Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU

5.1.2e

DG SANTE C3 – Health Security & Vaccination

IPCR Working-level Roundtable,
1 Feb 2021

Points for operationalisation

Council Recommendation 5451/21 (21 Jan)

Deliverable 1

1. MS to agree on, maintain and share with the ECDC and Commission a common list of COVID-19 rapid antigen tests that:
   - Are considered appropriate for use in the context of the situations described;
   - Carry CE marking;
   - Meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity;
   - Have been validated by at least one MS, providing details on such studies

   MS to agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures

Deliverable 2

2. MS to agree on a common standardised set of data to be included in the form for COVID-19 test result certificates

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Related action points - testing

Commission Communication - A united front to beat COVID-19 (19 Jan)

1. MS to implement Commission recommendations and swiftly agree on the Council Recommendation on the common framework for RATs
2. JRC to establish a common list of RATs, as agreed by MS with support from HSC
3. Commission and MS to establish a standard set of data to be included in COVID-19 test results form.
4. MS to update testing strategies to incorporate the use of RATs or to develop relevant guidance
5. MS to update testing strategies to reflect the new variants

Deliverable 1

What has been done until now?

1. Common list of RATs and their uses / MS testing strategies

HSC

- 17 Sept: Recommendations for a common EU testing approach for COVID-19
- Ongoing discussions at HSC meetings on MS testing strategies, use of RAT, etc.
- Circulation of several surveys (e.g. mutual recognition, context in which RAT is used)
- Weekly updated overview on the use of RATs in the EU

Other sources

- ISAA reports, JRC Database, FIND database, weekly ECDC country overviews, and many more…

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Deliverable 1

HSC overview table

- Information from 25 MS (CY and DK missing)
- As well as: Montenegro, North Macedonia, Norway, Switzerland, UK, Ukraine
- Last update: 4 February
- Information collected on:

State of play - overview	Testing strategy or guidance	Areas of application	Confirmatory testing	Specific RAT being used in practice / being validated	Validation studies

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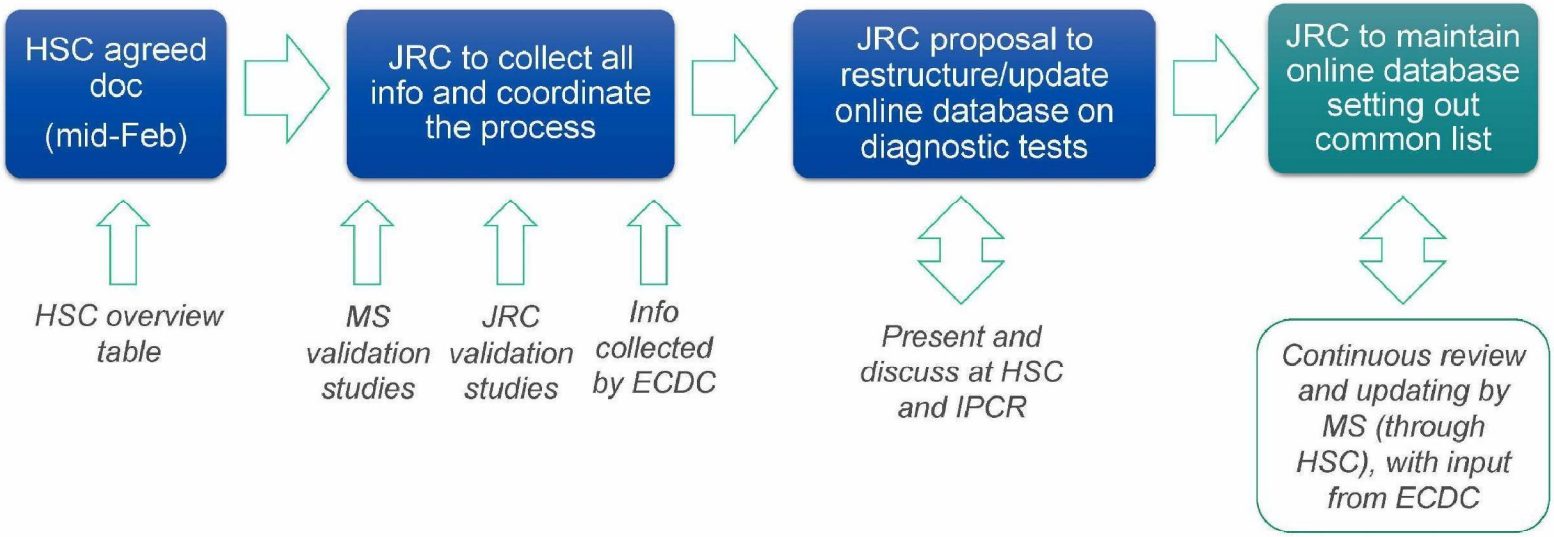
Deliverable 1

Next steps

1. Common list of RAT



Deliverable 2

What has been done until now?

2. Common standardised set of data to be included in COVID-19 test result certificates

HSC

- Survey last year on mutual recognition of COVID-19 test results
- Included the question which info and data should be provided by the test result as well as use of language

Linked to this:

- eHealth network: Guidelines on proof of vaccination for medical purposes - basic interoperability elements (27 January)

Next steps

Deliverable 2

2. Standardised set of data for COVID-19 test results

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Deliverable 2

Next steps

2. HSC agreement – For example:

Section	Data element	Description
Person ID	Name	The legal name of the tested person
	Person identifier	According to the policies applicable in each country
	Date of birth	Tested person's date of birth
Test information	Type of test	E.g. RT-PCR, RAT, LAMP, etc.
	Disease or agent targeted	COVID-19 / SARS-CoV-2 infection
	Result of the test	Result of the conducted test
	Date and time	Date and time when the test was conducted
	Sample origin	E.g. pharyngeal swab
Test centre/lab	Health professional ID	Name or health professional code responsible for conducting and/or validating the result
	Test centre ID	Name and address of the centre/lab that issued the result


IPCR Working-level Roundtable Agenda
Coronavirus Outbreak (COVID-19)
5.1.2e
DG Joint Research Centre
Health, Consumers & Reference Materials
Directorate
European
Commission

Preamble: any diagnostic test should comply with minimum performance criteria

- Commission Communication from 15.04.2020 on Guidelines on COVID-19 in vitro diagnostic tests and their performance.
- COVID-19 In Vitro Diagnostic Devices and Test Methods Database https://covid-19-diagnostics.jrc.ec.europa.eu/
- Scientific literature on COVID-19 Test Methods and Devices
- Development of reference materials, which can be used for (1) quality assessment of RT-PCR tests and (2) serological tests and its distribution to laboratories across the EU.

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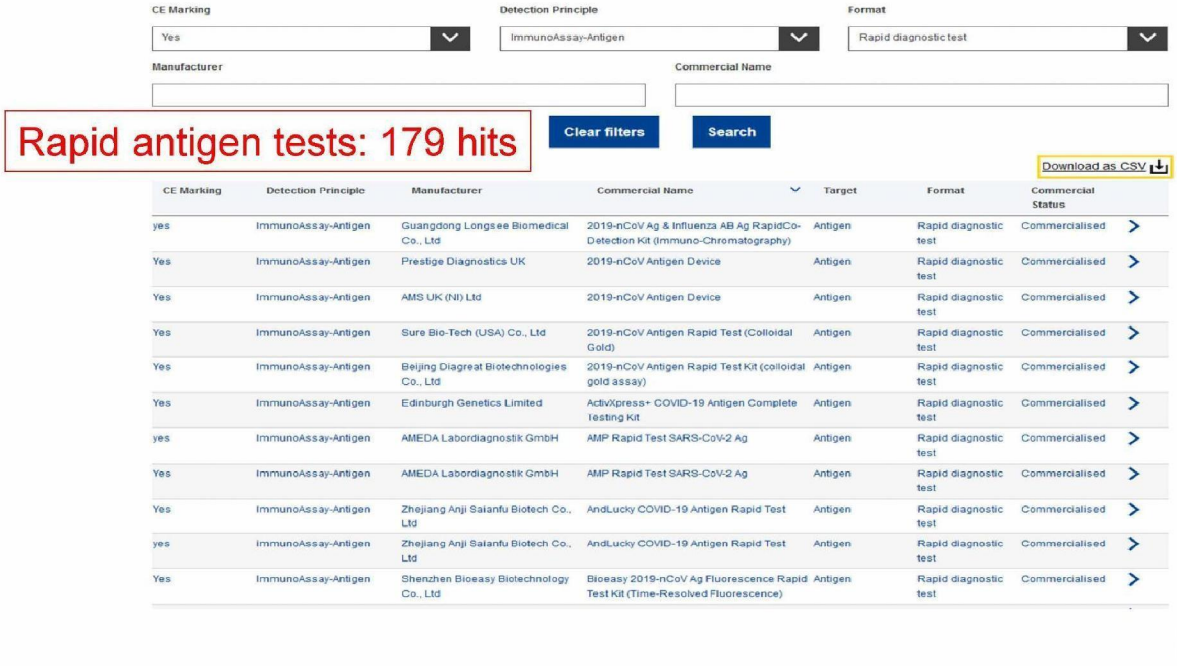
COVID-19 In Vitro Diagnostic Devices and Test Methods Database



CE Marking	Detection Principle	Manufacturer	Commercial Name	Target	Format	Commercial Status
yes	ImmunoAssay-Antigen	Guangdong Longsee Biomedical Co., Ltd	2019-nCoV Ag & Influenza AB Ag RapidCo-Detection Kit (Immuno-Chromatography)	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Prestige Diagnostics UK	2019-nCoV Antigen Device	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	AMS UK (NI) Ltd	2019-nCoV Antigen Device	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Sure Bio-Tech (USA) Co., Ltd	2019-nCoV Antigen Rapid Test (Colloidal Gold)	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Beijing Diagreat Biotechnologies Co., Ltd	2019-nCoV Antigen Rapid Test Kit (colloidal gold assay)	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Edinburgh Genetics Limited	ActivXpress+ COVID-19 Antigen Complete Testing Kit	Antigen	Rapid diagnostic test	Commercialised
yes	ImmunoAssay-Antigen	AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Zhejiang Anji Saianfu Biotech Co., Ltd	AndLucky COVID-19 Antigen Rapid Test	Antigen	Rapid diagnostic test	Commercialised
yes	ImmunoAssay-Antigen	Zhejiang Anji Saianfu Biotech Co., Ltd	AndLucky COVID-19 Antigen Rapid Test	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Shenzhen Bioeasy Biotechnology Co., Ltd	Bioeasy 2019-nCoV Ag Fluorescence Rapid Test Kit (Time-Resolved Fluorescence)	Antigen	Rapid diagnostic test	Commercialised

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Three key questions for adequate monitoring

1. Does a specific method detect the variant of interest and, conversely,
2. Is there a specific method for a variant of interest?
3. Are the reference materials effective?

Verification of the validity of the JRC reference material as quality control for the detection of the recent variant of COVID found in the UK

DEC 23 2020

The JRC has designed and is providing to laboratories the EURM-019 single stranded RNA (ssRNA) fragments of SARS-CoV-2 product.

Recently a variant of SARS-CoV-2 has been identified in the UK - SARS-CoV-2 VUI 202012/01 (here called the new variant). This variant differs in several positions from the reference SARS-CoV-2 sequence that was used as the basis for the development of the JRC reference materials.

A variant of SARS-CoV-2 has been identified recently in the UK - SARS-CoV-2 VUI 202012/01. It is very important for control authorities to know which methods can detect the new variant.
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The top 4 RATs in Europe (including CH, UK and Ukraine) as of today.

- Panbio™COVID-19 Ag Rapid Test Device (NP) [Abbott Rapid Diagnostics] used in 22 countries
- STANDARD™ Q COVID-19 Ag Test [Roche/SD BIOSENSOR] used in 18 countries
- STANDARD™ F COVID-19 Ag FIA [Roche/SD BIOSENSOR] used in 6 countries
- BD Veritor™ System [Becton Dickinson] used in 6 countries
- 72 other RATs used/evaluated in less than 3 countries

Next steps 1

- The JRC will verify the science behind the validation data available from the Member States and companies and verify the findings, eventually in laboratory settings;
- To validate antigen tests JRC plans to use the “gold standard” method of RT-PCR by benchmarking the antigen test samples against qPCR and digital PCR.
- JRC will further develop the common list of RATs;
- This will be linked the COVID-19 diagnostic tests database and transferred into a ‘decision tool’.

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Next steps 2

- JRC will collaborate with ECDC and Member States to agree on standardised data set format for reporting and incorporating validation data into the Database.
- JRC will collaborate with ECDC on developing harmonised guidelines for antigen test validations.

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Bioinformatics and surveillance of new variants

- Member States are responsible for sequencing, under the coordination/guidance from ECDC;
- The following questions may be addressed sustainably:
  - Are the vaccines developed or under development efficient against the new strains?
  - Do the detection methodologies currently used by Member States still detect the emerging variants?
  - Can variants' structures be predicted?

JRC proposed activities

- Organise a series of training webinars for MS;
- Provide a real-time overview of the phylodynamics analyses;
- The JRC will create, in collaboration with GISAID, a dashboard with SARS-CoV-2 sequence data to provide real-time information for the tracking of existing and new emerging variants, their geographical spread, the applicability of detection methods etc.