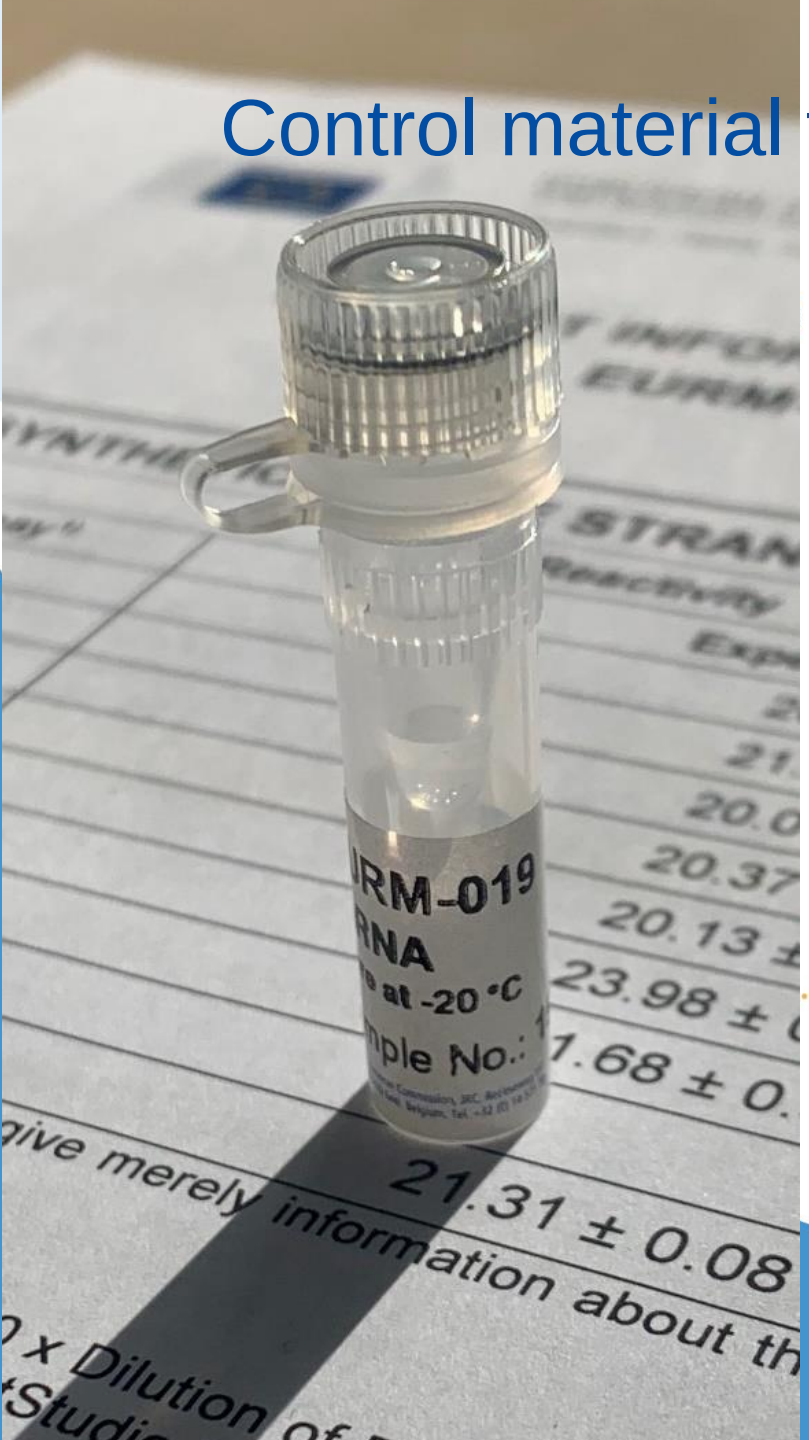
COVID-19 In Vitro Diagnostic Devices and Test Methods Database

https://covid-19-diagnostics.jrc.ec.europa.eu

JRC, Dir F – Health Consumers and Reference Materials

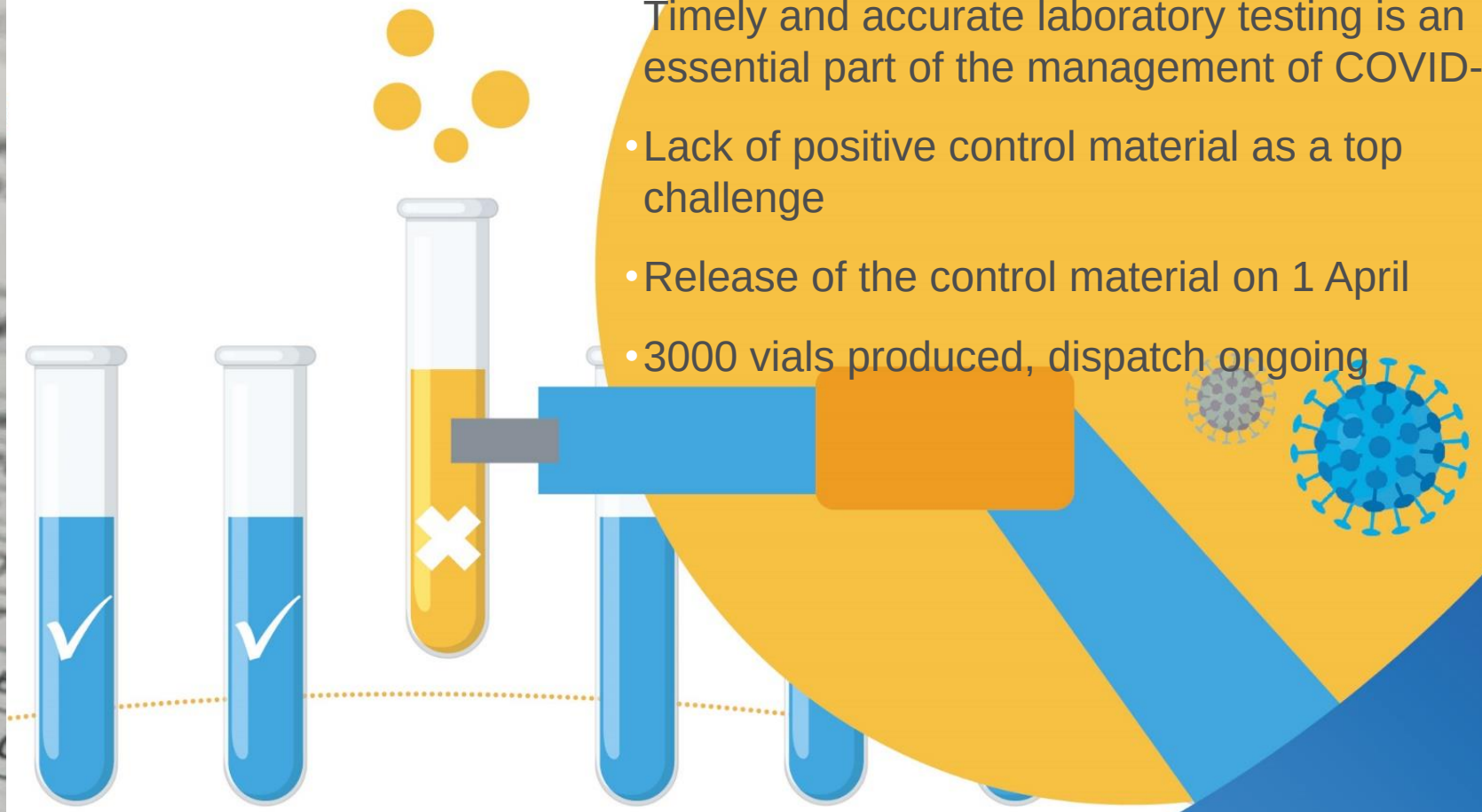
28/05/2020

Control material for WHO recommended RT-PCR protocols



Timely and accurate laboratory testing is an essential part of the management of COVID-19

- Lack of positive control material as a top challenge
- Release of the control material on 1 April
- 3000 vials produced, dispatch ongoing



#coronavirus

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The context

- Working document of Commission services “Current performance of COVID-19 test methods and devices and proposed performance criteria” (16 April 2020)
    - 467 devices revised and 120 scientific papers analysed [NA based approaches (RT-PCR); Immunological (antigen, antibody)]
- Communication from the Commission “Guidelines on in vitro diagnostic tests and their performance” (15 April 2020)
    - ... centralised overview of available information on test performance …
- Commission services roadmap for follow-up actions to implement the Communication

1. Publicly available information on commercial devices from manufacturers
2. Scientific literature (peer-reviewed articles, pre-prints)
3. Validation studies
4. Publications by health technology assessment bodies

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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

The objective of the JRC COVID-19 In Vitro Diagnostic Devices and Test Methods Database is to collect in a single place all publicly available information on performance of CE-marked in vitro diagnostic medical devices (IVDs) as well as in-house laboratory-developed devices and related test methods for COVID-19.

Read more >

Browse the data

COVID-19 in vitro diagnostic medical devices

The database contains publicly available in vitro diagnostic medical devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.

Scientific literature on COVID-19 test methods and devices

The database contains performance of test methods and devices for COVID-19 diagnostics retrieved from selected scientific literature and it is being updated periodically.

How the content of the DB is generated

Publicly available information

In vitro diagnostic medical devices

The information contained in this database in the "In vitro diagnostic medical devices" section is retrieved from the manufacturers webpages. Initial information about the presence of a new device is obtained via existing repository websites (e.g. FIND; 360Dx; Biocompare and others), by using the EMM (Europe Media Monitor)-finder application, keyword-based internet searches, scientific literature or direct communication. We acknowledge all the manufacturers and repository website owners of the devices that have been here analysed and mentioned.

Scientific literature

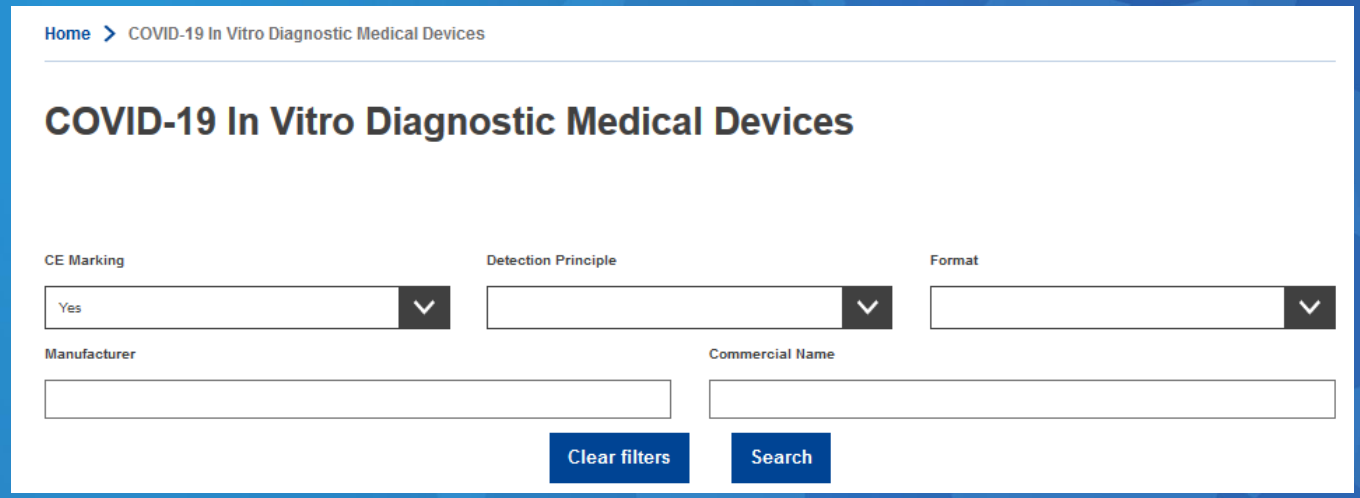
The information contained in this database in the " Scientific literature" section is retrieved from preprints and peer-reviewed articles searched through Scopus, bioRxiv, medRxiv, Europe PMC, and other repositories. Free full-text articles were retrieved from the sources above mentioned or from PubMed Central. Not open-access ones have been retrieved directly from the publisher by using the EC. Library subscription service. We acknowledge all the authors, publishers and literature repositories of the papers that have been here analysed and mentioned.

The database contains

Listing of existing In Vitro Diagnostic Medical Devices for COVID-19

Publicly available information on performance (as retrieved from manufacturers web pages) for commercially available CE-IVD marked devices

- 803 devices
- 347 CE-IVD marked (~ 43%)



Numbers refer to status on 20/05/2020

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The database contains

Detection_Principle	Listed	Information on Performance
NucleicAcid-PCR based	143	45
ImmunoAssay-Antibody	181	92
ImmunoAssay-Antigen	17	9
Immunochromatography Antibody	4	4
Immunochromatography Antigen	2	2
CE-IVD total	347	152

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Publicly available information on performance (as retrieved from manufacturers web pages) for commercially available CE-IVD marked devices

Numbers refer to status on 20/05/2020

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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

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COVID-19 In Vitro Diagnostic Medical Devices

CE Marking

Detection Principle

Format

Manufacturer

Commercial Name

Clear filters

Search

European Commission

CE Marking

Yes

Detection Principle

Format

Manufacturer

Commercial Name

Clear filters

Search

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CE Marking	Detection Principle	Manufacturer	Commercial Name	Target	Format	Commercial Status
Yes	ImmunoAssay-Antibody	JinHuan Medical Instrument Co., Ltd	(COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	IgG, IgM	Rapid diagnostic test	Commercialized
Yes	NucleicAcid-PCR based	1drop Inc.	1copy™ COVID-19 qPCR Kit	Nucleic acid	Manual NAT	Commercialized
Yes	ImmunoAssay-Antibody	Dynamiker Biotechnology (Tianjin) Co., Ltd.	2019 nCOV IgG/IgM Rapid Test	IgG, IgM	Rapid diagnostic test	Commercialized
Yes	ImmunoAssay-Antibody	Edinburgh Genetics Limited	2019 nCoV novel coronavirus antibody detection reagent (Colloidal gold)	IgG, IgM	Rapid diagnostic test	Commercialized
Yes	NucleicAcid-PCR based	Kogene Biotech	2019 Novel Coronavirus Real-time PCR Kit	Nucleic acid	Manual NAT	Commercialized
Yes	ImmunoAssay-Antibody	Innovita Biological Technology Co. Ltd	2019-nCoV Ab Test (Colloidal Gold) (IgM/IgG Whole Blood/Serum/Plasma Combo)	IgG, IgM	Rapid diagnostic test	Commercialized
Yes	ImmunoAssay-Antibody	Beijing Diagreat Biotechnologies Co., Ltd	2019-nCoV IgG Antibody Determination Kit	IgG	Rapid diagnostic test	Commercialized
Yes	ImmunoAssay-Antibody	Biolidics	2019-nCoV IgG/IgM Antibody Detection Kit	IgG, IgM	Rapid diagnostic test	Unknown

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COVID-19 In Vitro Diagnostic Medical Device - detail

1copy™ COVID-19 qPCR Kit

Manufactured by 1drop Inc.

Manufacturer website	http://www.1drop.co.kr/
CE Marking	Yes
Detection Principle	NucleicAcid-PCR based
Format	Manual NAT
Target	Nucleic acid
Commercial Status	Commercialized
Last Update	06/04/2020

Additional Information	https://www.jenabioscience.com//files/jenabioscience/datasheet_extern/PCR-703.pdf
Time	Not found
Throughput	Single tubes
Lod	200 copies/ml
Analytical Specificity	Not found
Positive Control	E gene plasmid and RdRp gene plasmid
Negative Control	DEPC distilled water

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.

Acknowledgements

The database contains

Performance of test methods and devices for COVID-19 diagnostics as retrieved from selected scientific literature.

Screened and selected more than 400 (preprint and peer reviewed) articles

Link/association

- between sc. articles and (WHO) test methods (38)
- between sc. Articles and reported devices

Numbers refer to status on 20/05/2020

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Detection Principle

Testing Method Category

WHO method(s)

Title

Clear filters

Search

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Title	Detection Principle	DOI	Testing Method Category	Peer Reviewed
Saliva Sample as a Non-Invasive Specimen for the Diagnosis of Coronavirus Disease-2019 (COVID-19): a Cross-Sectional Study	NucleicAcid-PCR based	10.1101/2020.04.17.20070045	WHO method(s)	yes (letter)
Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR.	NucleicAcid-PCR based	10.2807/1560-7917.ES.2020.25.3.2000045	WHO method(s)	yes
Detection of SARS-CoV-2 in Different Types of Clinical Specimens.	NucleicAcid-PCR based	10.1001/jama.2020.3786	WHO method(s)	yes
Development of a Laboratory-safe and Low-cost Detection Protocol for SARS-CoV-2 of the Coronavirus Disease 2019 (COVID-19).	NucleicAcid-PCR based	10.5607/en20009	WHO method(s)	yes

Scientific literature on COVID-19 Test Methods and Devices - detail

Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia.

DOI	10.1093/clinchem/hvaa029
Detection Principle	NucleicAcid-PCR based
Target	ORF1b-gene, N-gene
Testing Method	WHO-3
Reported Performance	Specificity: tested ; LOD: 10 cpr ; PCR Efficiency: tested
Sample Size	No clinical samples
Peer-reviewed	yes

Related methods

WHO-3

Scientific literature on COVID-19 Test Methods and Devices - detail

A field indoor air measurement of SARS-CoV-2 in the patient rooms of the largest hospital in Iran

DOI	10.1016/j.scitotenv.2020.138401
Detection Principle	NucleicAcid-PCR based
Target	RdRp-region, E-gene, S-gene
Testing Method	Individual-kit
Testing Method - Additional Info	Kit: ModularDx, Life Science, Berlin, Germany
Reported Performance	Not reported
Peer-reviewed	yes

Related devices

LightMix Modular SARS-CoV-2 (COVID19) E-gene

LightMix Modular SARS-CoV-2 (COVID19 RdRP-gene

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COVID-19 In Vitro Diagnostic Medical Device - detail

2019 nCOV IgG/IgM Rapid Test

Manufactured by Dynamiker Biotechnology (Tianjin) Co., Ltd.

Manufacturer website	http://en.dynamiker.com/
CE Marking	Yes
Detection Principle	ImmunoAssay-Antibody
Format	Rapid diagnostic test
Target	IgG, IgM
Commercial Status	Commercialized
Last Update	06/04/2020
Additional Information	http://en.dynamiker.com/index/index/pro_info/id/606.html
Test Type	Not found
Test Type Result	Qualitative
Format	Fingertip
Detection Principle Antibody	Not found
Specimen	Whole Blood
Antigen IgG	Yes
Antigen IgM	Yes
Antigen IgA	No
Guidance Available	Yes
Reader	Not Required
Time (Min)	10
Fp	Not Reported
Fn	Not Reported
Lod	Not Reported
Analysis of Cross Reactivity	Not Reported
Robustness	Not Reported
Precision	Not Reported
Calibration	Not Reported
Sensitivity Percent	Not Reported
Specificity Percent	Not Reported
Accuracy Percent	92
Reproducibility	Not Reported

Related Scientific Literature

Evaluation of antibody testing for SARS-Cov-2 using ELISA and lateral flow immunoassays

Immunological assays for SARS-CoV-2: an analysis of available commercial tests to measure antigen and antibodies

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Scientific literature on COVID-19 Test Methods and Devices - detail

Evaluation of antibody testing for SARS-Cov-2 using ELISA and lateral flow immunoassays

DOI	10.1101/2020.04.15.20065403
Detection Principle	ImmunoAssay-Antibody
Target	IgM/IgG; ELISA on S-protein
Testing Method	LFIA multiple-kits, ELISA individual-kit
Testing Method - Additional Info	9 commercial LFIA kits and 1 ELISA kit
Reported Performance	Sensitivity: 88% (ELISA), 55-70% (LFIA), 65-85% (RT-PCR) ; Specificity: 100% (ELISA), 95-100% (LFIA), 93-100% (RT-PCR)
Sample Size	152 samples
Peer-reviewed	no

Related devices

Wantai SARS-CoV-2 Ab Rapid Test
OnSite COVID-19 IgG/IgM Rapid Test
2019 nCOV IgG/IgM Rapid Test
Anti-SARS-CoV-2 ELISA (IgA)
Anti-SARS-CoV-2 ELISA (IgG)
2019-nCoV IgG/IgM Rapid Test Cassette
COVID-19 IgG/IgM Rapid Test Cassette
Anti-SARS-CoV-2 Rapid Test

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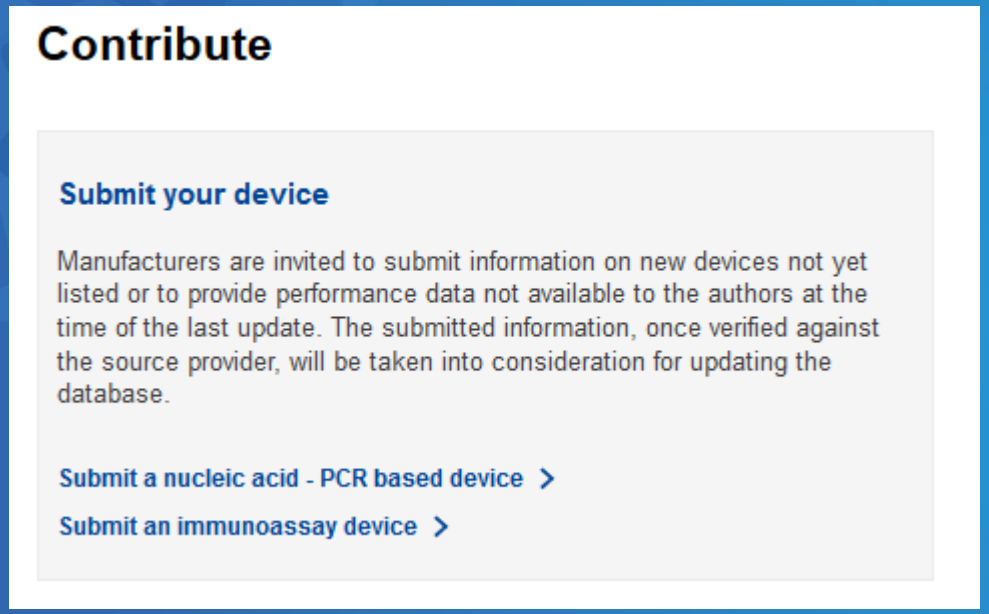

Possibility / invitation to

- Submit information on new (CE-IVD marked) devices
- Provide performance data not included in the database (not available/found)

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Parallel ongoing activities

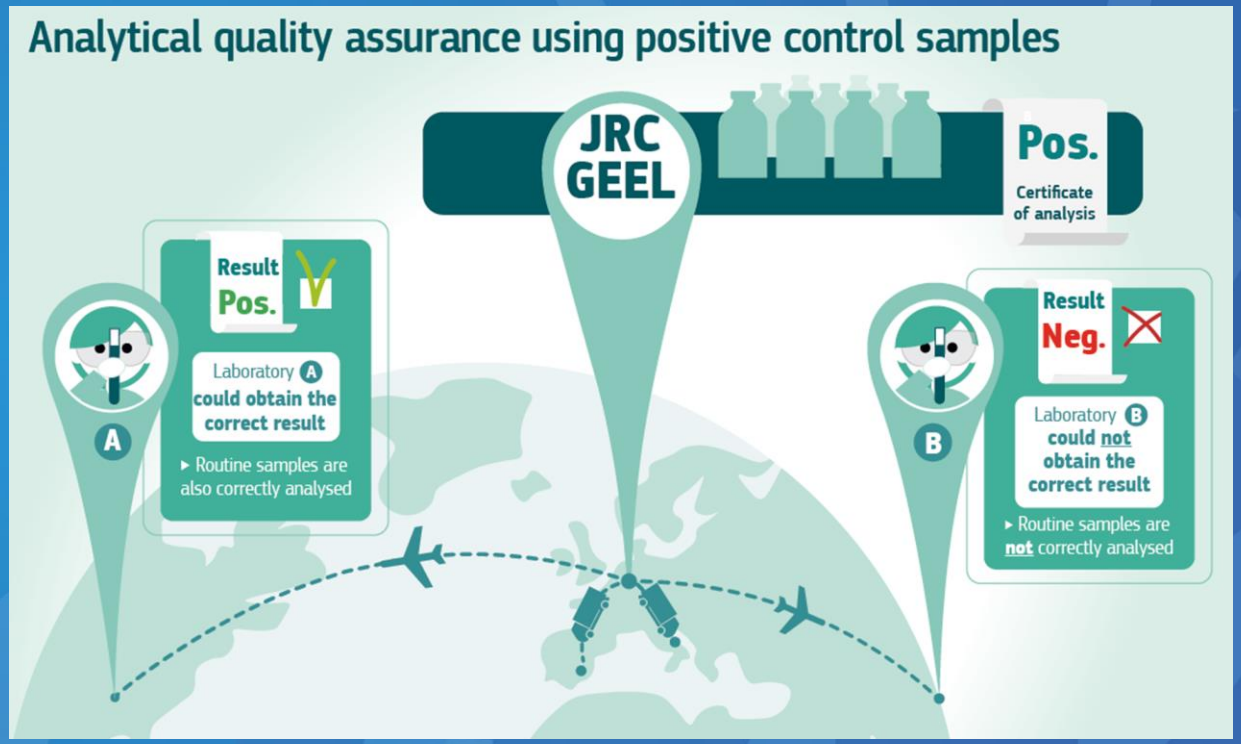
Studies of effectiveness of available serological tests

High-speed development of reference materials for serological testing

Digital PCR characterisation of the virus load of swab samples

Implementation of serological testing at Geel site and RNA (PCR) testing also at Ispra site

Support/promotion of standardisation and harmonisation (networking, reference materials, proficiency testing)



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Parallel ongoing activities

Genomics analysis of SARS-CoV-2:

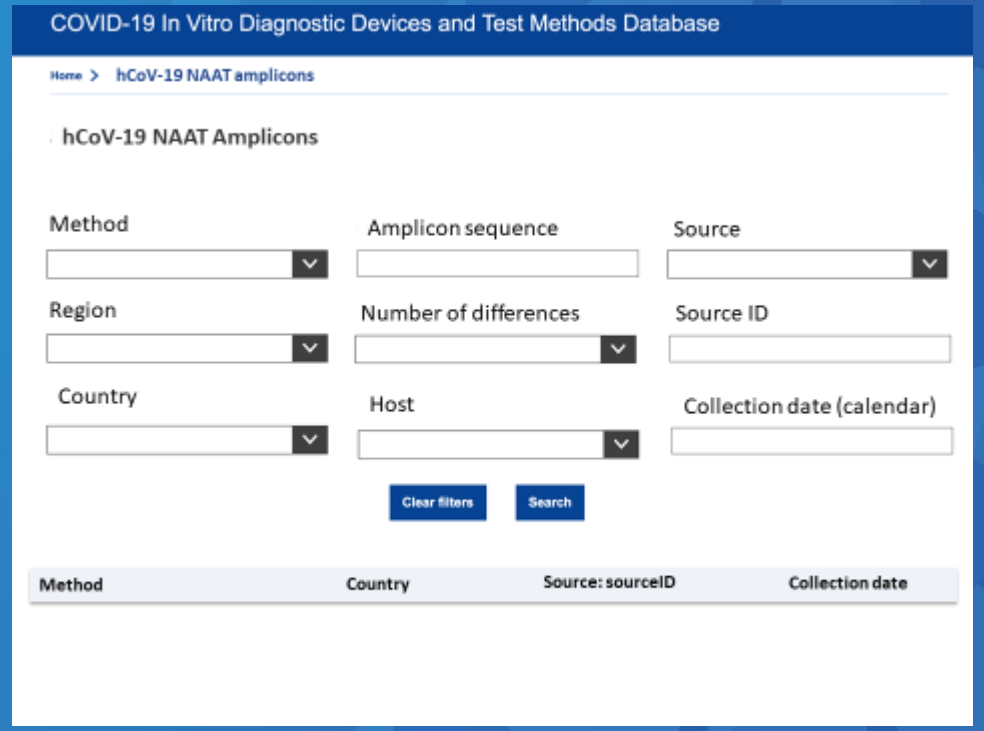
- Virus movement and spread tracing through analysis of (temporal) virus variation
- In silico analysis to verify whether the variations found in new genomic viral sequences can affect the efficiency of WHO proposed detection methods

In elaboration, coming soon

A new module to be added to the database that will contain amplicons collected by screening viral shared genomic sequences of SARS-CoV-2 by *in silico* determination of PCR-based molecular assays to diagnose COVID-19.

hCoV-19 NAAT Amplicons

The database contains amplicons collected by screening viral shared genomic sequences of hCoV-19 by *in silico* determination of PCR-based molecular assays to diagnose COVID-19



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Thank you

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