directory

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