INNO4COV-19
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INNO4COV-19

Deliverable D2.2

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1	30/09/2021	Draft structure of the deliverable	TCD
2	12/10/2021	First complete version	VITO
3		Revised and completed version for submission	VITO

Executive Summary

This document establishes the “Catalogue of the Service/Product portfolio sub-platform Innovative diagnostic and screening systems (SP1)" (D2.2) and it has been prepared by VITO in the framework of WP2 (SP1: Innovative diagnostic and screening systems). This deliverable gathers the services offered by the INNO4COV-19 members. The services were selected according to the needs requested by owners of technologies in the domain of Innovative diagnostic and screening systems, i.e. priority diagnostic assays and devices, as well as AI-based diagnostic tools to be applied on human derived samples or data.

Together with the deliverables D3.2, D4.2 and D5.2, this deliverable aims to present to the public a comprehensive list of the services offered by INNO4COV-19 platform, for technologies at the stage TRL6/7 or higher. It includes technical and consultancy services, the members that offer the service and the facilities certifications.

Catalogue of Services

SP1 – Innovative Diagnostic and Screening Systems

INNO4COV19 in the fight against COVID-19

INNO4COV19 Project creates a “lab-to-fab” platform & collaboration resource to enable companies & reference laboratories to develop and implement innovative technologies to fight COVID-19.

For further information please visit our website:
http://www.inno4cov19.eu/

SERVICES AVAILABLE IN SP1

Click on the service type for more details

Priority Diagnostic Assays and Devices
Product Verification
Analytical Validation
Clinical Validation
Precommercial (Scaling Up) and Manufacturing
Market Evaluation and Recommendation
Regulatory Assessment and recommendations

AI-based Diagnostics
AI development
AI deployment
AI Evaluation
AI Monitoring
Evaluation of cost-effectiveness
Certification as medical device

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PRODUCT VERIFICATION

In vitro preclinical research

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
LEITAT	ELISA	Screening of inhibitors of interaction ACE2/SPIKE and SARS-CoV-2 protease activity	(ISO 9001)
VITO	qPCR, digital PCR	Viral load analysis	Roche Lightcycler (384 well), Biorad QX200 ddPCR system. (ISO 9001, ISO 14001)
VITO	ELISA, multiplex protein assays	Analysis of cytokines, antibodies, or other proteins in liquid samples	MesoScale Discovery Quickplex SQ120 (multiplex, electrochemical), BMG Labtech ClarioStar absorbance plate reader (ELISA) (ISO 9001, ISO 14001)
VITO	LC-MS, MALDI imaging	Clinical sample fractionation and proteomics analysis	Thermo LTQ Velos Orbitrap, Thermo Exactive plus both online coupled to nanoLC; Bruker Rapiflex for MALDI imaging
iMM	ELISA, qPCR, flow cytometry	Analysis of viral load, immunological/biochemical biomarkers in clinical samples of patients with COVID-19 or other pulmonary infections	

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ANALYTICAL VALIDATION

Access clinical samples (matrices)

Partner offering the service	Services offered
iMM	Provision of plasma samples from healthy donors
VITO	Link to Belgian clinicians/biobanks to gain access to samples and ethics advise
UniBo	
BIOEUF	

Access (in)active SARS-CoV-2 and related viruses

Partner offering the service	Services offered
iMM	SARS-CoV-2 isolated from clinical samples

ANALYTICAL VALIDATION

Access to assay components

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
LEITAT	In house developed mouse mAbs, VHH and human scFv against several variants of SARS-CoV-2 Spike protein. Useful for diagnostic and for therapeutic purposes, since some of them are able to neutralize the interaction between Spike and ACE2. Mouse mAbs against human IgG, IgM, IgA	Mouse monoclonal antibodies were raised against SARS-Cov-2 Spike protein and some of them are able to recognize several Spike variants and neutralize the interaction with ACE2. Phage display libraries of VHH contains a wide range on single domain antibodies with recognition against all the variants described up to date. Phage display library of human scFv constructed from the immune repertoire of asymptomatic patients that tested positive in a PCR test and that showed a strong IgG response. This library contains a wide range of scFv that can be selected based on their recognition pattern and the neutralizing potential. The mouse monoclonal antibodies against human IgG, IgM and IgA are useful tools for the inclusion in serologic tests.	(ISO 9001)

ANALYTICAL VALIDATION

Reference methods & SOPs

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
VITO	qPCR, digital PCR	Viral load analysis	Roche Lightcycler (384 well), Biorad QX200 ddPCR system. (ISO 9001, ISO 14001)
VITO	ELISA, multiplex protein assays	Analysis of cytokines, antibodies, or other proteins in liquid samples	MesoScale Discovery Quickplex SQ120 (multiplex, electrochemical), BMG Labtech ClarioStar absorbance plate reader (ELISA) (ISO 9001, ISO 14001)
iMM	ELISA, qPCR, flow cytometry	Analysis of viral load, immunological/biochemical biomarkers in clinical samples of patients with COVID-19 or other pulmonary infections	

Quality control

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
VITO	Test validation	Depending on platform	Depending on platform (ISO 9001, ISO 14001)

Analytical performance testing

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
VITO	Intra/interlaboratory testing and validation	SOP writing, test material selection, logistics, training, data analysis	Depending on platform (ISO 9001, ISO 14001)

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ANALYTICAL VALIDATION

Data analysis/interpretation

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
VITO	Data science	Machine learning, biostatistics, etc	(ISO 9001, ISO 14001)

CLINICAL VALIDATION

Access clinical samples

Partner offering the service	Services offered
iMM	Provision of plasma samples from healthy donors (76 samples available) and Covid-19 patients (294 samples available)
VITO	Link to Belgian clinicians/biobanks to gain access to samples and ethics advise
UniBo	
BIOEUF	

Regulatory and ethical advise

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
Obelis	Regulatory and ethical advise	Advise on compliance with applicable regulations, guidance and Standards	MDR/IVDR Experts (ISO 13485:2016, ISO 9001)

Reference methods & SOPs

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
iMM	RT-PCR tests	Custom	
INL	RT-PCR tests	Custom	(ISO 9001:2015)

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PRECOMMERCIAL (SCALING UP) AND MANUFACTURING

Additional equipment, compatible readers

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
JOR	Absorbance, fluorescence, luminescence readers	Antibody, antigen, DNA, chemoluminescence-based, fluorescence-based or colorimetric	GENSPEED reader R2, Tecan plate reader (ISO 9001:2015)

Prototyping

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
JOR	R2R UV-nanoimprinting fabrication of foil based microfluidic chips (including biomolecule spotting/immobilization)	Antibody, antigen, DNA, chemoluminescence-based, fluorescence-based or colorimetric	(ISO 9001:2015)
LEITAT	Advisor on implementation of enzymatic signal enhancement on lateral flow assay	Custom	(ISO 9001)

PRECOMMERCIAL (SCALING UP) AND MANUFACTURING

Engineering support

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
JOR	Design, simulation and mastering of microfluidic chip	Custom	(ISO 9001:2015)
INL	Design, simulation and mastering of microfluidic chip	Custom	(ISO 9001:2015, ISO 13485:2016)

Manufacturing

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
JOR	Small series (for microfluidic chip)	Custom	(ISO 9001:2015)
INL	Manufacturing of small quantities of microfluidics devices	Custom	(ISO 9001:2015, ISO 13485:2016)

Access to complementary services

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
JOR	Nanoimprint tool manufacturing, assay development	Custom	(ISO 9001:2015)
INL	Nanofluidics devices design and prototyping	Custom	(ISO 9001:2015, ISO 13485:2016)

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MARKET EVALUATION AND RECOMMENDATION

Market analysis

Partner offering the service	Services offered	Description of the assay	Facility type
iMM	Market analysis and exploitation plan	Custom	

Partnering opportunities

Partner offering the service	Services offered	Description of the assay	Facility type
Biokeralty	Stakeholders database	Custom	
INL	Collaboration abroad Europe	Custom	(ISO 9001:2015)

Access to complementary services

Partner offering the service	Services offered	Description of the assay	Facility type
Biokeralty	Stakeholders database		

REGULATORY ASSESSMENT AND RECOMMENDATIONS

Regulatory roadmap

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
Obelis	Regulatory strategy	Consultancy on CE marking/MDR requirements	MDR/IVDR Experts (ISO 13485:2016, ISO 9001)

Adaptation to ISO 13485:2016

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
Obelis	Gap analysis report	Consultancy on ISO 13485 compliance	(ISO 13485:2016, ISO 9001)

Conformity assessment

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
Obelis	Regulatory strategy	Consultancy on CE marking/MDR requirements	MDR/IVDR Experts (ISO 13485:2016, ISO 9001)

Risk management

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
Obelis	Regulatory strategy throughout project stages and post-marketing	Consultancy on MDR & IVDR regulatory compliance for risk management	MDR/IVDR Experts (ISO 13485:2016, ISO 9001)

Data management

Partner offering the service	Services offered	Description of the assay	Facility type (Certification)
Obelis	Gap analysis report	Consultancy on GDPR compliance	GDPR Experts (ISO 13485:2016, ISO 9001)
Obelis	Gap analysis report	Consultancy on ISO 27001 compliance	Certified ISO 27001 expert

AI DEVELOPMENT

Development of new AI product

Partner offering the service	Services offered	Service type	Certification
LEITAT	Development of new AI models	Consultancy	ISO 9001

Enhancement of existing AI product

Partner offering the service	Services offered	Service type	Certification
LEITAT	Enhancement of AI models	Consultancy	ISO 9001

Data labeling

Partner offering the service	Services offered	Service type	Certification
LEITAT	Let medical experts label your data	Consultancy	ISO 9001

Reduction of data need

Partner offering the service	Services offered	Service type	Certification
LEITAT	Apply active learning techniques to identify the most valuable data to label	Consultancy	ISO 9001

Gathering of medical data

Partner offering the service	Services offered	Service type	Certification
LEITAT	Assist with the collecting of medical (hospital) data	Consultancy	ISO 9001

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AI DEPLOYMENT

Deployment of AI models on the cloud

Partner offering the service	Services offered	Service type	Certification
LEITAT	Deployment of AI in the cloud	Consultancy	ISO 9001

Performance optimization of AI deployed in the cloud

Partner offering the service	Services offered	Service type	Certification
LEITAT	Make AI models in the cloud more responsive	Consultancy	ISO 9001

Cost optimization of AI models deployed in the cloud

Partner offering the service	Services offered	Service type	Certification
LEITAT	Make AI models cheaper to run	Consultancy	ISO 9001

Data security enhancement to meet GDPR compliance

Partner offering the service	Services offered	Service type	Certification
LEITAT	GDPR and the MDR require that patient data is handled with great care. It has to be pseudonimized, encrypted, etc. Also the patient has the right to revoke his/her data at any moment in time.	Consultancy	ISO 9001

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AI EVALUATION

Evaluation of model performance

Partner offering the service	Services offered	Service type	Certification
VITO (with external parties)	Evaluation of model accuracy, AUC, F1 score	Service offered as cloud service through web application	(expected)

Evaluation of model robustness against data drift

Partner offering the service	Services offered	Service type	Certification
VITO	Evaluation of model robustness against data drift	Service offered as cloud service through web application	(expected)

AI MONITORING

Automated AI monitoring

Partner offering the service	Services offered	Service type	Certification
VITO	Both the FDA and MDR require the monitoring of medical AI. We offer an automated service to mitigate this task.	Service offered as cloud service through webapplication.	(expected)

Manual AI monitoring

Partner offering the service	Services offered	Service type	Certification
VITO (with external parties)	Both the FDA and MDR require the monitoring of medical AI. We employ medical experts and a telemedicine platform to meet this requirement.	Consultancy	(expected)

EVALUATION OF COST-EFFECTIVENESS

Determine most cost-effective workflows in clinical practice

Partner offering the service	Services offered	Service type	Certification
VITO (with external parties)	Compare cost-effectiveness of multiple workflows in clinical setting	Consultancy	(expected)

Quantify cost effectiveness in clinical practice

Partner offering the service	Services offered	Service type	Certification
VITO (with external parties)	Quantify the cost-effectiveness of AI in the clinical setting	Consultancy	(expected)

CERTIFICATION AS MEDICAL DEVICE

CE certification of AI as medical device

Partner offering the service	Services offered	Service type	Certification
OBELIS	Assist with all needed steps (e.g. design and development of quality management system) to obtain CE certification as a medical device or IVD	Consultancy	EN ISO 13485:2016