

# SELF-ASSESSMENT TOOL FOR MOLECULAR DIAGNOSTICS TO CHECK PRE-ANALYTICAL WORKFLOWS

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## 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 molecular diagnostics in personalized medicine.


## METHOD

The BBMRI.at and BBMRI-ERIC Biobanking Infrastructures have developed an online Self-Assessment Survey Tool. It is based on standards and allows medical laboratories to evaluate if their pre-analytical procedures meet the requirements of the standards.

## RESULTS **BBMRI Self-Assessment Survey Tool (SAS)** for assessing compliance of pre-analytical workflows of medical samples with CEN/TS & ISO Standards

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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\*: i.e:

- FFPE tissue - RNA (CEN/TS 16827-1:2015)
- FFPE tissue - proteins (CEN/TS 16827-2:2015)
- 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 - ccf DNA (CEN/TS 16835-3)
- Metabolomics in serum, plasma, urine (CEN/TS 16945:2016)

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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
- OPTIONAL:
- Submit report to BBMRI-ERIC
- Be reviewed by BBMRI-ERIC

Quality Label

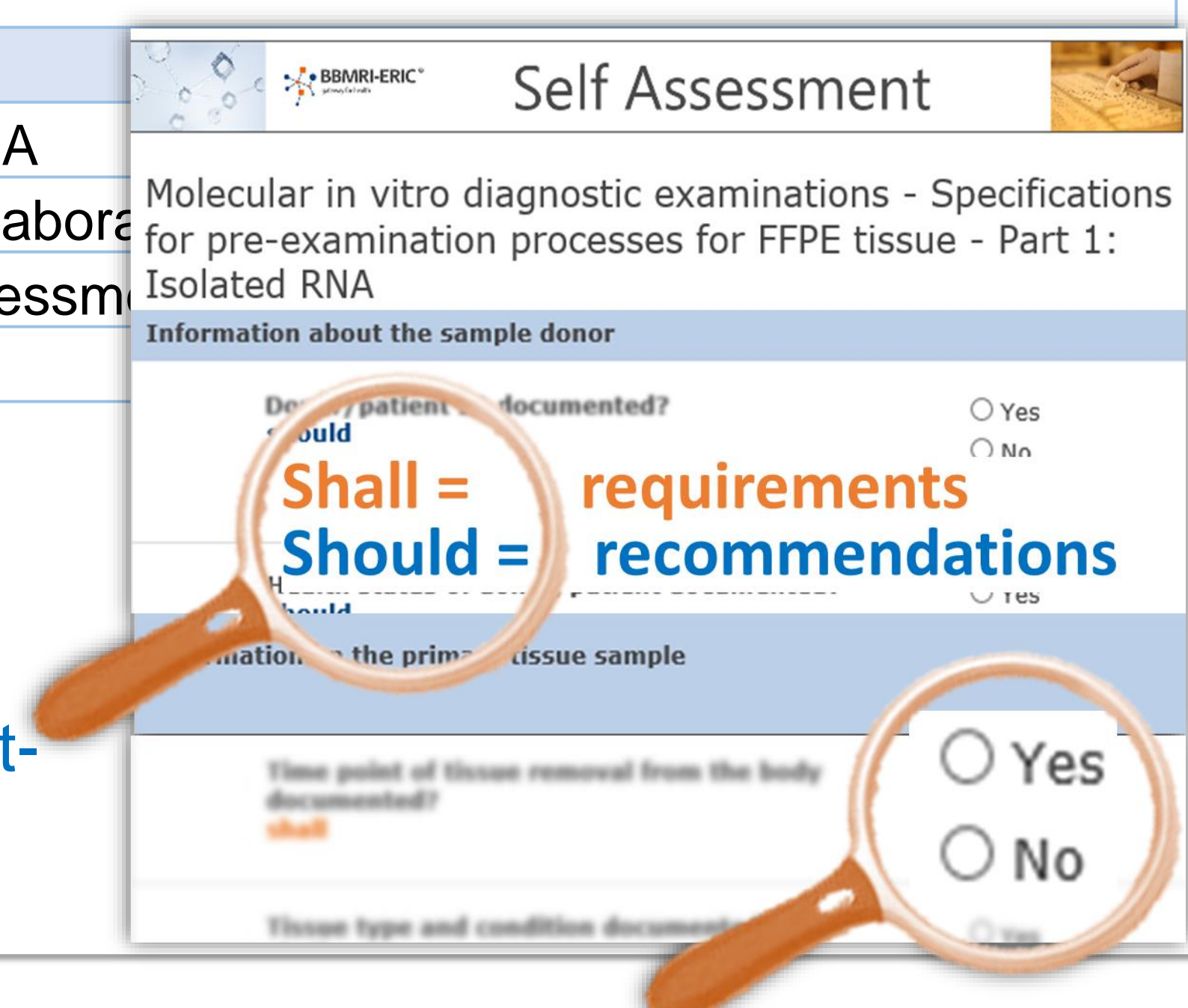
- Receive BBMRI-ERIC quality label for a sample collection
- Enhance visibility of your sample collection in the BBMRI-ERIC Directory

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Look inside the BBMRI SAS

<b>Inside the laboratory</b>
<ul style="list-style-type: none"> <li>• Primary tissue collection -</li> <li>• Transport conditions</li> </ul>
<b>Outside the laboratory</b>
<ul style="list-style-type: none"> <li>• Primary tissue sample receipt at laboratory</li> <li>• Evaluation of pathology of specimen and selection of sample</li> <li>• Post-fixation of frozen samples</li> <li>• Storage conditions</li> </ul>
<b>Isolation of total RNA</b>
<ul style="list-style-type: none"> <li>• General information for RNA</li> <li>• Using a commercial kit / a laboratory</li> <li>• RNA quantity &amp; quality assessment</li> <li>• Storage of isolated RNA</li> </ul>

For details go to [www.bbmri-eric.eu/services/self-assessment-survey/](http://www.bbmri-eric.eu/services/self-assessment-survey/)



## 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 where optimization measures are needed
- allows principal investigators to display their quality-labeled collections in the BBMRI-ERIC Biobank Directory