BECKMAN COULTER
ACCESS
Immunoassay Systems

Instructions For Use

ACCESS SARS-CoV-2 IgM QC
SARS-CoV-2 IgM

REF C58959

For Use Under the Emergency Use Authorization (EUA) Only

For *In Vitro* Diagnostic Use

Rx Only

FOR USE ON ACCESS FAMILY OF IMMUNOASSAY SYSTEMS

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

CAUTION

For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

INTENDED USE

The Access SARS-CoV-2 IgM QC is intended for monitoring system performance of the Access SARS-CoV-2 IgM assay.

The Access SARS-CoV-2 IgM QC is for use on the Access Family of Immunoassay Systems only.

SUMMARY AND EXPLANATION

Quality control (QC) materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access SARS-CoV-2 IgM immunoassay. In addition, they are an integral part of good laboratory practices. When performing assays with Access reagents for SARS-CoV-2 IgM, include quality control materials to validate the integrity of the assays. The assayed values should fall within the acceptable range if the test system is working properly.

TRACEABILITY

The analyte in the Access SARS-CoV-2 IgM QC is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511. The assigned values were established using representative samples from this lot of

QC, and are specific to the assay methodologies of the Access reagents. The values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

REAGENTS

CONTENTS

Access SARS-CoV-2 IgM QC
Ref. No. C58959: QC1-QC2, 4 mL/vial, 3 vials each level

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Vial is stable at 2 to 10°C for 30 days after initial use.
- Signs of possible deterioration are quality control values out of range.
- Refer to the QC value card for mean values and standard deviations (SD).

QC1:	Negative: TRIS buffer, defibrinated human plasma negative for anti-SARS-CoV-2, surfactant, protein (bovine), < 0.1% sodium azide and 0.5% ProClin* 300.
QC2:	Positive: TRIS buffer, defibrinated human plasma, human IgM conjugated to anti-SARS-CoV-2 antibodies, surfactant, protein (bovine), < 0.1% sodium azide and 0.5% ProClin 300.
QC Value Card:	1

*ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliated company of Dow.

WARNING AND PRECAUTIONS

- For Emergency Use Authorization (EUA) only
- **For *in vitro* diagnostic use.**
- Samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices,[1] regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- The antibody used to prepare the reagent is derived from human plasma. Always consider these products to be potentially infectious. Regardless of their origin, treatment, or prior certification, handle them according to universal precautions and good clinical laboratory practices. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers according to local regulations and guidelines.[2]
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.
- This product has not been FDA cleared or approved; this product 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 product has been authorized only for the presence of IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This product 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

REACTIVE INGREDIENTS

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

SARS-CoV-2 IgM QC1	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
SARS-CoV-2 IgM QC2	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

TESTING PROCEDURE(S)

PROCEDURE

Use the Access Immunoassay System to determine the concentration of SARS-CoV-2 IgM in the Access SARS-CoV-2 IgM QC materials in the same manner as a sample. Include quality control materials in each 24-hour time period, or as required by individual laboratory procedures, because samples may be processed at any time in a “random access” format rather than a “batch” format. More frequent use of controls or the use of additional controls is left to the discretion of the operator, based upon good laboratory practices or the laboratory accreditation requirements and applicable laws. Refer to the appropriate system manuals and/or Help system for information on quality control theory, configuring controls, quality control sample test request entry, and reviewing quality control data.

REPORTING RESULTS

EXPECTED RESULTS

For the value assignment of Access SARS-CoV-2 IgM QC material, select and assay a number of samples that are representative of the entire lot to provide a reliable estimate of the mean value. The mean values and standard deviations are listed on the QC value card. There are variations, such as technique, equipment, or reagents, which may cause results that are different from the listed values. Therefore, each laboratory should establish its own mean values and standard deviations (SD). Patient results should not be reported if QC values are outside of expected ranges.

PROCEDURAL NOTES

LIMITATIONS

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

ADDITIONAL INFORMATION

REVISION HISTORY

Revision A

New release.

Revision B

Expected results update.

SYMBOLS KEY

Glossary of Symbols is available at beckmancoulter.com/techdocs (document number C02724).

REFERENCES

1. Approved Guideline - Protection of Laboratory Workers From Occupationally Acquired Infections, M29-A4, 4th Edition, May 2014. Clinical and Laboratory Standards Institute.

2. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication, 5th ed., December 2009.

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