



OVERVIEW TABLE: Testing strategies and approaches by EU Member States concerning the use of rapid antigen tests (RAT)

State of play: as of **21 December 2020** (based on information shared through the HSC and collected through ISAA)

Text highlighted in yellow is new/adapted information compared to the last version shared with the HSC (27 Nov)

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|---------|--|--|---|--|--|--------------------|
| Austria | <p>Austrian testing strategy focuses on three categories of target groups:</p> <ol style="list-style-type: none"> 1. Symptomatic cases 2. Asymptomatic cases in the context of screenings, outbreak and contact management 3. Broad collectives during mass testing events and testing of specific target groups (e.g. teaching personnel) <p>Rapid antigen tests:</p> <ul style="list-style-type: none"> • Being used in practice • Only to be performed by trained personnel listed in the respective directive • The sensitivity of the currently available tests deviates from the manufacturer's information. | <p>Austrian testing strategy SARS-CoV-2 - 17 Dec</p> | <ul style="list-style-type: none"> • Symptomatic cases. • Asymptomatic cases in context of outbreak management, high-risk contacts and screening in facilities with highly exposed staff (e.g. healthcare) and during mass testing. | <ul style="list-style-type: none"> • Positive antigen test result must always be confirmed with a RT-PCR test. An exception is a positive antigen test result in symptomatic contact persons of category I. • For a negative antigen test results, doctors can consider a subsequent PCR test. Particularly in case of (worsening) symptomatic cases and in case of close contacts. In the other cases, a negative antigen test result is not confirmed by the PCR test. | <ul style="list-style-type: none"> • Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device ^{1,3} • Quidel Sofia 2 SARS Antigen FIA ¹ • SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test ^{2,3} • DIAQUICK COVID -19 Ag Cassette ^{2,3} • NADAL COVID -19 Ag Schnelltest ^{2,3} • Covid-19 Antigentest Orient Gene ^{2,3} • Siemens Clinitest Rapid COVID-19 Antigen Test ² <p>¹ The test is used by either a public (e.g. crisis response team of one district) or a private entity (e.g. private clinic in Vienna)</p> <p>² The Austrian Procurement agency has established a framework contract under which public entities can call off quantities</p> | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|----------|---|---|--|--|---|---|
| | | | | | ³ There has been an ad hoc analysis of the diagnostic parameters of the test (results are not publicly available) | |
| Belgium | <p>Rapid Antigen tests:</p> <ul style="list-style-type: none"> • Being used in practice • In general, not recommended, only in case of limited RT-PCR capacities, as an initial diagnostic/screening test to isolate positive cases or to reduce turnaround times (e.g. in healthcare settings) • In practice, RAT are mainly used in hospitals, in particularly (but not limited to) during out-of-office hours, for emergency admissions, when the regular laboratory is not running PCR tests anymore. • Must be performed by well-trained people • More data and research is required regarding the sensitivity of these tests as well as their purpose and cost-effectiveness. | <p>Testing strategy update: Case definition and testing (FR) (NL) (DE) – 23 Nov 2020</p> <p>Testing strategy update: use of saliva tests and RAT, based on scientific advice by Sciensano (FR) – 12 Oct 2020</p> <p>Testing strategy update: use of saliva tests and RAT, based on scientific advice by Sciensano (NL) – 12 Oct 2020</p> | <ul style="list-style-type: none"> • Symptomatic cases (symptoms less than a week) • Cluster research • In case of pooling techniques (testing of multiple samples at once so that positive cases can be rapidly identified) • Not recommended for repetitive testing (screenings) <p>More data and research is required to assess whether RAT can be used for asymptomatic cases including close contacts (with the purpose of quarantine shortening), testing of returning travellers from high-risk areas, or screening of visitors of healthcare facilities/nursing homes.</p> | <ul style="list-style-type: none"> • Negative antigen test result must be confirmed with a RT-PCR test. | <ul style="list-style-type: none"> • Coris BioConcept COVID-19 Ag Respi-Strip <p>Coris BioConcept's COVID-19 Ag Respi-Strip was approved in April 2020 by the Federal Agency for Drugs and Health Products for reimbursement, but is not on the list of recommended tests. Several other tests are under review by the Federal Agency for Medicines and Health Products, but no official opinion has yet been decided.</p> <p>Belgium has requested approval for reimbursement of the Panbio COVID-19 Ag Rapid Test by Abbott, which has been purchased by several laboratories.</p> | <p>Development and potential usefulness of the COVID-19 Ag Respi-Strip Diagnostic Assay in the Pandemic Context</p> <p>The testing strategy update includes scientific advice by Sciensano, a Belgian scientific institute, which includes various references to relevant studies and validations of RATs. The Annex provides an overview of the clinical performance of several RATs compared to RT PCR.</p> |
| Bulgaria | Bulgaria is currently considering the use of rapid antigen tests and discussions are ongoing. | | Triage before hospital admission in symptomatic cases, in line with the rapid AGT indications for use. | | | |
| Croatia | Croatia is currently updating its testing strategy to include rapid antigen testing as a diagnostic method, in response | | <ul style="list-style-type: none"> • Symptomatic cases (first 5 days after onset of symptoms) | <ul style="list-style-type: none"> • Negative antigen test result must be confirmed | <p>Being considered:</p> <ul style="list-style-type: none"> • ArcDia International Ltd mariPOC SARS-CoV-2 | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|----------------|--|-----------------------------|---|---|---|--------------------|
| | to a deteriorating epidemiological situation and limited RT-PCR testing capacities | | <ul style="list-style-type: none"> Screening in specific settings <p>RAT will not be used to test asymptomatic people</p> | with a RT-PCR test. | <ul style="list-style-type: none"> Coris BioConcept COVID-19 Ag Respi-Strip <p>Being validated:</p> <ul style="list-style-type: none"> SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |
| Cyprus | | | | | | |
| Czechia | <p>National testing strategy acknowledges RT-PCR as “golden standard” of testing methods. However, it approves use of RAT in case of lack of RT-PCR tests to:</p> <ol style="list-style-type: none"> 1. Diagnose patients with severe symptoms within 3 days from their onset or 2. When territorial outbreaks emerges. <p>Rapid antigen tests are also used for the purpose of targeted testing. In this context, a new emergency measure has been published ordering all providers of health services providing long-term inpatient care and all social service providers to carry out antigen tests on a regular basis (once in five days) to determine the presence of SARS-CoV-2 virus.</p> <p>SARS-CoV-2 antigen detection kits must be CE IVD certified and have a sensitivity of at least 90% and specificity of at least 97%.</p> | | <ul style="list-style-type: none"> Sever symptomatic cases (first 3 days after onset of symptoms) Outbreak clusters | <p>If the tested person has a positive test result and shows COVID-19 symptoms, appropriate quarantine measures are ordered.</p> <p>If the result of the antigen test is negative and the person still shows symptoms, or vice versa if the tested person is asymptomatic but the test result shows the presence of SARS-CoV-2 virus, the person is subsequently subjected to control testing carried out by RT-PCR method.</p> | <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device | |
| Denmark | | | | | • | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|---------|---|---|--|--|---|---|
| Estonia | Discussions are ongoing; Estonia is considering the use of rapid antigen tests | | | | | |
| Finland | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice | | | | <ul style="list-style-type: none"> ArcDia International Ltd mariPOC SARS-CoV-2 Quidel Sofia 2 SARS Antigen FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |
| France | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice Must have at least 80% sensitivity and 99% specificity. | Updated testing strategy (Order of 17 Oct, amending the order of 10 July, prescribing the general COVID-19 measures) (FR) - 17 Oct 2020 | <p>The 17/10/20 decree follow the opinion of the Haute autorité de santé, recommends different uses depending on the clinical situation. RAT can be used for:</p> <ol style="list-style-type: none"> Asymptomatic persons beyond "contact cases" or people detected within a cluster (airports, universities, retirement homes or prisons) Symptomatic persons <65 y.o if the test takes place less than 4 days after the appearance of the first symptoms. | The result, positive or negative does not need to be RT-PCR confirmed. | <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | Revue rapide sur les tests de détection antigénique du virus SARS-CoV-2 |
| Germany | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice Since 15/10/20 rapid antigen tests are part of the German national testing strategy RATs are primarily used for screening purposes of asymptomatic individuals and for quick differential diagnoses, | Infopage national testing strategy (DE) - 14 Oct 2020 Guidance for SARS-CoV-2 testing, including RAT (DE) | <p>RAT are primarily used for asymptomatic persons including:</p> <ul style="list-style-type: none"> Patients/residents, personnel and visitors of: hospitals/nursing care/ facilities for persons with disabilities, Rehabilitation, | It is mandatory to follow-up a positive rapid antigen test result with RT-PCR test | <p>Among others the following RTAs are validated:</p> <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag STANDARD Q COVID-19 Ag Test (SD Biosensor) Rida@Quick SARS-CoV-2 Antigen (R Biopharm) Standard™ F COVID-19 Ag FIA | <p>Validation studies regarding sensitivity of RAT ongoing; several tests are being validated.</p> Comparison of seven commercial SARS-CoV-2 rapid |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|---------|--|--|---|---|---|---|
| | with a focus on healthcare settings. | | Outpatient surgery, - Outpatient dialysis <ul style="list-style-type: none"> Personnel in doctor`s and dentist surgeries | | <ul style="list-style-type: none"> NADAL® COVID-19 Ag (nal von minden) Antigen Test SARS CoV-2(Dräger) SARS-CoV-2 Rapid Antigen Test (Roche) NowCheck COVID-19 Ag Test (Bionote) Standard™ Q COVID-19 Ag Test (SD Biosensor) | Point-of-Care Antigen tests |
| Greece | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice Being used in refugee camps, testing of the general population (metro in Athens) RAT is a pillar in the national testing strategy, because studies have shown that the viral load in asymptomatic patients is the same as that of patients who are symptomatic. Moreover, an essential need for increased testing with reliable quick results is clear. All rapid antigen tests are nasopharyngeal swab | | <ol style="list-style-type: none"> When PCR/ molecular tests are unavailable at all times (for instance at refugee camps). In large mass testing events, such as in city squares. Increasing availability to the public through performing rapid antigen testing at accessible and open locations has improved mass screening. In clinical settings for healthcare workers In areas reporting high case prevalence. | All patients with positive rapid antigen test result are re-examined with a PCR swab sample. The committee of specialists has decided that confirmation of positive antigen rapid tests with PCR will shortly cease. This allows for more prompt and just as accurate diagnoses. | Being used: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device | |
| Hungary | Rapid antigen tests are used to test suspected cases, and extensive and regular tests have started among health, social and public education workers. A positive antigen tests result is accepted, while a negative result have to be confirmed by a PCR test | Hungarian guidelines , including use of rapid antigen tests (HU) | <ul style="list-style-type: none"> Symptomatic cases. Asymptomatic cases (close contacts) in outbreaks screening in facilities with highly exposed staff: HCW, social workers | A positive antigen tests result is accepted, while a negative result have to be confirmed by a PCR test. The sampling has to be at once after the negative result | Being validated: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device Others will be validated too and other tests can be used, too | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|------------|--|---|---|----------------------------|--|---|
| | | | <ul style="list-style-type: none"> screening in educational facilities | of the Ag-test is visible. | | |
| Ireland | Discussions ongoing, rapid antigen tests are being validated | | | | Being validated: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |
| Italy | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice | Interim technical note on Laboratory tests for SARS-CoV-2 and their use in public health - 16 Oct 2020 | | | <ul style="list-style-type: none"> SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | Validation reports by the National Institute of Infectious Diseases Lazzaro Spallanzani produced for the following two rapid antigen tests: <ul style="list-style-type: none"> Bisensor Fujirebio |
| Latvia | Discussions ongoing, limited amount/types of rapid antigen tests are being approbated | Under development | | | Being approbated: <ul style="list-style-type: none"> SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |
| Lithuania | The use of antigen tests is being considered. An algorithm is being developed to identify needs. | | | | | |
| Luxembourg | Discussions ongoing, rapid antigen tests are being validated | | | | Being validated: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|-------------|---|---|---|-------------------|--|---|
| Malta | Rapid antigen tests: <ul style="list-style-type: none"> Using in practice | | Rapid tests were introduced at the end of October Boffa Hospital, and will be introduced in airports and at a second swabbing centre in the near future. Initially priority will be given to healthcare workers, including staff at care homes, and the airport. Schools will also have this sort of testing soon | | | |
| Netherlands | Several commercially available antigen tests and several tests are being developed in NL. | Advice by the outbreak Management Team on rapid antigen tests General doc (NL) Detailed annex (NL) – 12 October 2020 | | | Being used in practice: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device Quidel Sofia 2 SARS Antigen FIA SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test BD VeriTor COVID antigen test (Becton Dickinson) | Validation study results (NL) (4 Dec) |
| Poland | On 31 October, Poland updated its COVID-19 case definition for epidemiological supervision of SARS-CoV-2 infections, so that this definition also covers antigen tests results (when it comes to laboratory criteria). In line with this definition COVID19 case is confirmed: | | | | | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|----------|---|-----------------------------|---|-------------------|--|--------------------|
| | - either when SARS-CoV-2 nucleic acid is detected in clinical specimens, - or SARS-CoV-2 virus antigen(s) is / are detected in clinical specimens. | | | | | |
| Portugal | <p>Rapid antigen tests:</p> <ul style="list-style-type: none"> • Are being used in practice • The criteria for RDT-Ag selection for COVID-19 diagnosis, adopted at national level is: sensitivity $\geq 90\%$ and specificity $\geq 97\%$ | | <p>RAT have a better performance in patients with higher viral loads, which usually happens in the pre-symptomatic phase (1-3 days before symptoms) or in the symptomatic phases of the disease (5-7 days). Based on this, it was decided to recommend RAT use during the first 5 days (inclusive) of illness.</p> <p>Evidence shows that the viral load in asymptomatic patients is identical to that of symptomatic. It was therefore decided to also use RAT for the diagnosis of asymptomatic high-risks contact and for screening of asymptomatic people in specific settings when:</p> <ol style="list-style-type: none"> 1. The molecular testes are unavailable and/or turnaround time preclude clinical utility. 2. In order to quickly implement the appropriate Public Health measures in outbreaks and or | | <p>Being validated:</p> <ul style="list-style-type: none"> • Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device • SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA • MARK-B COVID-19 Ag S, Inocrowd • BIOCREDIT COVID-19 Ag | |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|----------|--|-----------------------------|---|-------------------|---|---|
| | | | social emergencies in particular sites/situations. | | | |
| Romania | Discussions ongoing, rapid antigen tests are being considered | | | | Being considered: <ul style="list-style-type: none"> • Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device • SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA • SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |
| Slovakia | Rapid Antigen tests: <ul style="list-style-type: none"> • Being used in practice • Nationwide antigen testing of all citizens above 10 years and below 65 years of age (three rounds of testing – 2 already took place). • Testing is done by army and volunteers. • As a follow up, SK wants to establish mobile antigen testing centres across the country, where anybody can get tested. • The goal is that 2% of the population is tested in those centres every week. | | Two rounds of nation-wide antigen testing already took place: <ul style="list-style-type: none"> • 1st round took place the weekend of 1 November where 3, 6 million people (out of 5, 5) were tested with the positivity rate of 1.06. This represent 65% of the whole population. • 2nd round took place last weekend and was limited to 45 districts with higher number of cases (above 1.07 positivity rate). Total number of population testes was more than 2 million • In both rounds, 50.000 people went into isolation of 10 days (plus their families) unless a confirmatory check by PCR test (if available). | | Rapid antigen tests were chosen by public procurement based on criteria sensibility, performance and price. | Population-wide testing - RAT study results |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|----------|--|--|--|---|--|--|
| | | | <ul style="list-style-type: none"> The 3rd round is ongoing in selected villages and towns <p>Antigen tests are also planned to be used in hospitals, nursery homes, schools and big companies.</p> <p>SK is currently not using the antigen tests at airports, but a pilot project will be deployed on the border with Ukraine (random checks with the antigen tests)</p> | | | |
| Slovenia | Discussions ongoing, rapid antigen tests are being validated | | | | Being validated: <ul style="list-style-type: none"> Quidel Sofia 2 SARS Antigen FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test | |
| Spain | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice Must have at least 80% sensitivity and 97% specificity. Pillar of the strategy for symptomatic patients (with 5 days or less of symptom evolution) in primary health care. | Updated testing strategy, including the use of rapid antigen tests (ES) - 15/12/2020 | <p>RAT is used to every symptomatic patient with 5 or less days of evolution of symptoms.</p> <p>RAT is used for the diagnosis of asymptomatic high-risk contact, people in high-risk or vulnerability settings and for screening of asymptomatic people in specific settings when:</p> <ol style="list-style-type: none"> The molecular testes are unavailable and/or turnaround time preclude clinical utility. | <p>Negative RAT results in symptomatic and asymptomatic people in high-risk or vulnerability settings are confirmed by a RT-PCR.</p> <p>Positive RAT results in mass screenings are confirmed by a RT-PCR in low prevalence settings.</p> | Used in practice: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device. SARS-CoV-2 Antigen Rapid Test (SD biosensor/Roche) BD Veritor Plus System for rapid COVID-19(SARS-CoV-2) testing for NASAL swab. CerTest SARS-CoV-2 CARD TEST LumiraDx SARS-CoV-2 Ag (LumiraDX) Ag detection by immunofluorescence from NASAL swabs | <p>Validated/evaluated by Instituto de Salud Carlos III</p> <p>Se: 91% Sp: 99%</p> <p>Se: 83-88% Sp: 99%</p> <p>Se: 92% Sp: 98,6%</p> <p>Se: 92,8% Sp:100%</p> <p>Se: 97,6% Sp:97,2%</p> |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANCE | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|---------|---|---|--|-------------------|--|--------------------|
| | | | 2. In order to quickly implement the appropriate Public Health measures in outbreaks and or social emergencies in particular sites/situations. | | Being validated: <ul style="list-style-type: none"> • Clinitest Rapid COVID-19 Antigen Test for the detection of SARS-CoV-2 by SIEMENS • ZandCell Rapid Antigen Test COVID-19 (Zandcell) for saliva sample • Panbio™ COVID-19 Ag Rapid Test Device for NASAL swab. • VITROS Immunodiagnostic Products SARS-CoV-2 Antigen (Ortho Clinical diagnosis). Nasopharyngeal swab for CLIA detection | |
| Sweden | Discussions ongoing (at regional level), rapid antigen tests are being considered/validated | Available here (26 Nov) | | | Being considered: <ul style="list-style-type: none"> • Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device • SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test <p>In addition to the indicated tests being considered by some regions in Sweden, smaller evaluations are also being performed for:</p> <ul style="list-style-type: none"> • BD Veritor • Healgen • Menarini • Humasi • Siemens CLINITEST Rapid COVID-19 Antigen Test | |

Other countries in the European region

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANC | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|-----------------|---|----------------------------|--|--|---|--|
| Montenegro | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice | | | | Using in practice: <ul style="list-style-type: none"> SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test Being considered: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device | |
| North Macedonia | Rapid Antigen tests: <ul style="list-style-type: none"> Being used in practice since 9 Nov Use included in national testing strategy Mainly used in primary care national testing points for COVID-19. All the tests are previously appointed with date and time through the national e-health system, Primary care physicians are responsible for appointments of their patients. From our experience in the field, we have almost the same percentage of positivity on a daily basis from RAT and RT-PCR. | | RAT used in case of: <ul style="list-style-type: none"> Symptomatic cases, ≤5 days from symptom onset Hospital admissions if urgent clinical decisions have to be made and the RT PCR turnaround time is more than 24h Health workers dealing with COVID - if symptomatic | <ul style="list-style-type: none"> No confirmatory PCR test needed on primary level if hospitalisation criteria are met than PCR test will be performed in the hospital For a negative antigen test results, doctors can consider a subsequent PCR test. Particularly in case of (worsening) symptomatic cases and in case of close contacts. In the other cases, a negative antigen test result is not confirmed by the PCR test. | <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device | No validation study yet |
| Norway | Discussions ongoing, rapid antigen tests are being validated as of end October | | | | Being considered: <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device | Evaluation of Abbot's Panbio COVID-19 rapid antigen test in Norway |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANC | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|-------------|--|---|--|--|--|--|
| Switzerland | <p>Rapid antigen tests are actively being used according to well-defined criteria.</p> <p>Two tests meet the validation criteria and others are currently being validated.</p> | <p>COVID-19 : recommandations pour le diagnostic en ambulatoire Intégration des tests rapides antigéniques dans la stratégie de dépistage (FR) - 2 Nov 2020</p> <p>COVID-19: Empfehlungen zur Diagnose im ambulanten Bereich Integration der Antigen-Schnelltests in die Teststrategie (DE) - 2 Nov 2020</p> | <p>Rapid antigen test have been validated in Geneva and validated antigen tests are being used</p> <p>A) for diagnostic purposes for non-risk patients in the first 96 hours after symptom onset</p> <p>B) for outbreak management (recommendation currently in development)</p> <p>C) to test persons at the earliest 5 days after a notified contact of the SwissCovid App</p> | <p>Not required if test performed according to testing criteria. If test performed in general population (low pre-test probability), – currently not recommended - positive tests require a PCR confirmation.</p> <p>If there is a high suspicion of COVID-19 (ie. Outbreaks in LTCF) a negative rapid test needs to be confirmed with PCR</p> | <p>Already validated:</p> <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device Standard Q COVID-19 Rapid Antigen Test (SD Biosensor/Roche) <p>Currently, many other RAT are being validated by the Swiss society of Microbiology. Further details on the website of the FOPH and the Swiss Society for Microbiology (SSM)</p> | <p>Clinical validation study performed by Geneva University Hospital</p> |
| UK | <p>Rapid Antigen tests:</p> <ul style="list-style-type: none"> Being used in practice Population screening in Liverpool and other locations Multiple pilots ongoing (e.g. private sector, schools, universities) High risk workplaces and critical industries Repeated testing of asymptomatic NHS staff | <p>Guidance: Assessment and procurement of coronavirus (COVID-19) tests - How the government assesses offers of COVID-19 tests from developers for procurement and use in the UK</p> <p>Guidance: How tests and testing kits for coronavirus (COVID-19) work - The different types of tests and testing kits for COVID-19, and the specifications for manufacturers</p> | <p>RATs are being used to support the whole city testing of Liverpool and other locations within the UK.</p> <p>Multiple pilots are ongoing across different sectors to identify asymptomatic cases.</p> | <p>Not in all cases currently. The policy on confirmatory PCR tests is still under review.</p> | <p>Using in practice:</p> <ul style="list-style-type: none"> Abbott Diagnostics Panbio™ COVID-19 Ag Rapid Test Device Innova COVID-19 Ag Rapid Test Device Orient Gene <p>Being validated:</p> <ul style="list-style-type: none"> SD BIOSENSOR, Inc. STANDARD F COVID-19 Ag FIA SD BIOSENSOR, Inc. STANDARD Q COVID-19 Ag Test DeepBlue COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) Fortress Diagnostics. Coronavirus Ag Rapid Test | <p>Preliminary report from the Joint PHE Porton Down & University of Oxford “SARS-CoV-2 test development and validation cell: Rapid evaluation of Lateral Flow Viral Antigen detection devices (LFDs) for mass community testing”.</p> |

| COUNTRY | STATE OF PLAY – Overview | TESTING STRATEGY / GUIDANC | AREAS OF APPLICATION - RAT | CONFIRMATORY TEST | RAT being used in practice/being validated | VALIDATION STUDIES |
|---------|--------------------------|----------------------------|----------------------------|-------------------|---|--------------------|
| | | | | | <ul style="list-style-type: none"> • Humasis • Hangzhou Alltest. COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) • Beier Bio/Mediport • Nantong Diagnostics • DNA Diagnostics • Quidel Sofia 2 SARS Antigen FIA | |