Fastep COVID-19 IgG/IgM Rapid Test Device

For Emergency Use Authorization Only
For prescription use only
For in vitro Diagnostic Use Only.

Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

INTENDED USE

The Fastep COVID-19 IgG/IgM Rapid Test Device is a rapid lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, plasma (sodium EDTA) and fingerstick whole blood. The Fastep COVID-19 IgG/IgM Rapid Test Device is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Fastep COVID-19 IgG/IgM Rapid Test Device should not be used to diagnose acute SARS-CoV-2 infection.
Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS-CoV-2 antibodies. The IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.
Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
The sensitivity of Fastep COVID-19 IgG/IgM Rapid Test Device early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
False positive results for Fastep COVID-19 IgG/IgM Rapid Test Device may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.
The Fastep COVID-19 IgG/IgM Rapid Test Device is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, rumny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The Fastep COVID-19 IgG/IgM Rapid Test Device is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antibodies in venous whole blood, serum or plasma. This test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The conjugate pad contains recombinant SARS-CoV-2 antigen (antigen is recombinant Nucleocapsid Protein and Spike Protein (S1)) conjugated with colloid gold.
During testing, the specimen binds with SARS-CoV-2 antigen- conjugated gold colloid coated particles in the test cassette. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a red line which confirm a reactive test result. Absence of a red line in the test region indicates a non-reactive test result.
To serve as a procedural control, a red line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
The presence of a red band(s) on the test region(s) indicates a positive result for the particular IgG and/or IgM antibodies, while its absence indicates a negative result. A red band at the control region (C) serves as a procedural control, indicating that membrane wicking is working.

REAGENTS AND MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Buffer
- Package insert
- Sterile safety lancet
- Alcohol Prep pad

Optional Materials

- External Negative and Positive control (Available upon request)

External Negative and Positive Control

Negative controls are lyophilized human serum samples and positive controls are lyophilized IgG and IgM against SARS-CoV-2. Two negative control vials are supplied. Reconstitute each negative control vial with 30 μL purified water. Transfer one reconstituted 30 μL negative control to the positive control vial to make ready-to-use positive control. Controls can be used like a serum sample. Store reconstituted controls at 4℃.

Materials Required but Not Provided

- Clock, timer, or stopwatch
- Specimen collection container

WARNING AND PRECAUTIONS

- For use under an Emergency Use Authorization Only.
- For *in* vitro Diagnostic Use Only.
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed.Erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield erroneous test result.
- Avoid skin contact with buffer containing sodium azide which is a skin irritant.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- Store the Fastep COVID-19 IgG/IgM Rapid Test Device at 2~30℃when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.
- Perform testing immediately after specimen collection. Serum and plasma specimens may be stored at 2-8℃ for up to 7 days. For long term storage, serum or plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 3 days after collection. Do not freeze whole blood specimens.
- Containers containing anticoagulants such as sodium EDTA, should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen serum or plasma specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

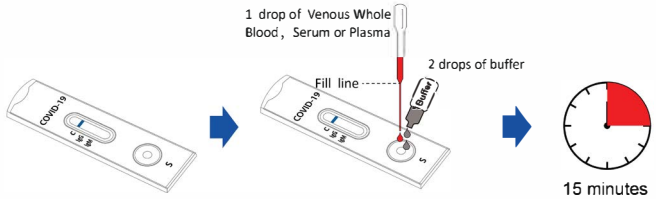
TESTPROCEDURE

Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30℃) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. **Note:There should be a blue line in the control region (next to "C"), discard the device if there is no blue line.**
3. Label the test with patient or control identification.
4. Add the specimens.

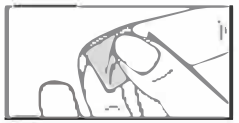
For Venous Whole Blood Specimens, Serum or Plasma Specimens

a) Using the provided disposable pipette, draw the specimen above the fill line (avoid the specimen entering the bubble of disposable pipette) and transfer one drop of the specimen into the specimen well of the test device, then add 2 drops of buffer and start the timer. Adding more or less drops of specimen may lead to incorrect results. Adding 1 drop of buffer or more than 4 drops of buffer may lead to incorrect results.

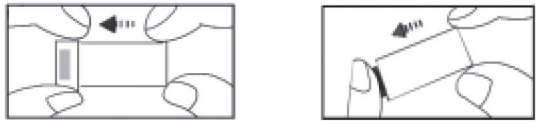


For Fingerstick Whole Blood

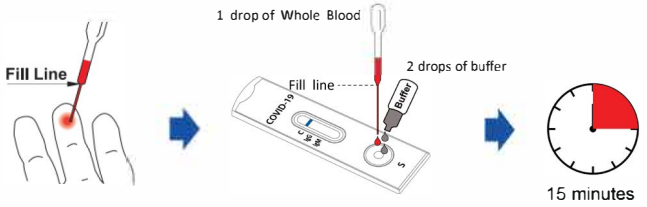
a) Clean the puncture site with the alcohol prep pad provided



b) Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.



c) Using the provided disposable pipette, draw the specimen above the fill line(avoid the specimenentering the bubble of disposable pipette) and transfer one drop (equivalent to 10μL) of the specimen into the specimen well of the test device, then add 2 drops of buffer and start the timer. Adding more or less drops of specimen may lead to incorrect results. Adding 1 drop of buffer or more than 4 drops of buffer may lead to incorrect results.



5. Wait for the blue line change to red line,read results at 15 minutes.
Note: Do not read results earlier than 15 minutes or after 30 minutes
Specimens can also be applied using a micropipette.

RESULT INTERPRETATION

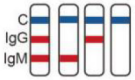
For Fastep COVID-19 IgG/IgMTest:

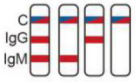
IgM and IgG Positive:*The colored line in the control region (C) changesfrom blue to red, and two colored lines should appear in IgG and IgM test regions. The color intensities of the lines do not have to match. The result is positive for IgM and IgG antibodies.

IgG Positive:*The colored line in the control region (C) changes from blue to red, and a colored line appears in the IgG test region. The result is positive for COVID-19virus specific-IgG antibodies.

IgM Positive:*The colored line in the control region (C) changesfrom blue to red, and a colored line appears in the IgM test region. The result is positive for COVID-19 virus specific-IgM antibodies.

Negative: The colored line in the control region (C) changes from blue to red. No line appears in IgM or IgG test regions.





Invalid: Control line (C) is still completely or partially blue, and fails to completely change from blue to red. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Procedural Controls

The Fastep COVID-19 IgG/IgM Rapid Test Device has built-in (procedural) controls.Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the blue band should be always located at the "C" region before testing, and the red band should be always present before result interpretation.

External Positive and Negative Controls

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

LIMITATIONS OF THE TEST

For use under an Emergency Use Authorization Only

1. Use of the Fastep COVID-19 IgG/IgM Rapid Test Device is limited to laboratory personnel who have been trained. Not for home use.
2. The Fastep COVID-19 IgG/IgM Rapid Test Device is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antibodies in venous whole blood, fingerstick whole blood, serum or plasma specimens only. Neither quantitative value nor the rate of increase in SARS-CoV-2 antibody concentration can be determined by this qualitative test.
3. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
4. Reading test results earlier than 15 minutes after the addition of Buffer may yield erroneous results. Do not interpret the results after 30 minutes.
5. Adding more or less than 1 drop of specimen may lead to erroneous results.
6. Adding 1 drop of buffer or more than 4 drops of buffer may lead to erroneous results.
7. The Fastep COVID-19 IgG/IgM Rapid Test Device will only indicate the presence of SARS-CoV-2 antibodies in the specimen and should not be used for the diagnosis of acute SARS-CoV-2. A molecular assay should be used to evaluate symptomatic patients for acute COVID-19.
8. In the early onset of symptom, anti-SARS-Cov-2 IgM and IgG antibody concentrations may be below detectable levels.
9. *SARS-CoV-2 IgG antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days.*
10. A high dose "hook effect" may occur where the color intensity of test band decreases as the concentration of anti-SARS-CoV-2 IgG/IgM increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the test band.
11. Results from immunosuppressed patients should be interpreted with caution.
12. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
13. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Antibodies may not be detected in the first few days of infection; the sensitivity of the Fastep COVID-19 IgG/IgM Rapid Test Device early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
14. It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
15. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
16. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
17. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
18. Not for the screening of donated blood.

The sensitivity of the test is impacted after being open for one hour-the intensity of the T line becomes weak. Testing must be performed within one hour after opening the pouch.

Conditions of Authorization for the Laboratory

The Fastep COVID-19 IgG/IgM Rapid Test Device Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and other authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

Authorized laboratories using the Fastep COVID-19 IgG/IgM Rapid Test Device ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product will include the test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including theauthorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materialsrequired to use your product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH（via email: CDRH-EUA-Reporting@fda.hhs.gov）and Assure Tech (Hangzhou Co., Ltd). (via email: contact@direagent.com) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Assure Tech. (Hangzhou Co., Ltd)**,** authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Study I

Total of 61 positive and 105 negative serum or venous whole blood samples were collected at 4 different study sites. These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Fastep COVID-19 IgG/IgM Rapid Test device for antibodies. The obtained PPA/sensitivity and NPA/specificity results are summarized in following tables.

Table 1. IgG/IgM PPAfor the Fastep COVID-19 IgG/IgM Rapid Test Device

Site	Days from symptom	# PCR Positive	IgG (Assure Device)			IgM (Assure Device)		
			Antibody Positive	PPA	95%CI	Antibody Positive	PPA	95%CI
(Site 1+3+4) Serum	0-7 days	8	7	87.5%	52.9%-97.8%	8	100%	67.6%-100%
	8-14 days	15	13	86.7%	62.1%-96.3%	13	86.7%	62.1%-96.3%
	≥15 days	25	25	100%	86.7%-100%	21	84%	65.3%-93.6%
(Site 2) Venous Whole Blood	0-7 days	1	1	100%	20.7%-100%	1	100%	20.7%-100%
	8-14 days	3	3	100%	43.9%-100%	3	100%	43.9%-100%
	≥15 days	9	9	100%	70.1%-100%	9	100%	70.1%-100%

Table 2. IgG/IgM NPA for the Fastep COVID-19 IgG/IgM Rapid Test Device

Site	# PCR Negative	IgG (Assure Device)			IgM (Assure Device)		
		Antibody Negative	NPA	95%CI	Antibody Negative	NPA	95%CI
(Site 1+3+4) Serum	96	96	100%	96.2%-100%	94	97.9%	92.7%-99.4%
(Site 2) Venous Whole Blood	9	9	100%	70.1%-100%	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	105	105	100%	96.5%-100%	103	98.1%	93.3%-99.5%

The NPA/specificity of the Fastep COVID-19 IgG/IgM Rapid Test Device for IgG/IgM is 99.04%.

Study II: Independent Clinical Agreement Validation

The COVID-19 IgG/IgM Rapid Test Device from Assure Tech. (Hangzhou) Co., Ltd. was tested on 2020-06-15 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples was confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the Fastep COVID-19 IgG/IgM Rapid Test Device. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Testing was performed by one operator using one lot of the Fastep COVID-19 IgG/IgM Rapid Test Device. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the Tables 3 and 4 below.

Table 3. Summary Results

Fastep COVID-19 IgG/IgM Rapid Test Device		Comparator Method			Total
		Positive (IgM/IgG) +	Negative (IgM/IgG) -	Negative, HIV+	
Positive	IgM+/IgG+	27	0	0	27
	IgM+, IgG-	3	1	0	4
	IgM-, IgG+	0	0	0	0
Negative	IgM-/IgG-	0	69	10	79
Total (n=110)		30	70	10	110

Table 4. Summary Statistics

Measure	Estimate	Confidence Interval
IgM+ Sensitivity (PPA)	(30/30) 100%	(88.7%; 100%)
IgM- Specificity (NPA)	(79/80) 98.8%	(93.3%; 98.8%)
IgG+ Sensitivity (PPA)	(27/30) 90.0%	(74.4%; 96.5%)
IgG- Specificity (NPA)	(80/80)100%	(95.4%; 100%)
Combined Sensitivity	(30/30) 100%	(88.7%; 100%)
Combined Specificity	(79/80) 98.8%	(93.3%; 98.8%)
Combined PPV for prevalence = 5%	80.8%	(40.9%; 96%)
Combined NPV for prevalence = 5%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	(0/10) 0% not detected	----------

Study III

Total of 42 positive and 113 negative fingerstick whole blood samples were collected and tested at 3 different POC sites. These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Fastep COVID-19 IgG/IgM Rapid Test device for antibodies. The PPA/sensitivity and NPA/specificity results are summarized in following tables.

Table 5. IgG/IgM PPA for the Fastep COVID-19 IgG/IgM Rapid Test Device

Site	Days from symptom	# PCR Positive	IgG (Assure Device)			IgM (Assure Device)		
			Antibody Positive	PPA	95%CI	Antibody Positive	PPA	95%CI

(Site 1+2+3)	0-7 days	2	0	0%	0%-57.5%	2	100%	42.5%-100%
	8-14 days	12	10	83.3%	55.2%-95.3%	10	83.3%	55.2%-95.3%
	⩾15 days	28	28	100%	91.2%-100%	25	89.3%	72.8%-96.3%

Site 1		IgG			IgM			IgG/IgM		
Days from symptom	# PCR positive	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI
0-7 days	0	0	NA	NA	0	NA	NA	0	NA	NA
8-14 days	0	0	NA	NA	0	NA	NA	0	NA	NA
≥15 days	11	11	100%	80.3%-100%	10	90.9%	62.3%-98.4%	11	100%	80.3%-100%
Site 2		IgG			IgM			IgG/IgM		
Days from symptom	# PCR positive	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI
0-7 days	2	0	0%	0%-57.5%	2	100%	42.5%-100%	2	100%	42.5%-100%
8-14 days	7	6	85.7%	48.7%-97.4%	7	100%	72.1%-100%	7	100%	72.1%-100%
≥15 days	9	9	100%	76.9%-100%	9	100%	76.9%-100%	9	100%	76.9%-100%
Site 3		IgG			IgM			IgG/IgM		
Days from symptom	# PCR positive	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI
0-7 days	0	0	NA	NA	0	NA	NA	0	NA	NA
8-14 days	5	4	80%	37.6%-96.4%	3	60%	23.1%-88.2%	5	100%	64.9%-100%
≥15 days	8	8	100%	74.7%-100%	6	75%	40.9%-92.9%	8	100%	74.7%-100%

Table 6. IgG/IgM NPA for the Fastep COVID-19 IgG/IgM Rapid Test Device

(Site 1+2+3)	# PCR Negative	IgG (Assure Device)			IgM (Assure Device)		
		Antibody Negative	NPA	95%CI	Antibody Negative	NPA	95%CI
Combined Sites	113	113	100%	97.7% -100%	113	100%	97.7%-100%

Site 1	IgG			IgM			IgG/IgM		
# PCR negative	Antibody negative	NPA	95% CI	Antibody negative	NPA	95% CI	Antibody negative	NPA	95% CI
20	20	100%	88.1%-100%	20	100%	88.1%-100%	20	100%	88.1%-100%
Site 2	**IgG**			**IgM**			**IgG/IgM**		
# PCR negative	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**
53	53	100%	95.1%-100%	53	100%	95.1%-100%	53	100%	95.1%-100%
Site 3	IgG			IgM			IgG/IgM		
# PCR negative	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**
40	40	100%	93.7%-100%	40	100%	93.7%-100%	40	100%	93.7%-100%

The NPA/specificity of the Fastep COVID-19 IgG/IgM Rapid Test Device for IgG/IgM in fingerstick whole blood samples is 100%.

Cross Reactivity

There was no cross-reactivity with plasma specimens meeting the disease state shown below. No IgM or IgG false positive results were observed with the following potential cross-reactants:

Table 7. Cross-reactivity Study Data of Fastep COVID-19 IgG/IgM Rapid Test Device

Conditions	Number of samples	Conditions	Number of samples
Anti-HAV IgM +	5	Lyme disease+	5
Anti-HEV IgG +	2	P. falciparum +	5
HBsAg +	5	P. vivax +	5
Anti-HCV +	5	Toxoplasma IgM +	5
Anti-HIV +	5	HAMA +	1
Anti-Rubella IgM +	5	RF +	5
Anti-CMV IgM +	5	ANA+	5
Anti-HSV-I IgM +	5	Anti-Influenza A IgM +	3
Anti-HSV-II IgM +	5	Anti-Influenza B IgM +	1
EBV IgM +	4	Anti-RSV IgM +	3
Anti-Dengue IgM +	5	Legionella pneumophila IgM+	2
Anti-Yellow fever +	5	Anti-Adenovirus IgM +	1
Anti-Zika IgG +	5	Anti-Mycoplasma pneumonia IgM +	3
Chagas Ab+	5	Anti-Chlamydia pneumonia IgM +	3
Anti-Syphilis IgG +	4	Anti-Chlamydia pneumonia IgG +	2
Anti-Tuberculosis +	5	Measles IgG +	1
Typhoid IgM +	5	Mumps IgG +	1

Interfering Substances

The assay performance of COVID-19 IgG/IgM Rapid Test Device is not affected by substances at concentrations listed below.

Table 8. Interference Study Data of Fastep COVID-19 IgG/IgM Rapid Test Device

Interfering substances	Concentration of analyate
Blood analytes	
Albumin	5 g/dL
Anticoagulants	
EDTA (sodium salt)	3.4 µmol/L
Heparin	3000 U/L
Sodium citrate	5 mg/mL
Potassium oxalate	2 mg/mL
Abnormal blood sample	
Visual hemolysis (Hemoglobin)	20 g/dL
Icteric (Bilirubin)	5 mg/dL
Lipemic (Triglycerides)	500 mg/dL
Common medicines	
Acetylsalicylic acid	3.62 mmol/L
Ascorbic acid (Vitamin C)	342 µmol/L
Amoxicillin	206 µmol/L
Fluconazole	245 µmol/L
Ibuprofen	2425 µmol/L
Loratadine	0.78 µmol/L
Nadolol	3.88 µmol/L
Naproxen	2170 µmol/L
Paroxetine	3.04 µmol/L
Anti-malarial medicines	
Quinine	148 µmol/L
Anti-tuberculosis medicines	
Rifampicin	78.1 µmol/L
Isoniazid	292 µmol/L
Ethambutol	58.7 µmol/L
Common consumables	
Coffee (caffeine)	308 µmol/L
Alcohol (ethanol)	86.8 mmol/L

LITERATURE REFERENCES

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2. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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