Supplementary Appendix

Supplement to: Drain PK. Rapid diagnostic testing for SARS-CoV-2. N Engl J Med. DOI: 10.1056/NEJMcp2117115

This appendix has been provided by the author to give readers additional information about the work.

APPENDIX for Rapid Diagnostic Testing for SARS-CoV-2

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Table S1. Rapid diagnostic tests with FDA EUA status for home-based use and settings with CLIA certificate of waiver for SARS-CoV-2.

Test Name; Manufacturer[1]	Target Analyte; Test Method	Specimen	Time to Result (minutes)	Lower Age Limit for Home Use (years)	Indication for Use (symptomatic; asymptomatic)	Accuracy[2] (PPA; NPA)
Tests for home-based use						
InteliSwab COVID-19 Rapid Test; OraSure Technologies	Antigen (nucleocapsid); LFA	Anterior nares	30-40	15	Symptomatic - within 7 days of onset Asymptomatic - test twice over 2-3 days	84%; 98%
Celltrion DiaTrust COVID-19 Ag Test; Celltrion USA	Antigen (nucleocapsid and RBD); LFA	Mid-turbinate nasal	15-20	14	Symptomatic - within 7 days of onset; Asymptomatic - test twice over 2-3 days	86.7%; 99.8%
QuickVue At-Home OTC COVID-19 Test; Quidel Corporation	Antigen (nucleocapsid); LFA	Anterior nares	10-15	2	Symptomatic - within 6 days of onset; Asymptomatic - test twice over 2-3 days	83.5%; 99.2%
Flowflex COVID-19 Antigen Home Test; Acon Laboratories	Antigen (nucleocapsid); LFA	Anterior nares	15-30	2	Symptomatic - within 7 days of onset or Asymptomatic (without serial testing)	93%; 100%
BD Veritor At-Home COVID-19 Test; Becton, Dickinson and Company	Antigen (nucleocapsid); LFA	Anterior nares	15-20	2	Symptomatic - within 7 days of onset; Asymptomatic - test twice over 2-3 days	84.6%; 99.8%
CareStart COVID-19 Antigen Home Test; Access Bio	Antigen (nucleocapsid); LFA	Anterior nares	10-15	2	Symptomatic - within 7 days of onset; Asymptomatic - test twice over 2-3 days	86.7%; 97.5%
BinaxNOW COVID-19 Antigen Self Test[3]; Abbott Diagnostics Scarborough	Antigen (nucleocapsid); LFA	Anterior nares	15-30	2	Symptomatic - within 7 days of onset; Asymptomatic - test twice over 2-3 days	91.7%; 100%
Ellume COVID-19 Home Test[4]; Ellume Limited	Antigen (nucleocapsid); LFA	Mid-turbinate nasal	15	2	Symptomatic - within 5 days of onset Asymptomatic (without serial testing)	96%; 100%
iHealth Covid 19 Antigen Rapid test; iHealth Labs	Antigen (nucleocapsid); LFA	Anterior nares	15	2	Symptomatic - within 7 days of onset; Asymptomatic - test twice over 2-3 days	94.3%, 98.1%
SCoV-2 Ag Detect Rapid Test; InBios International	Antigen (nucleocapsid); LFA	Anterior nares	20-25	2	Symptomatic - within 5 days of onset; Asymptomatic - test twice over 2-3 days	86.6%; 100%
Detect Covid-19 Test; Detect	Molecular (ORF 1ab gene); RT LAMP	Anterior nares	55	2	Symptomatic Asymptomatic - test twice over 2-3 days	90.9%; 97.5%
Lucira CHECK-IT COVID-19 Test Kit; Lucira Health	Molecular (N gene); RT LAMP	Anterior nares	30	2	Symptomatic Asymptomatic (without serial testing)	92%; 98%
Cue COVID-19 Test; Cue Health	Molecular (N gene); RT isothermal PCR	Anterior nares	20	2	Symptomatic Asymptomatic (without serial testing)	96.4%; 98.2%
Tests for use in Settings with CLIA Certificate of Waiver						

NIDS COVID-19 Antigen Rapid Test Kit; ANP Technologies	Antigen (nucleocapsid); LFA	Mid-turbinate nasal	15-30	N/A	Symptomatic - within 7 days of onset; Asymptomatic - test twice over 2-3 days	95.1%; 97.0%
LumiraDx SARS-CoV-2 Ag Test; LumiraDx UK	Antigen (nucleocapsid), Microfluidic IFA	Anterior nares or NP	12	N/A	Symptomatic - within 12 days of onset; Asymptomatic (without serial testing)	97.6%; 96.6%
Clip COVID Rapid Antigen Test; Luminostics (now Clip Diagnostics)	Antigen (nucleocapsid); Lateral flow IFA	Anterior nares	30	N/A	Symptomatic - within 5 days of onset	96.9%; 100%
Status COVID-19/Flu A&B; Princeton BioMeditech Corp	Antigen (nucleocapsid); LFA	Anterior nares or NP	15-20	N/A	Symptomatic - within 5 days of onset	93.1%; 100%
Sienna-Clarity COVID-19 Antigen Rapid Test Cassette; Salofa Oy	Antigen (nucleocapsid); LFA	NP	10-20	N/A	Symptomatic - within 6 days of onset	87.5%; 98.9%
GenBody COVID-19 Ag; GenBody	Antigen (nucleocapsid); LFA	Anterior nares or NP	15-20	N/A	Symptomatic - within 6 days of onset; Asymptomatic - test twice over 2-3 days	92.3%; 99.0%
INDICAID COVID-19 Rapid Antigen Test; PHASE Scientific International	Antigen (nucleocapsid); LFA	Anterior nares	20-25	N/A	Symptomatic - within 5 days of onset; Asymptomatic - test twice over 2-3 days	88.9%; 96.8%
SPERA COVID-19 Ag Test; Xtrava Health	Antigen (nucleocapsid); LFA	Anterior nares	15-30	N/A	Symptomatic - within 5 days of onset	91.8%; 96.9%
Xpert Xpress CoV-2/Flu/RSV plus; Cepheid	Molecular (N and E genes); RT-PCR	Anterior nares or NP	25	N/A	Symptomatic	100%; 100%
Accula SARS-CoV-2 Test; Mesa Biotech	Molecular (N gene); RT-PCR	Anterior nares or mid-turbinate nasal	30-60	N/A	Symptomatic	95.8%; 100%
ID NOW COVID-19; Abbott Diagnostics Scarborough	Molecular (RdRp gene); NEAA	Anterior nares or NP	13	N/A	Symptomatic - within 7 days of onset	94.7%; 98.6%
cobas SARS-CoV-2 for Liat System; Roche Molecular Systems	Molecular (N and ORF 1ab genes); RT-PCR	Anterior nares or mid-turbinate nasal or NP	20	N/A	Symptomatic Asymptomatic (without serial testing)	96.1%; 96.8%
BioFire Respiratory Panel 2.1-EZ; BioFire Diagnostics	Molecular (S and M genes; RT-PCR	NP	45	N/A	Symptomatic	98.4%; 98.9%
Visby Medical COVID-19 Point of Care Test; Visby Medical	Molecular (N1 gene); RT-PCR cartridge	Anterior nares or mid-turbinate nasal or NP	30	N/A	Symptomatic	100%; 95.3%
Talis One Covid-19 Test system; Talis Biomedical Corporation	Molecular (ORF 1ab and N genes); RT-PCR	Mid-turbinate nasal	30	N/A	Symptomatic	95.7%; 100%

EUA=Emergency Use Authorization; FDA=US Food and Drug Administration; IFA=immuno-fluorescence assay; LFA=lateral flow assay; M=membrane protein; N=nucleocapsid; NEAA=nicking enzyme assisted amplification; NP=nasopharyngeal; NPA=negative percent agreement; ORF=open reading frames; PCR=polymerase chain reaction; PPA=positive percent agreement; RBD=Receptor Binding Domains; RdRp=RNA dependent RNA polymerase; RT=reverse transcription; S=spike protein.

1. All RDTs approved for home-based use, except iHealth Covid 19 Antigen Rapid test by iHealth Labs, have also received approval for use in patient care settings operating under a CLIA Certificate of Waiver. Companies with a similar product approved for 'home-based use' were not listed again for the 'use in settings with a CLIA certificate of waiver' section. Each company was listed once in this table, except Abbott Diagnostics Scarborough, which has two different RDTs. The EUAs will remain in effect for the duration of the COVID-19 declaration justifying emergency use of in vitro diagnostics, unless revoked by FDA. To date, no RDTs have obtained full FDA approval.
2. All data presented on test accuracy were obtained from the FDA approval listing or a company website.[27] The accuracy of each test may be different in clinical practice and real-world settings.
3. A version of the BinaxNOW test is available and approved for CLIA-waived settings.
4. Ellume has issued a limited recall for RDTs with certain manufacturing lot numbers.