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EUROPEAN OMCL NETWORK

OCABR: COVID-19 Vaccines – OMCL Testing Capability List

Overview of OMCL testing capabilities with reference to potential COVID-19 vaccines to aid manufacturers to identify OMCLs for OCABR
Available upon request to involved manufacturers from EDQM

The R2 version replaces the previous version adopted 15/09/2020 and includes updates regarding to the technique of affinity characterisation by Fortebio and the e-mail address of the ANSM contact.

Date of Entry into Force: 15/10/20

EDQM Administrator Responsible: C. Milne

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OVERVIEW OF OMCL TESTING CAPABILITIES WITH REFERENCE TO POTENTIAL COVID-19 VACCINES

In the context of preparation for the OCABR of COVID-19 vaccines OMCLs have been surveyed based on current knowledge of potential control strategies for different vaccine platforms as communicated from manufacturers or authorities. The results provide a snapshot and are meant to help manufacturers to identify OMCLs that they can contact to arrange for OCABR. The list of tests is not exhaustive so it is important that contact be made directly with the involved OMCLs to clarify questions and explore possibilities.

NOTE: NIBSC UK is presently part of the EU OCABR network and thus included in the list. **Companies are strongly advised to always include (an) OMCL(s) from a remaining EU member state in their OCABR plans** to address the possibility that the UK is no longer included in mutual recognition of OCABR after the Brexit transition period.

This document is in 3 parts.

Part 1; A general overview of OMCLs potentially able to carry out OCABR of vaccines in different categories and an indication of possibilities to work with GMO material.

Part 2: A list of test methods with an indication of OMCLs that have, or are willing to acquire, the competence for OCABR testing

Part 3: The contact information for the different OMCLs listed

The list should be taken together with the recommendation document on method transfer for OCABR of potential COVID-19 vaccines PA/PH/OMCL (20) 88 available to involved manufacturers from EDQM on request at batchrelease@edqm.eu

Part 1: General Overview of OMCLs potentially able to carry out OCABR

Vaccine categories	OMCLs with the potential to test vaccines in the category depending on methods (see part 2)
Non-replicating viral vector	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NIBSC
Recombinant Protein subunit	ANSM, PEI, RIVM, Sciensano, Swissmedic, PZH, SUKL, BASG, ISS, NoMA, NIBSC, BDA
mRNA	ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, NIBSC, BDA
DNA	PEI, RIVM, BASG, NIBSC, ANSM
Live Attenuated	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NIBSC
Replicating viral vector	ANSM, PEI, RIVM, Sciensano, BASG, NIBSC

Able to handle GMOs	Normal timelines for authorisation
PEI (S1 + S2)	At least 6 weeks after application
ANSM (S1 + S2)	Less than 2 weeks
RIVM (S1 + S2)	Usually without delay after notification of authority
Swissmedic (S1 +S2)	Without delay after application
PZH (S1 +S2)	Immediate
SUKL (S1 +S2)	45 days or less from application, 1 week for COVID-19 vaccines
BASG (S1 +S2)	S1 in place, within 2 weeks for S2
ISS (S1 +S2)	2 months
NIBSC (S1 + S2)	1-4 weeks
Sciensano (S1 + S2)	48 hours to maximum 1 week if for COVID-19 vaccines
NoMA	Under discussion – please contact the OMCL

Part 2: OMCLs with competency or prepared to acquire competency in different test methods

OMCLs were surveyed based on the following techniques which may be potentially used as part of QC strategies for different products

All OMCLs surveyed are able to carry out Bacterial Endotoxin Test (Ph. Eur 2.6.14) in case of need.

Only very general descriptions of the tests were listed and OMCLs have given indications of their possibilities based on this. OMCLs will need full information on the specific test methods for any given vaccine to be able to determine if they will be able to take on the role as OCABR releaser. Please contact them directly for further information.

2.A – Identity testing

Assays surveyed as potentially used for identity testing	OMCLs with competence or willing to acquire competence
PCR	ANSM, PEI, RIVM, Sciensano, PZH, BASG, ISS, NoMA, NIBSC
Virus Particle-qPCR	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NoMA, NIBSC
Reverse transcriptase-PCR+ agarose gel	ANSM, PEI, RIVM, Sciensano, PZH, BASG, ISS, NoMA, NIBSC
Reverse Transcription/Sanger Sequencing	ANSM, PEI, Sciensano, PZH, BASG, ISS, NIBSC
Enzyme restriction analysis	ANSM, PEI, RIVM, Sciensano, PZH, BASG, ISS, NoMA, NIBSC
Viral protein fingerprinting by RP-HPLC	ANSM, PEI, RIVM, Sciensano, Swissmedic, BASG, ISS, NoMA, NIBSC
Capillary electrophoresis	ANSM, PEI, Swissmedic, BASG, ISS, NoMA, NIBSC
HPLC/UPLC	ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA NIBSC, BDA
Western-Blot	ANSM, PEI, RIVM, Sciensano, Swissmedic, PZH, BASG, ISS, NoMA NIBSC
Affinity by Fortebio (Biosensor Platform)	BASG, ISS
Binding ELISA	ANSM, PEI, RIVM, Sciensano, Swissmedic, PZH, SUKL, BASG, ISS, NoMA NIBSC, BDA
Plaque immunostaining method	ANSM, PEI, RIVM, Sciensano, SUKL, BASG, ISS, NoMA, NIBSC

2.B – Potency/Content testing

Assays surveyed as potentially used for potency/content testing	OMCLs with competence of willing to acquire competence
Transgene expression by ELISA (qualitative)	ANSM, PEI, RIVM, Sciensano, PZH, BASG, ISS, NoMA, NIBSC
Transgene expression by qPCR/spectroscopy	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NoMA, NIBSC
Infectious units by quantitative (qPCR, potency assay)	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NoMA, NIBSC
Infectivity assay by immunofluorescence unit (IFU)	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NIBSC
Infectivity assay by TCID50 (for measles virus)	ANSM, PEI, RIVM, Sciensano, SUKL, BASG, ISS, NoMA, NIBSC
High throughput cell-based infectivity method*	PEI, RIVM, Sciensano, NIBSC
Cell-based FACS assay	ANSM, BASG, ISS, NIBSC, PEI , Sciensano, Swissmedic
ELISA, capture detection ELISA	ANSM, PEI, RIVM, Sciensano, Swissmedic, PZH, SUKL, BASG, ISS, NoMA, NIBSC
Affinity characterisation by fortebio (Biosensor Platform: relative potency)	BASG, ISS
Reduced SDS-PAGE with densitometry	PEI, RIVM, Sciensano, Swissmedic, BASG, ISS, NoMA, NIBSC
Capillary Electrophoresis-SDS (reducing)	ANSM, PEI, Swissmedic, BASG, ISS, NIBSC
Size exclusion-HPLC	ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, NIBSC, BDA
Anion exchange HPLC	ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, NIBSC
RP-HPLC (integrity, excipient)	ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, NIBSC, BDA
BCA protein assay	ANSM, PEI, RIVM, Sciensano, Swissmedic, SUKL, BASG, ISS, NoMA, NIBSC
Virus particle-qPCR	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NoMA, NIBSC
Transcription assay	ANSM, PEI, RIVM, Sciensano, BASG, ISS, NIBSC
UV measurement: A260nm, A280nm, A260nm/A280nm	ANSM, PEI, RIVM, Sciensano, Swissmedic, PZH, SUKL, BASG, ISS, NoMA, NIBSC, BDA
Hydrophobic interaction chromatography (Plasmid forms: supercoiled, circular)	PEI, RIVM, BASG, ISS, NoMA, NIBSC
Fluorescence assay (RiboGreen assay)	ANSM, PEI, RIVM, Sciensano, Swissmedic, BASG, NoMA, NIBSC
* insufficient information available on technique - additional OMCLs may be included if more information available	

Part 3: List of OMCLs and Contact Information (alphabetical by country)

A full list of contact details for the Member states with supplementary information is available at https://www.edqm.eu/en/batch-release-human-biologicals-vaccines-blood-and-plasma-derivatives

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