



### Modular biomarker validation services - IBBL

IBBL provides research support on modular biomarker validation services.

The LIH-IBBL Translational Biomarker Group will offer to participating SMEs the following BM validation services:

- **BM pre-analytical validation:** to assess the pre-analytical variables dealing with BM robustness (ex.: collection tube, sample processing delays, sample freeze/thaw cycles, ischemia and fixation time, etc.)
- **BM analytical validation:** to assess the characteristic of the method of choice (ex: mass-spec versus ELISA, qPCR vs ddPCR, etc.) and its performance (ex: LOD/LOQ, linearity, trueness, etc.)
- **BM clinical verification:** this step is meant as a small scale testing (max 50 samples per each clinical case and appropriate control/s, if needed) to offer an overview of a potential clinical validation outcome, thus decreasing the chances of future cross-validation failures

Each SME can choose to request a full-fledged (all bullet-points above) service, in the order they wish.

Each SME can also select one or more validation item, again in the order they wish.

#### What you get



Meet expert in the field



Modular biomarker validation services



Up to a max. of € 30.000 voucher

## How it works

---

*Mandatory requirement: The SME must provide the sample to work on (in house) or must have already made arrangements with CROs or sample providers for the LIH-IBBL Translational Biomarker Group to acquire biospecimens within a reasonable time.*

---

<b>Who should apply</b>	Small and medium sized enterprises (SME) and Start-ups from the in vitro diagnostics area
<b>Number of available services</b>	1
<b>How applicants are selected</b>	Evaluation by IBBL and confirmed by Codex4SMEs consortium as a whole, evaluation criteria
<b>Evaluation criteria</b>	<ol style="list-style-type: none"> <li>1) Scientific excellence and innovation potential <ol style="list-style-type: none"> <li>a. Soundness of preliminary results/statistical analysis</li> <li>b. Status of biomarker proof-of-concept – to what extent has the biomarker been verified so far</li> <li>c. Clinical need for biomarker</li> <li>d. Commercialisation potential</li> <li>e. Innovation potential</li> </ol> </li> <li>2) Technical feasibility <ol style="list-style-type: none"> <li>a. Assay feasibility</li> <li>b. Access to biospecimens</li> <li>c. Is optimisation required?</li> <li>d. Homebrew or commercial assay</li> <li>e. Complexity of the biomarker/assay</li> </ol> </li> </ol> <p>Similar weight will be given to scientific excellence and innovation potential, and to technical feasibility.</p>
<b>Application open</b>	The deadline for submitting the application is published on the project website: see <a href="#">Overview</a> This service is granted only to <b>one</b> SMEs
<b>Programme dates</b>	Dates will be arranged individually
<b>Programme location</b>	IBBL
<b>Programme cost</b>	Free of charge
<b>Partners</b>	IBBL
<b>Contact</b>	<a href="mailto:codex4smes@ibbl.lu">codex4smes@ibbl.lu</a>
<b>Find out more and apply</b>	Applicants apply for services by submitting the <a href="#">application form</a> and the <i>de-minimis</i> self-declaration to Codex4SMEs partner <a href="mailto:codex4smes@ibbl.lu">codex4smes@ibbl.lu</a> before the closing date (see above).
<b>Contractual obligation</b>	<p>The successful applicants agree to</p> <ul style="list-style-type: none"> <li>• Sign a Non-Disclosure Agreement (NDA) with IBBL</li> <li>• Provide all information and documentation required to implement the biomarker validation plan, in particular full details of the materials and methods to allow IBBL to establish the method in its own laboratory</li> <li>• Acknowledge IBBL, and the Codex4SMEs partners in scientific publications and commercial brochures</li> <li>• Allow Codex4SMEs consortium to use the name of the winners for communication purposes</li> </ul>