

Catalogue of Services



INNO4
COV-19



TECHNICAL
PRODUCT



TECHNICAL
AI



BUSINESS
SUPPORT



REGULATORY
SUPPORT



INNO4
COV-19

[Product Verification](#)

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TECHNICAL – PRODUCT

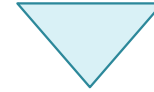
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
In-vitro preclinical research	Elisa assays	LEITAT	Screening of inhibitors of interaction ACE2/SPIKE and SARS-Cov-2 protease activity	ISO 9001
	qPCR, digital PCR	VITO	Viral load analysis	Roche Lightcycler (384 well), Biorad QX200 ddPCR system. ISO9001, ISO 14001, OHSAS 18001
	ELISA, multiplex protein assays	VITO	Analysis of cytokines, antibodies, or other proteins in liquid samples	MesoScale Discovery Quickplex SQ120 (multiplex, electrochemical), absorbance plate reader BMG Labtech ClarioStar (ELISA) ISO9001, ISO 14001, OHSAS 18001
	LC-MS, MALDI imaging	VITO	Clinical sample fractionation and proteomics analysis	Thermo LTQ Velos Orbitrap, Thermo Exactive plus both online coupled to nanoLC; Bruker Rapiflex for MALDI imaging
	Elisa assays, qPCR, flow cytometry	iMM	Analysis of viral load, immunological/biochemical biomarkers in clinical samples of patients with COVID-19 or other pulmonary infections	
	in vitro preclinical research	iMM	Antiviral Activity; Determination of plaque forming units (PFU) by plaque assay; BSL3 facility	
	In vitro preclinical screening	TCD	Biomarker detection, safety profiling, drug efficacy, High content screening	LBCAM Infrastructure equipped with Flow cytometry, High throughput, High content infrastructure

Product Verification



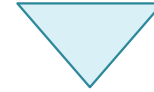
Service Required	Service Offered	Partner Providing Service	Assay Description
PPE verification	Filtering Half Mask testing	VITO	Filtering half mask EN149 accreditation
	Efficiency of air purifiers/air disinfection systems	VITO	Air purifier
	Filtering Flat material testing	VITO	Flat Filter material
	Effect of cleaning/sterilisation of filtering half mask on filtration efficiency, leakage and breathing resistance	VITO	Filtering half mask
	Release of additives from filtering half masks in inhaled air		Filtering half mask

Product Verification



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Access clinical samples (matrices)	Provision of plasma samples from healthy donors	iMM		
	Link to Belgian clinicians/biobanks to gain access to samples and ethics advise	VITO		
Access (in)active SARS-CoV-2 and related viruses	Sars-CoV-2 isolated from clinical samples	iMM		

Product Validation



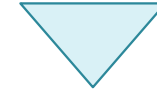
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Access to reference materials	In house developed mouse mAbs, VHH and human scFv against several variants of Sars-cov-2 Spike protein. Useful for diagnostic and for therapeutic purposes, since some of them are able to neutralize the interaction between Spike and ACE2. Mouse mAbs against human IgG, IgM, IgA	LEITAT	<p>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.</p> <p>Phage display libraries of VHH contains a wide range on single domain antibodies with recognition against all the variants described up to date.</p> <p>Phage display library of human scFv contracted 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.</p> <p>The mouse monoclonal antibodies against human IgG, IgM and IgA are useful tools for the inclusion in serologic tests.</p>	ISO 9001

Product Validation



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Reference methods & SOPs	qPCR, digital PCR	VITO	Viral load analysis	Roche Lightcycler (384 well), Biorad QX200 ddPCR system. ISO9001, ISO 14001, OHSAS 18001
	ELISA, multiplex protein assays	VITO	Analysis of cytokines, antibodies, or other proteins in liquid samples	MesoScale Discovery Quickplex SQ120 (multiplex, electrochemical), absorbance plate reader BMG Labtech ClarioStar (ELISA) ISO9001, ISO 14001, OHSAS 18001
	qPCR, digital PCR	INL	RT-qPCR	ISO9001, NP4457
	Elisa assays, qPCR, flow cytometry	iMM	Analysis of viral load, immunological/biochemical biomarkers in clinical samples of patients with COVID-19 or other pulmonary infections	
Quality control	Test validation	VITO	Depending on platform	Depending on platform

Product Validation



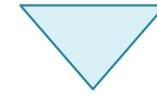
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Analytical performance testing	Intra/interlaboratory testing and validation	VITO	SOP writing, test material selection, logistics, training, data analysis ; RNA extraction, cDNA synthesis, spike-in control preparation	BLS2 Labs, RNALab, ISO9001, ISO 14001, OHSAS 18001 Depending on platform
	Intra / interlaboratory testing and validation	INL	RNA extraction, cDNA synthesis, spike-in control preparation	ISO9001, NP4457
Data analysis / interpretation	Data science	VITO	Machine learning, biostatistics, etc	
	Data science	INL	Machine learning, biostatistics, etc	ISO9001, NP4457
Study Design	Design of the tests roadmap to achieve study aim.	INL	Design of the tests roadmap to achieve study aim.	ISO9001, NP4457

Product Validation



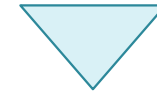
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Analytical validation	Access (in)active SARS CoV 2 and related viruses	iMM	Sars CoV 2 isolated from clinical samples	
	Microbiological tests	FEP	S1 safety conditions; germ load/bacterial exposure investigation	
	Microbiological tests	LEITAT	Bacterial exposure investigation (S2 safety conditions); bacterial filtration efficiency determination	
	Mechanical testing	INL	Young's modulus etc; temperature dependent; nano indentation	
	Mechanical testing	FEP	Young's modulus etc; temperature dependent; nano indentation	
	Adhesion testing	FEP	Peel and pull tests; cross hatch test; scratch adhesion test	
	Quality control	FEP	Optical spectrometry; topography (AFM, WLI, SEM); sheet resistance / surface resistivity; surface defect mapping	
	Quality control	LEITAT	Microscopy (optical & SEM); Dimensional analysis	

Product Validation



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Clinical Validation: Access clinical samples	Provision of plasma samples from healthy donors (76 samples available) and Covid-19 patients (294 samples available)	iMM		
	link to Belgian clinicians/biobanks to gain access to samples and ethics advise	VITO		
Clinical Validation: Regulatory and Ethical advice	Regulatory and ethical advise	Obelis	Advise on compliance with applicable regulations, guidance and Standards	MDR/IVDR Experts (ISO 13485:2016, ISO 9001)
Clinical Validation: Reference methods & SOPs	RT-PCR tests	iMM	Customised	
	RT-PCR tests	INL	Customised	ISO9001:2015
Electronic functional test	Electronic functional test	LEITAT		
	Electrical/electronic and mechanical characterization and functional testing	INL		ISO9001:2015

Product Validation



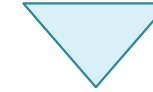
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Prototyping	Prototyping via 3D printing	FEP	Polymeric materials, rigid and flexible in combination dimension 30 x 30 x 30 mm ³	
	Prototyping via 3D printing and other small-scale prototyping (clean room facilities)	INL	SLM and FDM capabilities; clean room processes (wafer zoomn); Simulation, Design, fabrication, testing, characterization.	ISO9001, ISO13485
	Prototyping via 3D printing	LEITAT	Polymeric materials; metallic materials	
	Electronics development	LEITAT	Schematics and Layout designs. Sensors screening and front-end design. Interoperability electronics systems. IoT Devices.	
	Sensors	FEP	Vision Sensors	
	Wearables	FEP	Electronics and sensor integration	
	Data analysis	LEITAT	Data management, storage and analysis. Edge computing solutions	
	Data analysis	INL	AI, Data analytics	
	Product design and design engineering	LEITAT	Design product and apply product engineering.	
Additive manufacturing prototyping	LEITAT	Additive manufacturing as a fast manufacturing for pre-series using several materials: metal, resin, ABS, polyamide		

Precommercial (Scaling Up) and Manufacturing



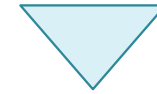
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Prototyping	Additive manufacturing prototyping	LEITAT	Additive manufacturing as a fast manufacturing for pre-series using several materials: metal, resin, ABS, polyamide	
	Antibodies - In house developed mouse mAbs, VHH and human scFv against several variants of Sars-cov-2 Spike protein. Mouse mAbs against human IgG, IgM, IgA	LEITAT	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 contracted 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	
	R2R UV-nanoimprinting fabrication of foil based microfluidic chips (including biomolecule spotting/immobilization)	JOR	e.g. antibody, antigen, DNA, chemiluminescence-based (GENSPEED reader R2), fluorescence-based or colorimetric	ISO 9001:2015

Precommercial (Scaling Up) and Manufacturing



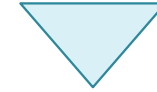
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Engineering support	Design, simulation and mastering of microfluidic chip	JOR		ISO 9001:2015
	Design, simulation and mastering of microfluidic chip	INL		ISO 9001:2015, ISO 13485:2016
	Consultancy and execution of engineering tasks, such as product design, connection between modules, etc.	INL		
	Product design and product engineering	LEITAT	Design and engineering of final product considering also the manufacturing process and certification requirements	
	Product design and product engineering	INL	Design and engineering of final product considering also the manufacturing process and certification requirements	ISO9001:2015, ISO13485:2016

Precommercial (Scaling Up) and Manufacturing



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Manufacturing and/or Fast prototyping short product series	Small series (for microfluidic chip)	JOR		ISO 9001:2015
	Manufacturing of small quantities of devices (e.g. microfluidics, sensors, others,...)	INL		ISO 9001, ISO13485,NP4457
	R2R UV-nanoimprinting fabrication of foil based microfluidic chips (including biomolecule spotting/immobilization)	JOR	e.g. antibody, antigen, DNA, chemiluminescence-based (GENSPEED reader R2), fluorescence-based or colorimetric	ISO 9001:2015
	Advisor on implementation of enzymatic signal enhancement on lateral flow assay	LEITAT		
	Electron beam sterilization	FEP	Flexible materials width < 1300 mm) like polymeric; films , textiles & fabrics , paper , metal foils liquids; bulk goods approx. . diameter < 10	
	Antibacterial / antiviral coating	FEP	Flexible materials width < 1300 mm) like polymeric; films , textiles & fabrics , paper , metal foils liquids; bulk goods approx. . diameter < 10	

Precommercial (Scaling Up) and Manufacturing



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Manufacturing and/or Fast prototyping short product series	Pre series Manufacturing	LEITAT	Additive manufacturing as a fast manufacturing for pre-series using several materials: metal, resin, ABS, polyamide	
	Mechanical manufacturing	FEP	CNC turning and milling; grinding	
	Mechanical manufacturing	INL	CNC turning and milling; grinding	
	Electric and electronic manufacturing	FEP	Circuit diagram design, wiring; IC design, CMOS manufacturing; CMOS adaptation and add-on processing; OLED manufacturing	
	Electronic manufacturing	INL	Simulation, Design, fabrication, testing and characterization (IC, CMOS)	Clean Room Facilities
	Electrospinning	LEITAT	Nanofiber fabrication equipment; Incorporation of anti bacterial nanomaterial; Adaptable process and Nanofiber design	
	Nanoimprint tool manufacturing, assay development	JOR		ISO 9001:2015
	Nano-fluidics devices design and prototyping	INL		

Precommercial (Scaling Up) and Manufacturing



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Product lifetime	Consultancy and Lifetime test for devices	LEITAT	Lifetime accelerated test with temperature, humidity and solar irradiance	ISO 105-B06, ISO 4892-2-2006, ISO 11341:2004, ISO 4892-2:2006
	Consultancy and Lifetime test for devices	INL	Lifetime accelerated test with temperature, humidity	ISO9011:2015

Precommercial (Scaling Up) and Manufacturing





TECHNICAL – AI

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[AI Deployment](#)

[AI Evaluation](#)

[AI Monitoring](#)

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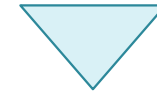
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Development of new AI product	Development of new AI models	LEITAT	Consultancy	ISO 9001
Enhancement of AI models	Enhancement of AI models	LEITAT	Consultancy	ISO 9001
Data labeling	Let medical experts label your data	LEITAT	Consultancy	ISO 9001
Reduction of data need	Apply active learning techniques to identify the most valuable data to label	LEITAT	Consultancy	ISO 9001
Gathering of medical data	Assist with the collecting of medical (hospital) data	LEITAT	Consultancy	ISO 9001

AI Development



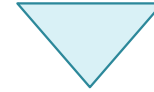
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Deployment of AI models on the cloud	Deployment of AI in the cloud	LEITAT	Consultancy	ISO 9001
Performance optimization of AI deployed in the cloud	Make AI models in the cloud more responsive	LEITAT	Consultancy	ISO 9001
Cost optimization of AI models deployed in the cloud	Make AI models cheaper to run	LEITAT	Consultancy	ISO 9001
Data security enhancement to meet GDPR compliance	GDPR and the MDR require that patient data is handled with great care. It has to be pseudonymized, encrypted, etc. Also the patient has the right to revoke his/her data at any moment in time.	LEITAT	Consultancy	ISO 9001

AI Deployment



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Evaluation of model performance	Evaluation of model accuracy, AUC, F1 score	VITO (with external parties)	Service offered as cloud service through web application	
Evaluation of model robustness against data drift	Evaluation of model robustness against data drift	VITO	Service offered as cloud service through web application	

AI Evaluation



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Automated AI monitoring	Both the FDA and MDR require the monitoring of medical AI. We offer an automated service to mitigate this task.	VITO	Service offered as cloud service through web application	
Manual AI monitoring	Both the FDA and MDR require the monitoring of medical AI. We employ medical experts and a telemedicine platform to meet this requirement.	VITO (with external parties)	Consultancy	

AI Monitoring





BUSINESS SUPPORT

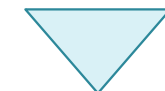
[Market & Business Recommendation](#)

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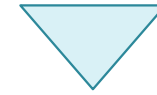
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Market analysis	Market analysis and exploitation plan	iMM		
Customer identification	Customer identification	iMM		
Benchmarking analysis	Identification of the main competitors	iMM		
Value proposition	Definition and validation of value propositions	iMM		
Business model	Definition and validation of business models	iMM		
Access to venture capital and other funding	Advice and support in fundraising efforts	iMM		

Market & Business Recommendation



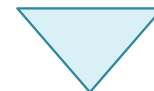
Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Partnering opportunities	Stakeholders database	Biokeralty	Consultancy	
Partnering opportunities	Collaboration abroad Europe	INL	Consultancy	
Access to complementary services	Stakeholders database	Biokeralty	Consultancy	
Access to Governmental institutions as clients (municipalities, regional government...)	Access to Portuguese networking	INL (Portugal)	Consultancy	

Market & Business Recommendation



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
IPR support	Consultancy in IPR issues	iMM	Consultancy	
Patent landscape analysis	Consultancy in IPR issues	INL	Consultancy	

IP Support



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Determine most cost effective workflows in clinical practice	Compare cost effectiveness of multiple workflows in clinical setting	VITO (with external parties)	Consultancy	
Quantify cost effectiveness in clinical practice	Quantify the cost effectiveness of AI in the clinical setting	VITO (with external parties)	Consultancy	

Evaluation of cost-effectiveness





REGULATORY SUPPORT

Regulatory Assessment and Recommendations

MENU

Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Regulatory roadmap	Regulatory strategy	Obelis	Consultancy on CE marking/MDR requirements	General regulatory, including GDPR, software, MDR/IVDR/ Cosmetics and PPE Experts
Adaptation to ISO 13485:2016	Gap analysis report	Obelis	Consultancy on ISO 13485 compliance	Obelis services are ISO 13485 and 9001 certified
Conformity assessment	Regulatory strategy	Obelis	Consultancy on CE marking/MDR requirements	MDR/IVDR Experts
Data management	Gap analysis report	Obelis	Consultancy on GDPR compliance	GDPR Experts
Data management	Gap analysis report	Obelis	Consultancy on ISO 27001 compliance	Certified ISO 27001 expert

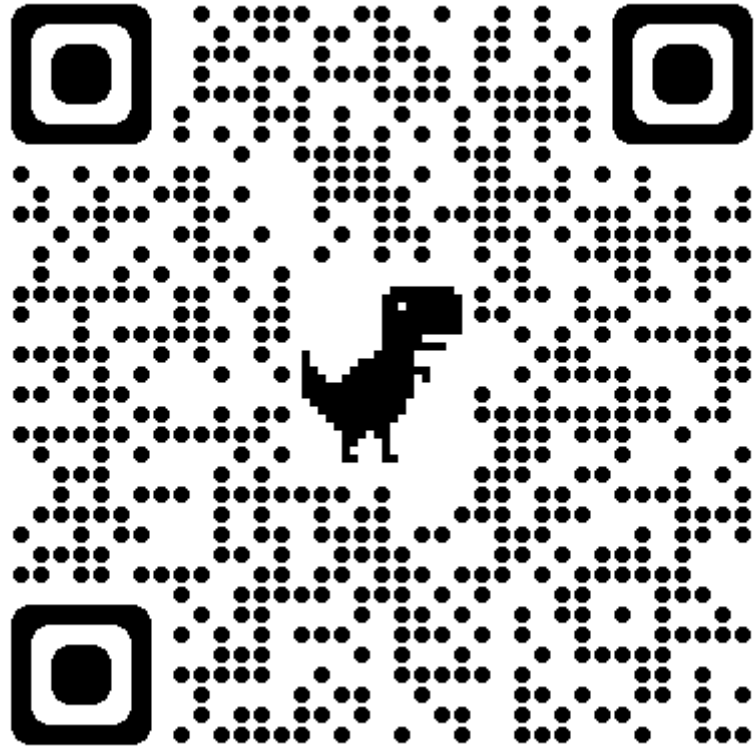
Regulatory Assessment and recommendations



Service Required	Service Offered	Partner Providing Service	Assay Description	Facilities / Certification
Textile Certification	Textile Certification	LEITAT		
Adaptation to ISO 13485:2016	Implementation of quality management system compliant with ISO 13485	INL		
Textile Certification test EPIS	Consultancy and Certification Textile for PPI and other purposes	LEITAT	Certification PPI	EN 1486:2008,
Textile Certification wearables	Consultancy and Certification Textile for wearable	LEITAT	No specific Certification for wearable but it can be selected depending of utility	
CE certification of AI as medical device	Assist with all needed steps (e.g. design and development of quality management system) to obtain CE certification as a medical device or IVD	Obelis		EN ISO 13485:2016

Regulatory Assessment and recommendations





INNO₄COV-19 Project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101016203