

**Instructions For Use**

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**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 Calibrators are intended to calibrate the Access SARS-CoV-2 IgM assay for the *in vitro* qualitative detection of SARS-CoV-2 IgM antibodies in human serum, serum separator tubes and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, sodium citrate) for use on the Access Family of Immunoassay Systems only.

**SUMMARY AND EXPLANATION**

The Access SARS-CoV-2 IgM Calibrator is used to establish calibration (determine the cut-off value) for the Access SARS-CoV-2 IgM assay. By comparing the light intensity generated by a sample to the cut-off value, the presence or absence of SARS-CoV-2 IgM antibodies in the sample is determined.

**TRACEABILITY**

The analyte in the Access SARS-CoV-2 IgM Calibrator 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 calibrator, 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 Calibrator

Ref. No. C58958: C0-C1, 2.0 mL/vial

- 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 90 days after initial use.
- Signs of possible deterioration are quality control values out of range.
- Refer to calibration card for exact concentrations.

<b>C0:</b>	TRIS buffer, surfactant and protein (bovine), < 0.1% sodium azide and 0.5% ProClin* 300.
<b>C1:</b>	TRIS buffer containing anti-SARS-CoV-2 IgM positive plasma, surfactant, and protein (bovine), < 0.1% sodium azide and 0.5% ProClin 300.
<b>Calibration Card:</b>	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,<sup>1</sup> 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.<sup>2</sup>
- 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 C0

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 C1

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](https://beckmancoulter.com/techdocs)

# **CALIBRATION**

## **CALIBRATION INFORMATION**

The Access SARS-CoV-2 IgM Calibrators are provided as: negative and positive. Assay calibration data are valid up to 28 days.

Run the calibrators in triplicate.

## **TESTING PROCEDURE(S)**

### **PROCEDURE**

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

## **PROCEDURAL NOTES**

### **LIMITATIONS**

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

## **ADDITIONAL INFORMATION**

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## **REVISION HISTORY**

### **Revision A**

New release.


## **SYMBOLS KEY**

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

## REFERENCES

1. Approved Guideline - Protection of Laboratory Workers From Occupationally Acquired Infections, M29-A4, 4<sup>th</sup> 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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