

Application number	Manufacturer	Test Name	Technology	Test type (POC, multi-analyte POC, or self test)	Patient population from the indications statement (symptomatic, asymptomatic, etc.)	Symptomatic, Asymptomatic, Serial Asymptomatic	Users from the indications statement	Trained Operator (Y/N)	Sample type	Clinical sensitivity	Clinical specificity	Time to result (Does not include sample collection and preparation)	Number of samples per test	Is the device a stand alone device? (Yes/No)	Approved Reagent Shelf Life
312836	Cepheid	XpertXpress SARS-CoV-2	Molecular (Nucleic acid)	POC	Individuals suspected of COVID-19	Symptomatic	Trained operators proficient in use of GeneXpert systems	Y	NP swab, Nasal swab, Nasal, Nasal Wash/aspirate, and Gargle and spit (Gargle and spit was authorized through the Expanded use pathway and is not on the IFU)	97.80%	100.00%	45 min	Up to 4 in the machine, 1 per cartridge.	No, GeneXpert system required	12 months when stored at 2-28°C.
315999	Hyris	bCube	Molecular (Nucleic acid)	POC	Individuals suspected of COVID-19	Symptomatic	Trained health-care professional	N	NP or nasal swab	100.00%	100.00%	1 hour 45 min	6 or 16 (Amendmend 328818 for a 36 well cartridge and allows for 16 samples)	No, bCube machine required	12 months when stored at -20 °C. Real-time stability studies are still underway.
320087	Abbott	ID Now	Molecular (Nucleic acid)	POC	Individual suspect of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms	Symptomatic	medical professionals or trained operators	Y	NP, Nasal, or throat swab	92.90%	98.20%	13 min	1	No, ID now machine required	12 months expiry when stored at 2-30°C (expanded use). Real-time stability studies are still underway.
321164	Roche	Cobas Liat SARS-CoV-2 & Influenza A/B	Molecular (Nucleic acid)	multi-analyte POC	Individuals suspected of a viral respiratory infection	Symptomatic	Healthcare provider and trained operators	Y	NP or nasal swab. Self Collected Nasal swabs under the supervision of a Heath Care Provider	100.00%	100.00%	20 min	1	No, Cobas Liat Analyzer required	12 months when stored at 2-89C. Real-Time stability studies are still underway.
321634	Cepheid	XpertXpress SARS-CoV-2/Flu/RSV	Molecular (Nucleic acid)	multi-analyte POC	Individual suspected of respiratory viral infection consisten with COVID-19 by their healthcare provider	symptomatic	Trained operators proficient in use of GeneXpert systems	Y	NP swabs, nasal swabs, or nasal wash/aspirate	SARS-CoV-2 97.9%, Flu A 100%, Flu B 100%, RSV 100%	SARS-CoV-2 100%, Flu A 100%, Flu B 99.0%, RSV 100%	45 min	Up to 4 in the machine, 1 per cartridge.	No, GeneXpert system required	10 months when stored at 2-28°C. Real-time stability studies are still underway.
320577	Abbott	Panbio NP	Antigen	POC	Individuals who are suspected of COVID-19 by their healthcare provider	Symptomatic	Healthcare professionals who are proficient in performing rapid lateral flow tests	N	NP swab and Nasal	91.40%	99.80%	15 min	1	Yes, stand alone cassette	24 months when stored at 2-30°C. Real-time stability studies are still underway.
318420	Becton Dickinson	Veritor	Antigen	POC	Individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms, or serial testing of asymptomatic populations using the Sofia SARS Antigen FIA test, at a minimum every 3 days/72 hours.	Symptomatic and serial asymptomatic	The BD Veritor System for Rapid Detection of SARS-CoV-2 is intended for use in point of care settings, by laboratory personnel and healthcare providers appropriately trained in the use of the BD Veritor System	N	Nasal Swab	83.9% (Symptomatic; clinical performance has not been established for serial testing)	99.83%	15 min	1	Optional, BD Veritor Analyzer or visual read (expanded use). The visual read cannot be used for serial asymptomatic testing.	12 months when stored at 2-30°C. Real-time stability studies are still underway.
314994	Quidel	Sofia SARS Antigen FIA	Antigen	POC	Individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms, or serial testing of asymptomatic populations using the Sofia SARS Antigen FIA test, at a minimum every 3 days/72 hours.	Symptomatic and serial asymptomatic	Trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using Sofia and Sofia2 instruments	Y	Nasal swab	Symptomatic: 96.7%. Serial asymptomatic: 91.6 %	100.00%	15 min	1	No, Sofia Machine required	24 month shelf life at 15-30°C (amendment 330790 authorized 2021-04-23). Real-time Stability studies are still underway.
324506	Abbott	Panbio nasal	Antigen	POC	individuals who are suspected of COVID-19 by their healthcare provider	Symptomatic	Health care professionals and Trained operators	Y	Nasal swab collected by a Health Care professional or self collected under the supervision of a Health Care professional	91.10%	99.80%	15 min	1	Yes, Stand alone cartridge	24 months when stored at 2-30°C. Real-time Stability studies are still underway.
313054	SD biosensor	Standard Q Covid-19 Ag Test	Antigen	POC	Individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of symptoms.	Symptomatic	In both laboratory and point of care settings by trained laboratory personnel or healthcare professionals	N	NP swab	86.20%	97.93%	15 min	1	Yes, Stand alone cartridge	24 months when stored at 2-30°C. Real-time Stability studies are still underway.
312782	Assure Serology	Assure COVID-19 IgG/IgM rapid test	Serology	POC	Patient Population not specified in IFU	Symptomatic	In both laboratory and point of care settings by trained laboratory personnel or healthcare professionals	N	human whole blood (including venous whole blood and capillary whole blood), serum, or plasma. Only fingerstick blood can be used at the point of care	IgG = 100% ; IgM = 89.3% in fingerstick whole blood samples	100.00%	15 min	1	Yes, Stand alone cartridge	24-month shelf life Real-time Stability studies are still underway
313076	BTNX serology	Rapid Response COVID-19 IgG/IgM rapid test device	Serology	POC	Patient Population not specified in IFU	Symptomatic	In both laboratory and point of care settings by trained laboratory personnel or healthcare professionals	N	human whole blood (including venous whole blood and capillary whole blood), serum, or plasma. Only fingerstick blood can be used at the point of care	IgG = 100 %; IgM = 89.3% in fingerstick whole blood specimens	100% for IgG and 98.1% for IgM	15 min	1	Yes, Stand alone cartridge	24-month shelf life. Real-time Stability studies are still underway
321478	Assure antigen	Covid-19 Antigen Rapid Test Device	Antigen	POC	Individuals suspected of COVID-19 within the first 5 days of symptom onset without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests.	Symptomatic and serial asymptomatic	In both laboratory and point of care settings by trained laboratory personnel or healthcare professionals	N	NP swab and Nasal	93.1% (Symptomatic; clinical performance has not been established for serial testing)	98.30%	15 min	1	Yes, Stand alone cartridge	24 months when stored at 2-30 °C. Real-time Stability studies are still underway.
321669	BTNX Antigen	Rapid Response Covid - 19 Antigen Rapid Test Device	Antigen	POC	from individuals suspected of COVID-19 within the first 6 days of symptom onset and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over two (or three) days with at least 24 hours (and no more than 36 hours) between tests.	symptomatic and serial asymptomatic	In both laboratory and point of care settings by trained laboratory personnel or healthcare professionals	N	nasopharyngeal (NP) or nasal swabs	90.2% (Symptomatic; clinical performance has not been established for serial testing)	100.00%	15 min	1	Yes, Stand alone cartridge	24 monts at 2-30 °C. Real-time Stability studies are still underway.
329037	Lucira	Lucira CHECKIT COVID-19 Test	Molecular (Nucleic acid)	self test	Individuals with or without COVID-19 symptoms aged 14 and older.	Symptomatic and asymptomatic	Over-the-counter self test	N	Self collected nasal swab in ages 14 and older	91.7% (symptomatic and asymptomatic)	98.20%	30 min	1	Yes, stand alone cartidge	9 months shelf-life at 15-30°C (Amendment 332550). Real time stability studies are still underway.
323000	Cue Health	Cue COVID-19 Test	Molecular (Nucleic acid)	self test	Samples should be collected from individuals suspected of COVID-19 infection or exposure, as determined by their healthcare provider	symptomatic and asymptomatic	The Cue COVID-19 Test is intended for use by healthcare providers and operators working in a point of care professional environment as well as self-administration	Y	Nasal swabs or self-collected direct nasal swabs	Point of Care 92%, Self-testing 97.4% (symptomatic and asymptomatic)	Point of Care 98%, Self-testing 99.1%	20 min	1	No, The cue health monitoring system is required	4 months at 15-30°C for the test cartridge. 6 months at 15-30°C for the controls. 12 monts at 15-30°C for the wands. Real-time stability studies are still underway.
318801	Artron Laboratories	COVID-19 IgM/IgG Antibody test	Serology	POC	Patients with suspected SARS-CoV-2 infection	Symptomatic	point-of-care setting by by healthcare professionals trained in the techniques of in vitro diagnostics procedures and proper infection control procedures	N	human serum, plasma, venous whole blood, or finger stick whole blood samples	92.16% (igg) >14 Days	99.75%	15 min	1	Yes, stand alone cartridge	18 months at 2-30°C. Real time stability studies are still underway.
328889	SD biosensor Nasal	SARS-COV-2 RAPID ANTIGEN TEST NASAL AND STANDARD Q-COVID-19 AG TEST	Antigen	POC	Individuals suspected of COVID-19 with clinical symptoms onset within 5 days.	Symptomatic	Laboratory or point-of-care setting by healthcare professionals	N	Nasal swabs, and self collected nasal swabs under the supervision of an Health Care Professional	professionally collected specimens 86.7%; self-collected specimen under the supervision of a HCP: 88.9%	professionally collected specimens 99.1%; self-collected specimen under the supervision of a HCP: 99%	15 min	1	Yes, stand alone cartridge	15 months at 2-30°C. Real time stability studies are still underway
321882	Quidel	SOFIA 2 FLU+SARS ANTIGEN FIA	Antigen	multi-analyte POC	Individuals suspected of respiratory viral infection with clinical symptoms onset within 5 days	Symptomatic	Laboratory or point-of-care setting by health care professionals or trained operators	Y	Nasal swabs	FluA: 100%; FluB: 100%; SARS-CoV-2: 95.2%	Flu A was 96.6% ; Flu B was 98.2% ; SARS-CoV-2: 100%	15 min	1	No, sofia analyzer required	24 months at 15-30°C. realtime stability studies are still under way.
322914	Quidel	Quickvue SARS Antigen Test	Antigen	POC	individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over 2 (or 3) days with at least 24 hours (and no more than 36 hours) between tests	symptomatic and serial asymptomatic	Trained clinical laboratory personnel and individuals proficient in performing the test	Y	Nasal	96.6% (Symptomatic; clinical performance has not been established for serial testing)	99.30%	10 min	1	Yes, stand alone cartridge	24 months shelf-life at 15°C to 30°C. Real time stability studies are still underway.
326827	Princeton Biomeditech Corp.	Status COVID-19/flu	Antigen	multi-analyte POC	Individuals who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider, within the first five days of onset of symptoms	Symptomatic	Medical professionals and laboratory personnel trained to perform the test	N	Nasal or NP	SARS CoV-2 = 93.1%; Influenza A = 100%; Influenza B = 100%	SARS CoV-2 = 100%; Influenza A = 100%; Influenza B = 100%	15 min	1	Yes, stand alone cartridge	12 months at 2°C to 30°C. Real time stability studies are still underway.
332680	Becton Dickinson	Bd Kit For Rapid Detection Of SARS-CoV-2	Antigen	POC	Individuals who are suspected of COVID-19 by their healthcare provider, within the first 5 days of the onset of symptoms	Symptomatic	Healthcare professionals	N	Nasal	84.00%	99.00%	15 min	1	Yes, stand alone cartridge	10 months at 2°C to 30°C. Realtime stability studies are underway
331681	Quidel	Quickvue At-home Otc COVID-19 Test	Antigen	self test	individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests	Symptomatic and serial asymptomatic	self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older	Y	Self-collected (unobserved) Nasal swab specimens from individuals aged 14 years and older or with adult-collected Nasal samples from individuals aged 2 years or older	81.3% (Symptomatic; clinical performance has not been established for serial testing)	99.30%	10 min	1	Yes	24 monthes at 15°C-30°C. Realtime stability studies are still underway.
333567	Ellume	Ellume COVID-19 Home Test	Antigen	self test	individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection	Symptomatic and asymptomatic	Home Test is authorized for non prescription home	Y	nasal swabs that are self-collected by an individual aged 16 years or older or are collected by an adult from an individual 2 years of age and olde	95% (symptomatic and asyhmptomatic)	97.00%	15 min	1	Smart Phone required	12 months at 2°C to 30°C. Real-time stability studies are still underway.