Table S1: Selected direct POCT (antigen/RNA) - WHO TPP Criteria

	World Health Organization v.1.0		FDA EUA Selected Direct (antigen/RNA) POCT (performance based on manufacturer's claims)							...ed Direct (antigen/RNA) POCT (performance based on independent		
	Acceptable	Desirable	BinaxNOW COVID-19 Ag Card	Sofia 2 Flu+SARS Antigen FIA	LumiraDx SARS-CoV2 Ag Test	COVID-19 Home Test	MobileDetect Bio BCC19 Test (RT-LAMP)	AQ-TOP Plus COVID-19 Rapid Test (RT-LAMP)	SARS-CoV-2 Detectr Test (RT-LAMP)	Bioeasy Diagnostic kit - COVID-19 Ag test	Sofia 2 SARS Antigen FIA	Standard Q Covid-19 Ag FIA
Manufacturer			Abbott	Quidel Corporation	LumiraDx	Ellume	DetectaChem Inc.	SEASUN BIOMATERIALS, Inc.	Mammoth Biosciences, Inc.	Shenzhen Bioeasy Biotechnology Co.,Ltd.	Quidel Corporation	SD Biosensor, INC.
Country			USA	USA	UK / USA	Australia	USA	Korea	USA	China	USA	Korea
URL			https://dam.abbott.com/en-us/homepage/coronavirus/BinaxNOW-Fact-Sheet-Final.pdf	https://www.quidel.com/immunoassays/sofia-2-flu-sars-antigen-fia	https://www.lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antigen-test	https://www.ellumehealth.com	https://mobiledetectbio.com/	http://www.seasunbio.com/english/products4.html	https://mammoth.bio/covid/	http://en.bioeasy.com/?p=1038	https://www.quidel.com/immunoassays/sofia-2-flu-sars-antigen-fia	http://sdbiosensor.com/xe/product/7672
Intended Use	1) In areas with confirmed SARS-CoV-2 community wide transmission or confirmed outbreaks in closed or semi-closed communities and in high risk groups; 2) In suspected SARS-CoV-2 outbreak situations; 3) Monitor trends in disease incidence		qualitative detection of SARS-CoV-2 antigen in patient care setting; POCT	qualitative detection of SARS-CoV-2 antigen in patient care setting; POCT	qualitative detection of SARS-CoV-2 antigen in patient care setting; POCT	qualitative detection of SARS-CoV-2 antigen; non-prescription home use	qualitative detection of SARS-CoV-2 RNA	qualitative detection of SARS-CoV-2 RNA	qualitative detection of SARS-CoV-2 RNA	qualitative detection of SARS-CoV-2 in patient care setting; POCT	qualitative detection of SARS-CoV-2 in patient care setting; POCT	qualitative detection of SARS-CoV-2 in patient care setting; POCT
Target Population / patient	patients with respiratory symptoms or fever or other symptoms (diarrhoea, anosmia) and either a known contact with a confirmed or probable COVID-19 patient OR living in an area of cluster OR community transmission, and close contact of index patients (confirmed COVID-19 patients)		individuals suspected of COVID-19 within 7 days of sympton onset	individuals suspected of COVID-19 within 5 days of sympton onset	individuals suspected of COVID-19 within 12 days of sympton onset	individuals suspected of COVID-19	individual suspected of COVID-19	individual suspected of COVID-19	individual suspected of COVID-19	individual suspected of COVID-19	individuals suspected of COVID-19 within 5 days of sympton onset	post
Target use setting	outside laboratories including routien screening points of health care facilities to health care workers or lab techs with appropriate training to use the test.	same as acceptable but can be self-administered and/or performed by trained lay workers (volunteer, community health workers)	patient care setting; CLIA certified labs	patient care setting; CLIA certified labs	patient care setting; CLIA certified labs	non-prescription home use	certified laboratories	certified laboratories	certified laboratories	not specified (patient care setting / labs)	patient care setting; CLIA certified labs	not specified (patient care setting / labs)
Target molecule	SARS-CoV biomarker (RNA, antigen) specific for acute (first week after onset of symptoms/current infection)	SARS-CoV-2 only biomarker specific for acute and subacute (first 2 weeks after onset of symptoms/current infection)	SARS-CoV-2 nucleocapsid protein (and SARS-CoV)	SARS-CoV-2 nucleocapsid protein	SARS-CoV-2 nucleocapsid protein	SARS-CoV-2 & SARS-CoV nucleocapsid protein	SARS-CoV-2 N and E genes	SARS-CoV-2 ORF1ab and N genes	SARS-CoV-2 N genes	n/a	SARS-CoV-2 nucleocapsid protein	SARS-CoV-2 nucleocapsid protein
Analytical sensitivity / LOD	~ 10^6 genomic copies/ml	~ 10^4 genomic copies/ml	22.5 TCID$_{50}$/swab (1125 TOD50/ml)	113 TCID$_{50}$/ml	32 TCID$_{50}$/ml	6310 TCID$_{50}$/ml	75 copies/µl	1 copies/µl	20 copies/µl	n/a	113 TCID50/ml	494.5 TCID50/ml
Analytical specificity	detects all SARS-CoV-2 viral strains and dose not react with other human coronavirus (except SARS-CoV-1) or any other common diseases with similar symptoms (influenza A, B, RSV, malaria, dengue)	detects all SARS-CoV-2 virla strains and dose not cross react with other human CoV or common diseases with similar symptoms	no cross-reactivity in a panel of high prevalence respiratory pathogens	no cross-reactivity in a panel of high prevalence respiratory pathogens	no cross-reactivity in a panel of high prevalence respiratory pathogens	no cross-reactivity in a panel of high prevalence respiratory pathogens	no cross-reactivity in a panel of high prevalence respiratory pathogens	no cross-reactivity in a panel of high prevalence respiratory pathogens	no cross-reactivity in a panel of high prevalence respiratory pathogens	n/a	no cross-reactivity in a panel of high prevalence respiratory pathogens	n/a
Sensitivity (or PPA)	≥ 80%	≥ 90%	97.1% (85.1 - 99.9)	96.7((83.3-99.4)	97.6% (91.6-99.3)	95% (82-99)	97.7% (88-100)	100% (91-100)	95% (83.5.98.6)	93.9% (86.5-97.4)	93.8% (79.2-99.2)	90.6% (75-98)
Specificity (or NPA)	≥ 97%	≥ 99%	98.5% (92.0-100%)	100% (97.9-100)	96.6% (92.7-98.4)	97% (93-99)	100% (94.3-100)	100% (94-100)	100% (94.2-100)	100% (92.1-100)	96.9% (83.8-99.9)	96.9% (83.8-99.9)
Type of analysis	qualitative (yes/no), semi-quantitative, or quantitative	N/A	lateral flow immunoassay	lateral flow immunofluorescent	microfluidic immunofluorescence	lateral flow immunofluorescent	RT-LAMP	RT-LAMP	CRISPR-based RT-LAMP	fluorescent immunochromatographic, double antibody sandwich rxn	lateral flow immunofluorescent	fluorescent immunoassay
Interpretation	visual manual and/or hardware reader (proprietary or smart phone)	visual manual read or digital readout via smartphone app reader with connectivity	visual manual read	digital readout	digital readout	digital readout (smartphone)	visual color recognition	digital readout	digital readout	digital reader, fluorescence analyzer	digital readout	digital readout
Sample type	nasopharyngeal, oropharyngeal, nasal swab, nasal wash, sputum	anterior nares (swab), saliva/oral fluid, sputum	nasal swab	nasal swab	nasal swab	nasal swab	nasal swab	nasal swab; BAL	nasal swab / wash	nasal swab	nasal swab	nasal swab
Sample collection device	compatible with an existing swab material	compatible with multiple swab materials (self-collection or no swab e.g. saliva)	swabs in the kit ONLY	swabs in the kit ONLY	recommended swab (not included)	swabs in the kit ONLY	recommended swab (not included)	recommended swab (not included)	recommended swab (not included)	not provided	swabs in the kit ONLY	swab provided in kit
End use profile	trained staff in health care facilities	trained staff or community level (lay person) or self-administered	medical professional or trained staff in certified patient care setting	trained clinical laboratory personnel and individuals trained in point of care settings	trained clinical laboratory personnel and individuals trained in point of care settings	home use	trained lab personnel	trained lab personnel	trained lab personnel	trained medical / lab operator	trained clinical laboratory personnel and individuals trained in point of care settings	professional use
Training needs	0.5 days with instructions for use and quick reference guide(s)	2hr with instructions, quick reference guide including smart phone app(s)	N/A (procedure card included)	N/A	N/A	no	Yes	Yes	Yes	n/a	N/A	n/a
Sample preparation steps	1	0	1	1	1	1	1	1	1	1	1	1
Reagents reconstitiuon	very simple reconstituon	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use
Sample min volume	single swab and minimal extraction buffer/diluent		single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer	single swab + extraction buffer
Need to transfer a precise volume of sample	autofill or graduated volume markings on sample transfer device	no, or limited to a number of drops	no, few drops	no, few drops	no, few drops	no, few drops	pipette fixed volumes	pipette fixed volumes	pipette fixed volumes	no, few drops	no, few drops	no, few drops
Number of timed steps	≤ 3	1, with the potential for digitally guided workflows and built-in timers to reduce user errors on timed steps	1	1	1	1	2	2	2	1 (automatic by analyzer)	1	1
Time to result	≤ 40 min	≤ 20 min	15min	15min	12min	15min	30min	30min	45min	10min	15min	30min
Sample stability pre-testing	30min (10-35oC); 2-4hr (4-8oC); several days frozen (min -20oC)	test compatible with both dry and preserved samples; 3hr (10-40oC); 24hr (4-8oC); months frozen	<1hr room temp	48hr room temperature or 2-8oC	5hr room temp; 5 days frozen 80oC	n/a	n/a	n/a	n/a	<24hr at 2-8OC; or -70oC long-term	48hr room temperature or 2-8oC	24h room temperature; 2-8oC for 48hr
Result validity stability	fixed reading time	stored image or 6 weeks	<30min	<30min	n/a	n/a	n/a	n/a	n/a	n/a	<30min	n/a
Invalid rate	<2% invalid results with correct use by operator	<0.5% invalid results with correct use	n/a	n/a	n/a	8%	n/a	n/a	n/a	n/a	n/a	n/a
Operating conditions	15-35oC, 25-80% RH up to 1500m	10-40oC, 25-90% RH up to 3000m	Room temperature	room temperature	10-30 oC; RH 10-90%	room temperature	room temperature	room temperature	room temperature	2-35oC; RH 40-90%	room temperature	room temperature
Test kit stability and storage	12mo 4-30oC; tolerates brief period >40oC; RH 75%	18-24mo at 4-40oC; tolerates freezing and brief period >40oC; RH 75%	2-30oC (use immediately)	room temperature, 15-30oC	2-8oC	2-30oC	freeze at -20oC	freeze at -20oC	freeze at -20oC	2-30 oC	room temperature, 15-30oC	room teperature (2-30oC)
Stability of kit once opened	30min	1hr	N/A	12hr	30 day	60min	n/a	n/a	n/a	60min	12hr	n/a
Specimen capacity & throughput	>5/hr per operator	>10/hr per operator	n/a	n/a	n/a	n/a	n/a	n/a	1500 sample in 8hr	n/a	n/a	n/a
Safety precautions	standard respiratory sample collection safety precautions recommended;	tests that minimize the need for biosafety requirement are strongly preferred (e.g. with a self-sample collection device with virus inactivation)	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions	standard respiratory sample precautions
Quality control	internal control (for sample flow/migration); positive and negative controls sold separately;	internal control; lyophilized positive control and negative control provided in the kit;	internal control; pos/neg control	internal control; pos/neg control	internal control; pos/neg control	internal control	internal control; pos/neg control	internal control; pos/neg control	internal control; pos/neg control	internal control	internal control; pos/neg control	internal control; pos/neg controls separate
Remote connectivity capacity	not required for reader independent tests; if device-based: remote export of data possible	test is compatible with readers and other data capture devices; internal memory to store results even if power cut and with the ability to report to country health information management systems using on onboard unique identifier or other personal data protection safetguard linking the test to the user.	no	n/a	optional	Smartphone compatible	n/a	n/a	n/a	n/a	n/a	n/a
Need for additional equipment	handheld or on desktop (<1kg); battery or solar power operated; >8hr rechargable battery life	no additional equipment required, but if required, it should have potential for digital connectivity through smartphone applications	no	Sofia / Sofia 2 instrument	LumiraDx Instrument (portable)	Smartphone	MD-Bio Heater (or thermal cycler)	CFX 96 PCR system	CFX 96 PCR system	Yes, fluorescece analyzer	Sofia / Sofia 2 instrument	Standard F Analyzer
Need for maintenance/spare parts	none, swap out or replace ancillary device when needed	none required as device-free	n/a	n/a	n/a	n/a	n/a	n/a	n/a	none required	n/a	n/a
Waste/disposal requirements	routine biohazard waste	not applicable	biohazard waste	biohazard waste	biohazard waste	General waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste
Manufacturing	ISO 13485: 2016 compliant	WHO or stringent regulatory authority emergency use listing/authorization or WHO prequalification or other stringent regulatory authority approval	FDA EUA	FDA EUA	FDA EUA	FDA EUA	FDA EUA	FDA EUA	FDA EUA	CE	FDA EUA	CE
Accessibility		to maximize accessiblity, all product manufacturers should have the capability to rapidly scale-up production and offer the product at a cost that allows borad use, including in low- and middle-income countries.	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Table S2: Selected indirect POCT (antibody) - WHO TPP Criteria

	World Health Organization v.1.0		FDA EUA Selected Antibody POCT													FIND Selected Antibody POCT							
	Acceptable	Desirable	COVID-19 IgG/IgM Rapid Test	Wantai SARS-CoV-2 Ab Rapid Test	RightSign COVID-19 IgG/IgM Rapid Test	LYHER COVID-19 IgM/IgG Combo Test	healgen COVID-19 IgG/IgM Rapid Test	Orawell IgM/IgG Rapid Test	Rapid COVID-19 IgM/IgG Combo Test	COVID-19 IgM/IgG Antibody Detection Kit	SGTi-flex COVID-19 IgG	SARS-CoV-2 IgG/IgM Rapid Test	COVID-19 IgM/IgG Gold	AllTest COVID-19 IgG/IgM Rapid Test	COVID-19 IgG/IgM Rapid Test	Healgen COVID-19 IgM/IgG Rapid Test	COVID-19 IgM/IgG Rapid Test	Wondfo SARS-CoV-2 Ab Test	AMP Rapid SARS-CoV-2 IgM/IgG Test	SARS-CoV-2 IgM/IgG Rapid Test	NG IgG/IgM Rapid Test
Manufacturer			Assure Tech. (Hangzhou) Co., Ltd.	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Hangzhou Biotest Biotech Co., Ltd.	Hangzhou Laihe Biotech Co., Ltd	Verify Diagnostics	Jiangsu Well Biotech Co., Ltd.	Megna Health Inc.	Nirmidas Biotech	Sugentech, Inc.	Xiamen Biotime Biotechnology Co., Ltd	Technogenetics srl	Hangzhou Alltest Biotech Co., Ltd.	VivaChek Biotech (Hangzhou) Co., Ltd.	Verify Diagnostics	BioMedomics, Inc.	Guangzhou Wondfo Biotech Co., Ltd, China	AMEDA Labordiagnostik GmbH	MEDsan GmbH	NG Biotech Laboratoires
Country			China	China	China	China	USA	China	USA	USA	Korea	China	Italy	China	China	USA	USA	China	Austria	Germany	France
URL																					
Intended Use	easy to use test that can be used at the POC to detect prior SARS-CoV-2 infection		POC in patient care setting; Labs; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	professional use only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use	for professionals only; not home use
Target Population / patient	General population involved in survey; groups at high risk of exposure to		general population	general population	general population	general population	general population	general population	general population	general population	general population	general population		general population	general population	general population	general population	general population	general population	general population	general population
Target use setting	outside labs; health facilities; community settings; by health care workers or lab techs	same as acceptable + can be performed by trained lay workers	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.		trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.	trained lab personnel; not home use.
Target molecule	at least one isotype; other biomarkers specific to prior infection		NP, Spike	Spike	spike RBD domain	S1 spike domain	S1 spike domain	spike RBD domain	NP	S1 & RBD domains of Spike	NP & Spike RBD	spike			S1 spike domain						
Analytical sensitivity / LOD	currently no standard/units to express LOD; min detectable concentration of analyte	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Analytical specificity	detect only SARS-CoV-2 specific isotype or biomarker	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sensitivity (PPA)	>90%	>95%	100% (88.7-100)	100% (88.7-100)	100% (95.4-100)	100% (88.7-100)	100% (88.7-100)	100% (93.8-100)	100% (88.7-100)	100% (88.3-99.1)	96.7% (83.3-99.4)	100% (88.7-100)	99.2% (95.4-100)	98.1% (89.9-100)	97.30%	97% (82.8-100)	97% (92.3-100)	100% (83.9-100)	95.7% (90.8-98.4)	95.1% (83.5-99.4)	96.9% (93.9-90.6)
Specificity (NPA)	>97%	>99%	98.8% (93.3-99.8)	98.8% (93.3-99.8)	100% (95.4-100)	98.8% (93.3-99.8)	97.5% (91.3-99.3)	94.8% (88.5-97.8)	95% (87.8-98)	97.9% (92.6-99.4)	100% (95.4-100)	96.2% (89.5-98.7)	98.2% (96.1-99.5)	100% (83.9-100)	100%	97.5% (91.1-99.7)	97.3% (90.1-99.7)	100% (83.9-100)	97.4% (86.2-99.9)	98% (89.4-100)	100% (92.9-100)
Type of analysis	qualitative	n/a	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow	qualitative; lateral flow
Interpretation	visual; portable automated reader	visual - device free	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual	visual
Sample type	plasma; serum;		whole blood; serum/plasma; fingerstick blood	whole blood; serum/plasma; fingerstick blood	whole blood; serum/plasma	serum/plasma	whole blood; serum/plasma; not fingerstick blood	whole blood; serum/plasma; not fingerstick blood	serum/plasma	serum/plasma	venous blood, serum, plasma (not fingerstick)	venous blood, serum, plasma (not fingerstick)		whole blood (fingertip/venous), serum, plasma	whole blood (fingertip/venous), serum, plasma	whole blood; serum/plasma; not fingerstick blood	whole blood (capillary, venous), serum, plasma	whole blood/serum/plasma	whole blood/serum/plasma	whole blood (fingerstick), serum, plasma	whole blood (fingerstick), serum, plasma
Test kit format	kit contains material for sample collection	same plus controls	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included		internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included	internal control; pos/neg control not included
End use profile	Health care facility worker	Lay person / non-professional staff	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel		trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel	trained lab personnel
Training needs	<0.5 days	<2hr (quick reference)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sample preparation steps	1	0				0	1 (separate plasma/serum)	0		0	1 (separate plasma/serum)	1 (separate plasma/serum)		0			0			0	
Reagents reconstitution	if very simple to do	no, ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use		ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use	ready to use
Need to transfer a precise volume of sample	if autofill or volume marking	no or a few drops	fill line	10ul	10ul	fill line (10ul)	10ul	fill line (5ul)	fill line (10ul)	fill line (10ul)	10ul	one drop (10-15ul)		10ul (fill line)	10ul (fill line)	fill line (5ul)	15ul blood; 10ul serum/plasma	n/a	10ul whole blood, 5ul serum/plasma	10ul (fill line)	n/a
Number of timed steps	<2	1				1			1			1					1				
Time to result	<40min	<20min	15min	15min	10min	10min	10min	10min	10min	10min	10min	20min		10min	15min	10min	10min	15min	10min	10min	15min
Sample stability pre-testing	30min RT (10-35oC); 8hr (2-8oC)	3hr RT (10-35oC); 24hr (2-8oC)	whole blood 3 days at 2-8oC; serum/plasma 7 days 2-8oC	serum/plasma 7 days 2-8oC or 3 wks -15oC; whole blood used immediately	serum/plasma 3 days at 2-8oC; 20oC for longer-term; whole blood 2 days at 2-8oC; do not freeze blood	2-8oC for 2 days; <-20oC long-term	serum/plasma at 2-8oC; 20oC for 1mo; whole blood 2 days at 2-8oC; do not freeze blood	serum/plasma 2-8oC for 5 days; -70oC for longterm	serum/plasma <3 days at 2-8oC; -20oC for <3mo; -70oC longterm;	4-8oC <3 days; -20oC <1 mo;	2-8oC <5 days; -70oC longterm;	serum/plasma <14 days at 2-8oC; -20oC for <3mo; whole blood 2-8oC <3 days;		serum/plasma 7 days at 2-8oC; 20oC for long-term; whole blood 2 days at 2-8oC; do not freeze blood		serum/plasma 3 days at 2-8oC; 20oC for 1mo; whole blood 2 days at 2-8oC; do not freeze blood	anticoagulated blood 2-8oC for 5 days; serum/plasma 20&oC 5 days or -20oC longterm;		serum/plasma 3 days at 2-8oC; 20oC for longterm; whole blood 2 days at 2-8oC; do not freeze blood	
Result validity stability	fixed reading time	stored images or 6 weeks	30min	20min	20min	n/a	15min	20min	15min	20min	30min	30min		20min	20min	15min	15min	15min	n/a	15min	n/a
Invalid rate	<5% invalid results with correct use	<1% invalid results with correct use	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Operating conditions	15-35oC; 20-80% RH; altitude 1500m	10-40oC; 25-90% RH; altitude 3000m	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature		room temperature	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature	room temperature
Test kit stability and storage	12mo, 2-30oC, 70% RH;	18-24mo, 2-40oC, 90% RH	2-30oC;	2-30oC for 9mo	2-30oC;	2-30oC, dark	2-30oC;	2-8oC <3mo;	4-30oC;	4-25oC	3-8oC	5mo at RT; 9mo at 2-8oC		2-30oC;	2-30oC;	2-30oC;	2-30oC;	2-30oC;	2-30oC;	2-30oC;	2-30oC;
Stability of kit once opened	1hr	4hr	1hr	0.5hr	1hr	0.5hr	1hr	2-8oC <7 days	use immediately	15min	30 days at 2-8oC	use immediately		1hr	1hr	1hr	1hr	n/a	n/a	n/a	n/a
Specimen capacity & throughput	>5/hr per operator	>10/hr per operator	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Safety precautions	standard blood collection safety precautions		standard	standard	standard	standard	standard	standard	standard	standard	standard	standard		standard	standard	standard	standard	n/a	standard	standard	n/a
Quality control	internal control (sample flow/migration); positive / negative controls sold separately	internal control; lyophilized positive/negative controls provided	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional			internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	internal control; positive, negative controls optional	n/a	internal control; positive, negative controls optional	internal control; positive, negative controls optional	n/a
Remote connectivity capacity	device-based: remote export of data possible; no device: export through separate 3rd party reader	test is compatible with readers and other data capture devices	no	no	no	no	no	no	no	no	no	no		no	no	no	no	n/a	n/a	n/a	n/a
Need for additional equipment	handheld <1kg; battery or solar power; >8hr rechargeable battery life	no additional equipment	no	no	no	no	no	no	no	no	no	no		no	no	no	no	n/a	n/a	n/a	n/a
Need for maintenance/spare parts	none, swap out or replace device	none required as device free	no	no	no	no	no	no	no	no	no	no		no	no	no	no	n/a	n/a	n/a	n/a
Waste/disposal requirements	standard biohazardous waste disposal	small environmental footprint; recyclable or compostable plastic	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste	biohazard waste		biohazard waste	biohazard waste	biohazard waste	biohazard waste	n/a	biohazard waste	biohazard waste	n/a
Accessibility	to maximise accessibility, all product manufacturers should have the capability to rapidly scale-up production and offer the product at a cost that allows broad use, including in low- and middle-income countries.		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a