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CoV-2 IgG II

REF 06S6101

H18536R02

# AdviseDx SARS-CoV-2 IgG II Calibrator Kit

FOR USE WITH

Alinity i

Revised March 2021.

## For use under an Emergency Use Authorization (EUA) Only

Prescription Use only.

For *In Vitro* Diagnostic Use Only.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

For laboratory professional use only.

## NAME

AdviseDx SARS-CoV-2 IgG II Calibrator Kit (also referred to as CoV-2 IgG II Cals)

## INTENDED USE

The AdviseDx SARS-CoV-2 IgG II Calibrator Kit is for the calibration of the Alinity i system when used for the qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum (including collected using a serum separator tube) and plasma (acid citrate dextrose, sodium citrate, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, and sodium heparin).

For additional information, refer to the AdviseDx SARS-CoV-2 IgG II reagent package insert and the Alinity ci-series Operations Manual. The AdviseDx SARS-CoV-2 IgG II assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

## CONTENTS

The **CAL A** contains phosphate buffer and protein (bovine) stabilizer. The **CAL B** - **CAL F** contain anti-SARS-CoV-2 IgG (human, monoclonal) in phosphate buffer with protein (bovine) stabilizer. The calibrators contain different concentrations of anti-SARS-CoV-2 IgG. Preservative: ProClin 300.

The calibrators are at the following target concentrations:

Calibrator	Quantity	SARS-CoV-2 IgG
		CONC
		AU/mL <sup>a</sup>
<b>CAL A</b>	1 x 2.0 mL	0.00
<b>CAL B</b>	1 x 2.0 mL	8.33
<b>CAL C</b>	1 x 2.0 mL	13.33
<b>CAL D</b>	1 x 2.0 mL	116.66
<b>CAL E</b>	1 x 2.0 mL	1000.00
<b>CAL F</b>	1 x 2.0 mL	1666.67

<sup>a</sup> The AdviseDx SARS-CoV-2 IgG II assay is run with a prediluted protocol for samples and controls using a dilution factor of 1:30. Assay calibrators are run using an undiluted protocol. Therefore, the calibrator concentrations are 1/30 of the values shown in the user interface.

## MATERIALS REQUIRED BUT NOT PROVIDED

- 04R1001 Alinity ci-series Calibrator/Control Replacement Caps

## STANDARDIZATION

The AdviseDx SARS-CoV-2 IgG II Calibrators are manufactured gravimetrically and are referenced to an internal reference standard at each concentration level.

## PRECAUTIONS

### For Use Under An Emergency Use Authorization Only.

This assay is only for *in vitro* diagnostic use under the FDA Emergency Use Authorization.

- IVD**
- For *In Vitro* Diagnostic Use
- Rx ONLY**
- This product 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 or high complexity tests.
- The emergency use of 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The following warnings and precautions apply to: **CAL A** - **CAL F**



<b>WARNING</b>	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
H402	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
<b>Prevention</b>	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
P273	Avoid release to the environment.
<b>Response</b>	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
<b>Disposal</b>	
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at [www.corelaboratory.abbott](http://www.corelaboratory.abbott) or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

## PREPARATION FOR USE

- Thaw completely at room temperature (15 to 30°C).
- Prior to each use, mix by gentle inversion.

## STORAGE

- This product is shipped on dry ice.
- Protect from light.
- Do not use past expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
<b>Unopened</b>	-20°C or colder	Until expiration date	
<b>Opened</b>	2 to 8°C	Up to 30 days after thaw, not to exceed expiration date printed on the bottle	Return to original carton to protect from light. Store tightly capped with new replacement cap. Store in upright position.

The system will track In-use Stability, which is the time the calibrator is outside of refrigerated storage while on the analyzer. The analyzer will not allow the use of the calibrator if the In-use Stability has been exceeded. Maximum In-use Stability can be found in the Assay Parameter Report. For additional information on calibrator In-use Stability, refer to the Alinity ci-series Operations Manual, Section 5. For additional information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

## INSTRUMENT PROCEDURE

- Test the calibrators in replicates of 2.
- The calibrator vials are placed directly on the instrument and automatically processed using the barcode on the calibrator vials.
- Calibrator lots may be configured using the bar code label on the calibrator carton.
- The acceptable calibration is stored by the Alinity i analyzer for use with any reagent kit of that lot. The calibration should be used in conjunction with control ranges to determine the validity of the calibration.
- For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.
- For instructions on ordering and loading calibrators on the instrument, refer to the Alinity ci-series Operations Manual, Section 5.
- Refer to the Alinity ci-series Operations Manual for details on performing calibration.

## QUALITY CONTROL PROCEDURES

A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.

For information on ordering controls, refer to the Alinity ci-series Operations Manual, Section 5.

Once a calibration is accepted and stored, it may be used for 30 days. During this time, all subsequent samples may be tested without further calibration unless:

- A reagent kit with a new lot number is used.
- Daily quality control results are outside of quality control limits used to monitor and control system performance.






This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

For additional information, refer to the AdviseDx SARS-CoV-2 IgG II reagent package insert and the Alinity ci-series Operations Manual.

## INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, if calibration does not meet the appropriate package insert and/or Alinity ci-series Operations Manual criteria, or if controls do not meet the appropriate criteria.

## Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Upper limit of temperature
	Use by/Expiration date
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>REF</b>	List Number
<b>SN</b>	Serial number
Other Symbols	
<b>AFTER THAW</b>	After thaw store at
<b>CAL A</b>	Calibrator (A,B,C,D,E or F)
<b>CONC</b>	Concentration
<b>CN</b>	Control Number
<b>FOR USE WITH</b>	Identifies products to be used together
<b>INFORMATION FOR USA ONLY</b>	Information needed for United States of America only
<b>PRODUCT OF IRELAND</b>	Product of Ireland
<b>PROTECT FROM LIGHT</b>	Protect from light
<b>Rx ONLY</b>	For use by or on the order of a physician only (applicable to USA classification only).
<b>UNTIL FIRST USE</b>	Until first use store at
<b>WARNING: SENSITIZER</b>	Warning: May cause an allergic reaction.

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

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