



# Synthetic Biomaterials

Technical Work Area 40

## Project 9 Validating biosensor binding kinetics for microorganism antigens

### Objectives

The aim of this work is to provide comparability datasets for the binding kinetics of antigens and antigen displaying virus-like particles (VLPs), e.g., affinity, kinetics and ranking of antigens, to bespoke antibodies.

### Background

The study will use *de novo* synthetic VLPs displaying antigens – synthetic peptides and native antigens to compare the binding response to antibodies. Antigens are derived from SARS-CoV-2 spike protein and *E. coli* endotoxin (LPS). The obtained datasets will support the validation of VLPs and biosensor platforms as candidate reference materials.

### Standardization needs

There is a pre-standardisation need for:

- protocols and standards for antigen detection and biosensors
- assigned values consistent between laboratories
- procedures for quantitative analysis of the values by reproducible measurements
- performance validation of reference materials in biologically native and near-native environments.

- ability to produce and characterise materials to a common biophysical specification

### Relevant guidelines & standards

ISO 10993-5:2009 (biocompatibility of medical devices)  
 ISO17034 (reference materials production)  
 CHMP/GTWP/671639/2008  
 ISO Guide 35 Reference materials  
 ISO 13022:2012  
 CCQM BIPM  
 ISO 13485:2016

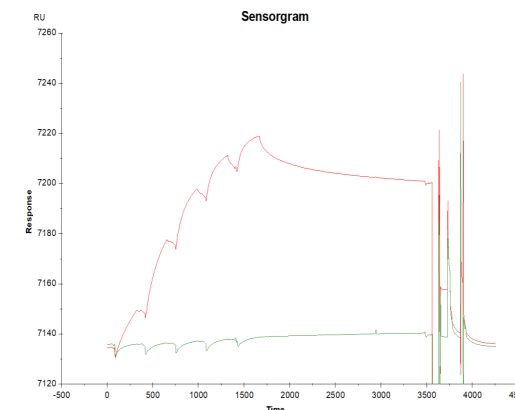
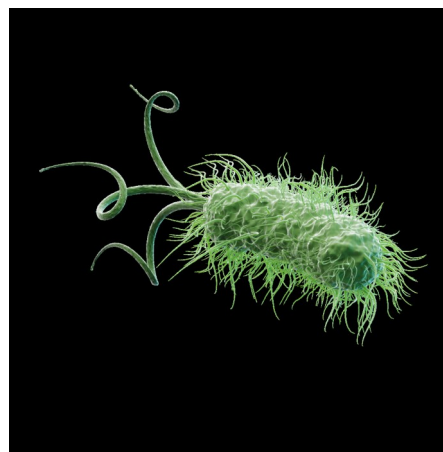
### Relevant Committees

ISO/TC 276 - Biotechnology  
 ISO/TC 229 - Nanotechnology  
 ISO 15194:2009 - VD  
 ISO/TC REMCO

### Work Programme

- Materials (antigens, antibodies, VLPs) are prepared and distributed
- Materials are characterised by participating laboratories
- Data is analysed with uncertainty evaluations

# CALL FOR PARTICIPATION



**Figure:** (left) A schematic of a bacterium and (right) an example of a binding sensograms for SARS-CoV-2 antigens binding to immobilised antibodies performed on a Biacore T200.

### Second stage analysis

- Procedures developed will be repeated by a smaller group of participants to assess the test parameters using self-assembled antigen-displaying virus-like particles.

### Knowledge Transfer

International round-robin tests, good practice guidelines, peer-review publications and presentations in conferences and standardisation venues.

### Status

Study in progress since May 2022

### Additional Volunteers Welcome

**Participants fund their involvement in the project.**

### For more information on participation, please contact:

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