

MosaiQ COVID-19 Antibody Magazine	COV	REF 128002
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INSTRUCTIONS FOR USE

For *in vitro* diagnostic and Laboratory Professional use only
 For use under Emergency Use Authorization (EUA) Only
 Prescription Use Only

INTENDED USE

The MosaiQ COVID-19 Antibody Magazine is a solid-phase photometric immunoassay performed on single use microarrays for use on the automated **MosaiQ 125** instrument for the qualitative detection of total (IgM and IgG) antibodies to SARS-CoV-2 in human serum, dipotassium (K2) and tripotassium (K3) EDTA plasma. The **MosaiQ COVID-19 Antibody Magazine** 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 how the presence of antibodies confers protective immunity. The MosaiQ COVID-19 Antibody assay should not be used to diagnose or exclude acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests.

Results are for the detection of SARS-CoV-2 total (IgM and IgG) antibodies. 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 results to the appropriate public health authorities.

The sensitivity of the MosaiQ COVID-19 Antibody assay 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 with the MosaiQ COVID-19 Antibody assay 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 a second, different IgG and/or IgM assay.

The MosaiQ COVID-19 Antibody assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

At the end of December 2019, Chinese public health authorities reported several cases of acute respiratory syndrome in Wuhan City, Hubei province, China. Chinese scientists soon identified a novel coronavirus as the main causative agent. The disease is now referred to as coronavirus disease 2019 (COVID-19), and the causative virus is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is a new strain of coronavirus that has not been previously identified in humans.¹

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a beta coronavirus that causes the Coronavirus Disease 2019 (COVID-19) and pandemic. SARS-CoV-2 is mainly transmitted through droplets and contact routes, and the virus infects human cells via binding to angiotensin converting enzyme² (ACE2).^{2,3} Infection with SARS-CoV-2 can cause mild symptoms including a runny nose, sore throat, cough and fever. However, it can be more severe for some people and can lead to pneumonia or breathing difficulties. The elderly and people with pre-existing medical conditions (such as, diabetes and heart disease) appear to be more vulnerable to becoming severely ill with the virus.

Based on previous studies on SARS, an incubation period from three to fourteen days after onset of symptoms may be expected.⁴ Specific antibodies to SARS-CoV-2 may be detectable in COVID-19 patients during the symptomatic phase of the disease after RNA is no longer detectable.^{5,6} The persistence of IgG antibodies allows identification of people who have been infected in the past, and likely have recovered from the illness.⁷ It is unknown if IgG antibodies to SARS-CoV-2 confer immunity to infection. IgG detection and other serological assays will likely play an important role in research and surveillance.⁸

PRINCIPLE OF THE PROCEDURE

The **MosaiQ COVID-19 Antibody Magazine** is used in combination with the MosaiQ System for the automated determination of the presence of antibodies against SARS-CoV-2 antigens in serum and EDTA plasma specimens, which are produced as part of an immune response against the virus⁹. The use of this magazine in association with the **MosaiQ 125** instrument and associated MosaiQ reagents supports the high throughput screening of blood products for professional use within a clinical laboratory setting. The **MosaiQ COVID-19 Antibody Magazine** contains preprinted single use microarrays containing probes of antigens for the presence of antibodies against SARS-CoV-2 within serum and EDTA plasma specimens. MosaiQ microarray technology utilizes miniaturized serological techniques and permits a source efficient means of performing testing of blood specimens.

The **MosaiQ COVID-19 Antibody Magazine** test combines antigen-antibody interactions with automated image capture and analysis of the reaction.

Each microarray contains the magazine is composed of the following panels:

- COVID-19 panel for the qualitative determination of human antibodies against SARS-CoV-2.
- Empty panel without any preprinted probes.

The patient or control specimen and **MosaiQ Sample Diluent 2** are dispensed together by the **MosaiQ 125** instrument into the COVID-19 panel containing the printed antigens and controls. An incubation step allows antibodies to bind the printed antigens. The removal of unbound antibodies using **MosaiQ Wash Buffer 1** precedes addition of **MosaiQ Detection Reagent 1**, a solution containing gold-conjugated secondary antibody that will bind to the human antibodies (IgG and IgM).

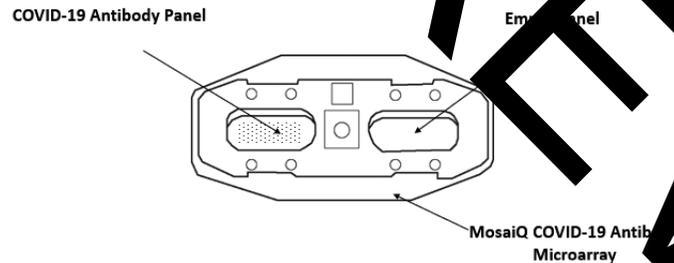
A second wash with **MosaiQ Wash Buffer 1** removes excess detection reagent, while an additional wash with **MosaiQ Wash Buffer 2** prepares the panel for the next stages of the assay.

Finally, the addition of the **MosaiQ Enhancement Reagents 1 and 2** allows silver to nucleate around bound gold nanoparticles of the secondary antibody conjugate and subsequent washing with purified water reveals an optically detectable probe ready for imaging and analysis by the **MosaiQ 125** instrument.

REAGENTS

MosaiQ COVID-19 Antibody Magazine	
Catalogue number	128002
Quantity	1 MosaiQ COVID-19 Antibody Magazine per cardboard box
Sufficient for	(1 x 250) 250 assays

Each microarray consists of two panels; one panel intended for SARS-CoV-2 testing and one empty panel. The magazine has a RFID (Radio Frequency Identification) tag which contains information necessary for the traceability and on-board management such as: catalogue number, lot number, expiry date, quantity and on-board stability.



- The **MosaiQ COVID-19 Antibody Magazine** is provided as a ready to use product intended to be loaded for testing onto the **MosaiQ 125** instrument. Each magazine (250 microarrays) is packed in a blister with an inert atmosphere.
- This product does not contain natural rubber or latex.
- This product contains bovine serum albumin (BSA) from animals declared free from Transmissible Spongiform Encephalopathies (TSE) / Bovine Spongiform Encephalopathies (BSE) disease in its clinical forms.

COVID-19 panel

The COVID-19 panel of the microarray contains 1 testing probe in duplicate positions on the array, and 10 control probes.

Testing and positive control probes are diluted in a buffer solution containing glycerol, phosphate-buffered saline (PBS) and sucrose. The negative control probes are made of glycerol, PBS and sucrose solution.

All the probes are printed on functionalized glass and covered with a preservative coating.

N° of probe	Reagent	Reactive ingredient
2	SARS-CoV-2 Antigen	Solution containing SARS-CoV-2 spike protein antigens in a buffered solution
6	Positive control (system processing controls)	Bovine serum albumin conjugated with gold nanoparticles to confirm proper addition of the enhancement reagents during processing. Also aids in the software image detection/analysis
2	Positive control (system processing controls)	Monoclonal anti-E antibodies (mouse monoclonal IgM antibodies from DEM1 cell line) to confirm proper addition of the detection reagent during processing
2	Negative control	Not applicable

Empty panel

This panel does not contain any printed material and does not support any testing.

WARNINGS AND PRECAUTIONS

- For use under Emergency Use Authorization only.
- This test has not been FDA-cleared or -approved; this test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for detection of antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- 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.
- For professional use only.
- For *in vitro* diagnostic use only.
- Rx only.
- Use of recommended equipment/material and strict adherence to the procedures are mandatory.
- Do not use if blister or magazine is damaged.
- All specimens from human origin should be considered as potentially infectious. Strict adherence to Good Laboratory Practice (GLP) regulations can ensure personal safety.
- This product contains human and animal blood derivatives. Human blood materials from which this product is derived was found non-reactive for HBsAg, Anti-HCV, Anti-HIV-1 and Anti-HIV-2. Normal blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices.
- Refer to the Safety Data Sheet for specific safety information.
- Waste material containing blood specimen or biological products should be considered biohazardous and disposed in compliance with all local and national regulations.

STORAGE AND HANDLING

- Store at ambient temperature (15-25°C) until the expiration date.
- Do not use microarrays beyond the labeled expiration date (year, month, day: YYYY-MM-DD).
- Do not freeze and expose to excessive heat.
- Store in the original unopened blister package.
- Once opened, stable for 24 hours on-board the instrument.

SPECIMEN COLLECTION AND PREPARATION

- Fresh plasma specimens collected in EDTA anticoagulant and serum specimens can be used.
- Fresh specimens must be stored at 2-8 °C and not tested immediately.
- Fresh specimens must be tested within 72 days of collection.
- Frozen plasma collected in EDTA and frozen serum specimens (stored at < -20°C) can be used.
- Fresh frozen specimens can undergo up to three freeze/thaw cycles
- Specimens must be at ambient temperature prior to use.
- Centrifuge specimen at 2000 to 3000 g for 2 minutes.
- Minimum fill volume in standard sample tubes must be ≥ 500 µL, the assay uses 5 µL for the test.
- Do not use hemolyzed specimens.
- De-cap specimen tubes before loading on the **MosaiQ 125** instrument.
- Load the specimen tubes into **MosaiQ 125** instrument via sample rack.

REAGENT PREPARATION

Refer to instructions of the **MosaiQ 125** instrument for detailed procedure to load **MosaiQ COVID-19 Antibody Magazine**.

PROCEDURE

This product has been designed for use only with the MosaiQ System.

Material provided

MosaiQ COVID-19 Antibody Magazine.

Material required but not provided

The assay is performed on the **MosaiQ 125** instrument using the following products:

Product name	Lot #
MosaiQ 125 Instrument	126001
MosaiQ Sample Diluent 1	155001
MosaiQ Sample Diluent 2	155002
MosaiQ Wash Buffer 1	155003
MosaiQ Wash Buffer 2	155004
MosaiQ Detection Reagent 1	155005
MosaiQ Enhancement Reagent 1	155007
MosaiQ Enhancement Reagent 2	155008

For other specific materials needed for the test procedure, please refer to the **MosaiQ 125** instrument user manual.

Test procedure

Testing must be performed using the Disease Screening (DS) test order.

Loading:

1. Open the magazine blister immediately prior to use.
2. Open the magazine station door.
3. Carry out a visual check of the alignment of microarrays. Do not use if misaligned, contact Quotient support.
4. Load the magazine.
5. Close the magazine station door.
6. Wait until the system initializes the loading drum and scans the magazine.

Removing:

1. Open the magazine station door.
2. Pull the upper part of the empty magazine from the drum and lift the magazine out.
3. Close the magazine station door.
4. Dispose the empty magazine.

Please refer to **MosaiQ 125** instrument user manual for detailed information.

QUALITY CONTROL

The **MosaiQ COVID-19 Antibody Q-Control** product is to be used as a system control for the **MosaiQ COVID-19 Antibody Magazine**.

MosaiQ COVID-19 Antibody Q-Control should be run at a minimum with each day of use, and following a change in magazine lot number. This is in addition to any local, state and/or federal regulations, accrediting groups or laboratory standard quality control procedures or internal requirements for quality control testing that may be established in your facility. **MosaiQ COVID-19 Antibody Q-Control** is only for use with the MosaiQ System when using the **MosaiQ COVID-19 Antibody Magazine** and should not be used on any other testing platform.

MosaiQ COVID-19 Antibody Q-Control product does not have assigned values; the result is qualitative only. For further information with regards to the **MosaiQ COVID-19 Antibody Q-Control** product, please refer to the dedicated Instructions for Use.

Both positive and negative control materials should result in the expected **PASSED** status in the QC test module as described in the **MosaiQ 125** User Manual.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If the quality control material does not perform as expected, repeat testing with a fresh vial. If the performance does not return to the expected level, contact Customer Service.

INTERPRETATION OF RESULTS

Upon completion of the testing procedure, the panel's reactive pattern is analyzed by the instrument software. The instrument will perform a logical interpretation of probe reactivity to support a qualitative result determination for SARS-CoV-2 antibodies. The reported result displayed by the **MosaiQ 125** instrument is available under the Report tab:

Test results status displayed below C19 (NR: Non-Reactive / R: Reactive / IND: Indeterminate)					
SARS-CoV-2 Antibody test results are Non-Reactive		SARS-CoV-2 Antibody test results are Reactive		SARS-CoV-2 Antibody test results are Indeterminate. No IND results are reported outside of the laboratory.*	
	box containing "NR" in green		box containing "R" in red		"IND" in black

Images of the reported results (R or NR or IND) displayed in the Report tab are shown below:

Reported Result	Reported Result	Reported Result

Image of the result overlay displayed in the Finished tab is shown below:

S000563363	2020-08-26	13:14	Finished	C19 R
S000560231	2020-08-26	13:14	Finished	C19 NR
S000563363	2020-08-26	13:14	Finished	C19 IND

* Note: An **IND** reading is invalid and is equivalent to no result. No **IND** results should be reported outside of the laboratory. Retesting is required. Subsequent **IND** readings should be investigated as per laboratory standard operating procedure.

For information only, the **MosaiQ 125** instrument displays the detailed results for each testing probes in the Disease Screen Profile tab (refer to **MosaiQ 125** instrument user manual). The **MosaiQ 125** instrument generates flags in response to different circumstances that are explained here:

#	Name	Reason	Action to be taken
1	Data Reduction Error (DRE)	There is no data returned.	If a data reduction error occurs no results are generated. Retesting is required. Subsequent data reduction errors should be investigated as per laboratory standard operating procedure.
2	Processing Error (PE)	Issue during sample aspiration and/or dispensing	If a processing error occurs no results are generated. Retesting is required. Subsequent processing errors should be investigated as per laboratory standard operating procedure.

LIMITATIONS

- For use under Emergency Use Authorization only.
- For *in vitro* diagnostic use.
- For professional use only.
- Endogenous interferences have not been demonstrated.
- Do not use grossly hemolyzed or lipemic samples.
- The assay provides a means of investigation of adaptive immune response to infection with SARS-CoV-2 but does not provide information on an active or current infection. Adaptive immune responses may be detected weeks or months post-infection.
- The test has not been authorized for semi-quantitative detections of total SARS-CoV-2 antibodies.
- This device should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 with a molecular assay should be performed to evaluate acute infection in symptomatic individuals.
- Results obtained with this assay may not be used interchangeably with values obtained with different manufacturers' test methods.
- A positive result may not indicate previous SARS-CoV-2 infection. 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.
- SARS-CoV-2 antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days. SARS-CoV-2 antibodies may be below detectable levels in patients who are less than 8 days from taking a PCR test.
- A negative result for an individual subject indicates the absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies that are detected and are not 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.
- Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.
- Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
- Specimens with direct evidence of antibodies to non SARS-CoV-2 coronavirus strains (common cold) such as HKU1, NL63, OC43 or 229E have not been evaluated with this assay.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

- The performance of this device has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this assay should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The specimens for the negative agreement study were all collected prior to December 2019. The specimens for the positive percentage agreement were collected in April 2020 from four geographical locations (across USA, Scotland, Spain, and Switzerland). The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The **MosaiQ COVID-19 Antibody Magazine** Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>. However, to assist clinical laboratories using the **MosaiQ COVID-19 Antibody Magazine**, the relevant Conditions for Authorization are listed below. Authorized laboratories* using the **MosaiQ COVID-19 Antibody Magazine** will include the test result

- reports and all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the **MosaiQ COVID-19 Antibody Magazine** will use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other auxiliary reagents and authorized materials required to use the **MosaiQ COVID-19 Antibody Magazine** are not permitted.
- Authorized laboratories that receive the **MosaiQ COVID-19 Antibody Magazine** will notify the relevant public health authorities of their intent to run the **MosaiQ COVID-19 Antibody Magazine** prior to initiating testing.
- Authorized laboratories using the **MosaiQ COVID-19 Antibody Magazine** will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the **MosaiQ COVID-19 Antibody Magazine** and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@hhs.gov) and Quotient Suisse SA at MosaiQfeedback@quotientbd.com any suspected occurrence of false positive or false non-reactive results and significant deviations from the established performance characteristics of the **MosaiQ COVID-19 Antibody Magazine** of which they become aware.
- All laboratory personnel using the **MosaiQ COVID-19 Antibody Magazine** must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the **MosaiQ COVID-19 Antibody Magazine**.
- Quotient Suisse SA, authorized distributor, and authorized laboratories using the **MosaiQ COVID-19 Antibody Magazine** 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.
- The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests" as "authorized laboratories."

SPECIFIC PERFORMANCE CHARACTERISTICS

Cross Reactivity

The **MosaiQ COVID-19 Antibody Magazine** assay was evaluated for potential cross-reactivity with other medical conditions using 181 SARS-CoV-2 seronegative samples (collected before September 2019).

No false positive results were observed with the potential cross-reactants summarized in table below:

Sample type	Number of samples (tested in replicates of three)	Non-reactive	Reactive
ANA Positive plasma	5	5	0
Lupus	7	7	0
Rheumatoid Factor Antibody Positive plasma	10	10	0
HSV-2 IgG Positive plasma	8	8	0
HSV-1 IgG Positive plasma	8	8	0
Rubella IgG Positive plasma	7	7	0
EBV IgG Positive Plasma	10	10	0
Varicella zoster IgG or IgM Positive plasma or serum	7	7	0
Toxoplasma IgG Positive Plasma	9	9	0
Drug Abuser serum Barbiturates	3	3	0
Drug Abuser serum Oxycodone	2	2	0
Drug Abuser serum Benzodiazepines	2	2	0
Lyme IgG Positive plasma	10	10	0
ALT Positive serum	5	5	0
HTLV-I Antibody positive plasma	1	1	0
HTLV-II Antibody positive plasma	9	9	0
HBsAg Positive plasma	6	6	0
Cardiolipin IgA Positive APS plasma	7	7	0
HCV RNA Plasma	7	7	0
HIV 1/2 Antibody Positive plasma	6	6	0
Leptospira IgG positive	3	3	0
Yeast / Candida Albicans	6	6	0
Influenza B Virus Antibody IgA positive	8	8	0
Influenza A IgM & IgG and Influenza B IgM & IgG Antibody positive	4	4	0
Influenza A IgM & IgG Antibody positive	1	1	0
Influenza A IgG Antibody positive	3	3	0
Influenza A IgG and Influenza B IgG Antibody positive	4	4	0
Influenza A IgM & IgG and Influenza B IgG Antibody positive	3	3	0

Adenovirus Antibody positive	5	5	0
Polio virus Antibody positive	4	4	0
Echovirus Antibody positive	5	5	0
Coxsackie B Antibody positive	6	6	0

Clinical Agreement

Clinical agreement studies were performed to establish the performance characteristics in terms of Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA). Positive samples used to demonstrate sensitivity/PPA were taken from patients diagnosed as positive by PCR at least 7 days prior to the collection of the blood sample that was tested in this study.

	True Negative (TN)	True Positive (TP)	False Negative (FN)	False Positive (FP)	Total number of samples
Number of samples	400	30	0	1	431
NPA	99.8% (95% CI: 98.6 - 99.9%)				

Specificity NPA (TN+FP): 99.8% clinical agreement across samples 401 samples presumed negative

Sensitivity/PPA (TP+FN) was correlated with days post PCR specimen collection. The results are summarized in the table below:

Days Post PCR Specimen Collection*	Number of Samples Tested	MosaiQ COVID-19 Antibody Magazine Test Results		
		Total Antibody Positive Results	Total Antibody PPA	95% CI
0-7 days	0	0	N/A	N/A
8-14 days	15	15	100%	78.2 - 100%
≥ 15 days	15	15	100%	78.2 - 100%

*SARS-CoV-2 positive PCR result confirms presence of virus. Immune response in patient is expected to be latent following initial viral infection.

N/A = Not Applicable

External Clinical Agreement

An additional clinical agreement study was conducted at a site external to the manufacturer to establish the performance characteristics in terms of Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA).

Positive samples used to demonstrate sensitivity/PPA were taken from patients diagnosed as positive by PCR at least 7 days prior to the collection of the blood sample that was tested in this study.

	True Negative (TN)	True Positive (TP)	False Negative (FN)	False Positive (FP)	Total number of samples
Number of samples	407	94	6	1	508
NPA	99.8% (95% CI: 98.6 - 100%)				

Specificity/NPA (TN+FP): 99.8% clinical agreement across samples 408 samples presumed negative. Sensitivity/PPA (TP+FN) was correlated with days post PCR specimen collection. The results are summarized in the table below:

MosaiQ COVID-19 Antibody Magazine Test Results				
Days Post PCR Specimen Collection*	Number of Samples Tested	Total Antibody Positive Results	Total Antibody PPA	95% CI
0-7 days	5	5	100%	47.8 – 100%
8-14 days	9	9	100%	66.4 – 100%
≥ 15 days	86	80	93%	85.4 – 97.4%

*SARS-CoV-2 positive PCR result confirms presence of virus. Immune response in patients is expected to be latent following initial viral infection

Matrix Equivalency

Matrix studies were conducted using matched non-reactive and reactive EDTA plasma and serum specimens from the same donors as well as contrived positive samples representing moderate positive and low positive states of reactivity (1:2 and 1:4, respectively). The contrived positive samples were generated by spiking neat reactive serum into negative serum and neat reactive plasma into negative plasma at the respective dilutions. PPA was 100% across all dilution levels and NPA was 99.8%. Overall agreement between EDTA plasma and serum specimens was 98.6%. The results of the study show consistent performance across claimed specimen matrices, EDTA plasma and serum.

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SYMBOLS

 Caution	 Consult instructions for use	 In vitro diagnostic medical device	 Catalogue number	 Batch code	 Use-by date	 Temperature limitation
 Contains sufficient for <n> tests	 Do not use if package is damaged	 Manufacturer	 This way up	 Keep dry	 Rx Only	 MosaiQ COVID-19 Antibody Magazine

REMOVED

MosaiQ™ Covid-19 Antibody Q-Control

For use as system controls for the MosaiQ COVID-19 Antibody Magazine



MosaiQ COVID-19 Antibody Q-Control

REF 155027



For *in vitro* diagnostic and Laboratory Professional use only
 For use under Emergency Use Authorization (EUA) Only
 Prescription Use Only

INTENDED USE

The **MosaiQ COVID-19 Antibody Q-Control** is intended to monitor the system suitability of the **MosaiQ COVID-19 Antibody Magazine** used for the qualitative detection of total IgG and IgM antibodies to SARS-CoV-2 virus in human serum and plasma. It is intended for professional use within a clinical laboratory environment.

SUMMARY AND EXPLANATION

In response to infection by an infectious agent (bacteria or virus) the body creates antibodies that are specific to the infectious agent. This enables the body to combat the infection and, in many cases, clear the infection. Antibodies that are developed during this immune response remain in the body and circulating blood for a period of time, depending on multiple factors (i.e. level of exposure, antibody class).

The **MosaiQ COVID-19 Antibody Q-Control** uses a sample with IgG antibodies against SARS-CoV-2 antigens to obtain a positive result and a sample with no antibodies present to obtain a negative result. The **MosaiQ COVID-19 Antibody Q-Control** is used in combination with the MosaiQ System and the **MosaiQ COVID-19 Antibody Magazine** to reproduce the detection of such antibodies which are produced as part of an immune response against the virus (1).

PRINCIPLE OF THE PROCEDURE

MosaiQ COVID-19 Antibody Q-Control has been designed for use with *in vitro* assay procedures for purposes of monitoring test performance. **MosaiQ COVID-19 Antibody Q-Control** does not have assigned quantitative values and has been formulated to produce reactivity only with the MosaiQ Instrument when using the **MosaiQ COVID-19 Antibody Magazine**.

REAGENTS

REF	MosaiQ COVID-19 Antibody Q-Control	Symbols/colors	Vial capacity	Quantity in final packaging
155027	Vial 1 & 2	POS (Black tube cap)	1.0 mL	2 vials
	Vial 3 & 4	NEG (White tube cap)	1.0 mL	2 vials

- **MosaiQ COVID-19 Antibody Q-Control** vials 1 & 2 are manufactured with monoclonal antibody reactive to SARS-CoV-2 in a buffered diluent containing BSA.
- **MosaiQ COVID-19 Antibody Q-Control** vials 3 & 4 are manufactured in a buffered diluent containing BSA, non-reactive to SARS-CoV-2.
- The **MosaiQ COVID-19 Antibody Q-Control** is provided as a ready to use product intended to be loaded for testing onto the MosaiQ instrument.
- This product does not contain natural rubber or latex.
- This product contains bovine serum albumin from animals declared free from Transmissible Spongiform Encephalopathies (TSE) / Bovine Spongiform Encephalopathies (BSE) disease in its clinical forms.

WARNINGS AND PRECAUTIONS

- For professional use only.
- For *in vitro* diagnostic use only.
- For use under Emergency Use Authorization (EUA) Only
- For prescription use only.
- The controls are used with the **MosaiQ COVID-19 Antibody Magazine** test. This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate to high complexity tests.
- This test has been authorized only for detection of antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics 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. § 360bbb3(b), unless the declaration is terminated or authorization is revoked sooner.
- Use of recommended equipment/material and strict adherence to the procedures are mandatory.
- Do not use if the packaging is damaged.
- Wear appropriate protective clothing and gloves following Good Laboratory Practices.
- Refer to the Safety Data Sheet for specific safety information.
- This product contains biological materials and must be considered as potentially able to transmit infectious agents.
- Waste material containing blood specimen or biological products should be considered biohazardous and disposed in compliance with all local and national regulations.
- Follow your local regulation regarding the precautions for handling **MosaiQ COVID-19 Antibody Q-Control** and human blood, (for example the Centers for Disease Control (CDC) in USA).

- Do not pipette by mouth; do not eat or drink in areas where specimens are being handled.
- Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution or equivalent.
- Do not reuse empty containers.

Material required but not provided

MosaiQ COVID-19 Antibody Q-Control must be processed on the MosaiQ instrument when using the following products:

STORAGE AND HANDLING

- Store at 2-8 °C.
- When not used, each vial must be stored at 2-8 °C upright in the kit box where they have been supplied to avoid leakage.
- After opening, record the date opened on the vial; the opened vial must be discarded after 14 days within its period of validity (verify the expiry date on the vial).
- Do not use beyond the expiry date (year, month, day: YYYY-MM-DD).
- Do not freeze vial, it may have variable adverse effects upon test results.
- Use of controls not stored according to directions or opened controls may produce erroneous results.

REAGENT PREPARATION

- Mix the contents of the vials by gentle inversion.
- Always remove the cap before use and recap after use.
- Process the assay by running **MosaiQ COVID-19 Antibody Q-Control** as described in the MosaiQ instrument user manual.
- Do not mix the caps:
 - **MosaiQ COVID-19 Antibody Q-Control** vials 1 & 2 must be recapped with the black cap.
 - **MosaiQ COVID-19 Antibody Q-Control** vials 3 & 4 must be recapped with the white cap.
- Tube caps must be kept away from potential contaminants, after opening the tubes put the caps on a cleaned surface.
- Once the vials are recapped, clean surfaces that have been in contact with the caps.
- Avoid microbial contamination of the controls when opening and closing the vials.
- Alterations in physical appearance or color may indicate instability or deterioration of **MosaiQ COVID-19 Antibody Q-Control**.
- In case of doubt regarding the **MosaiQ COVID-19 Antibody Q-Control** solution integrity, it must be discarded.
- Each vial should be loaded onto the instrument in the same manner as a routine patient sample. Refer to instructions of the MosaiQ instrument for detailed procedure.
- The qualitative expected response from each control will be provided to the instrument automatically; therefore, no operator interpretation is required.
- Return controls to refrigerated storage immediately after use (stability at room temperature has not been established).

PROCEDURE

This product has been designed for use only with the MosaiQ System.

Material provided

MosaiQ COVID-19 Antibody Q-Control

Product name	REF
MosaiQ COVID-19 Antibody Magazine	128001
MosaiQ Sample Diluent 2	155002
MosaiQ Wash Buffer 1	155003
MosaiQ Wash Buffer 2	155004
MosaiQ Detection Reagent 1	155005
MosaiQ Enhancement Reagent 1	155007
MosaiQ Enhancement Reagent 2	155008

QUALITY CONTROL

MosaiQ COVID-19 Antibody Q-Control product do not have assigned values; the result is qualitative only.

MosaiQ COVID-19 Antibody Q-Control is only for use with the MosaiQ System when using the **MosaiQ COVID-19 Antibody Magazine** and should not be used on any other testing platform.

MosaiQ COVID-19 Antibody Q-Control must not be substituted to the control reagents used as part of quality control programs followed by the laboratories.

INTERPRETATION OF RESULTS

The positivity and negativity of the **MosaiQ COVID-19 Antibody Q-Control** has been determined as follows:

MosaiQ COVID-19 Antibody Q-Control	Test Assay	Acceptance criteria
Vials 1 & 2 SARS-CoV-2 reactive.	MosaiQ COVID Assay	Positive
Vials 3 & 4 SARS-CoV-2 non-reactive.	MosaiQ COVID Assay	Negative

Note: If the MosaiQ COVID-19 Antibody Q-Control do not provide expected results, retesting is required. Subsequent discrepant results should be investigated as per laboratory standard operating procedure.

LIMITATIONS

- Procedure and interpretation instructions provided with the MosaiQ instrument must be followed. Deviations from procedures recommended may produce unreliable results.
- **MosaiQ COVID-19 Antibody Q-Control** is provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure.

BIBLIOGRAPHY

1 - European Centre for Disease Prevention and Control (2020) COVID-19 Available from:
<https://www.ecdc.europa.eu/en/covid-19-pandemic>

SYMBOLS

 Consult instructions for use	REF Catalogue number	LOT Batch code	IVD In vitro diagnostic medical device	 Use by date	 Temperature limitation	 Do not use if package is damaged
 Manufacturer	 This way up	CE CE marking	POS Positive Control Reactive for SARS-CoV-2	NEG Negative Control Non-reactive for SARS-CoV-2	CONTROL Control	

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