SARS-CoV-2 External Controls

V3.X *(RUO)*

User Guide

Version 1 – Revision 0

For Research Use Only (RUO). Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.

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Application

For Research Use Only (RUO). Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.

This product is ready to use, composed of inactivated full process controls, designed to evaluate performance of molecular tests.

This product can be used for verification of the ABL DeepChek® and UltraGene® assays, training of laboratory personnel for the set-up of the ABL DeepChek® and UltraGene® assays and to monitor ABL DeepChek® and UltraGene® assays-kit lot performance.

This product is sold as consumable testing materials only with ABL DeepChek® and UltraGene® assays.

This product is ready-to-use in the PCR reactions and shall not be included during viral RNA extraction.

Principles of the assay

This product, a 5-member panel, is heat inactivated viral culture fluids, non-infectious, from various SARS-CoV-2 isolates with established reactivity for SARS-CoV-2 Variant of Concern (VOC) RNA.

Assay components

Label	Volume	Color cap	Storage
Control WT	20 µL	Orange	-25°C / -15°C
Control Alpha	20 µL	Yellow	-25°C / -15°C
Control Beta	20 µL	Pink	-25°C / -15°C
Control Gamma	20 µL	Green	-25°C / -15°C
Control Delta	20 µL	Blue	-25°C / -15°C

*Table 1: Volumes and storage conditions of the **SARS-CoV-2 External Controls V3.X (RUO)***

Reagent storage and handling

The controls should be stored at -20 °C or below.

Materials required but not provided

A “no template” (negative) control (NTC) consisting of Water (molecular grade) shall be used and is needed to detect cross-contamination during all reaction steps and to determine validity of the test run.

Warnings and precautions

- **For Research Use Only (RUO). Not for use in diagnostic procedures.** No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.
- Repetitive freezing and thawing is not recommended. Titer will be altered by multiple freeze-thaws.
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- It must be used within a Biological Safety Level 2 facility or cabinet. Please consult your institution’s regulations regarding the use of this product. For a detailed discussion on biological safety see the 5th edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by the CDC at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm.
- Each laboratory must evaluate the product and establish their own acceptance criteria.
- Store assay reagents as indicated on their individual labels.
- Do not mix reagents from different kit lots.
- Reagents must be stored and handled as specified in these instructions for use. Do not use reagents past the expiration date.
- Work surfaces and pipettes should be cleaned and decontaminated with cleaning products such as 10% bleach, “DNAZap™” or “RNase AWAY®” to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
- Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious specimens.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Always use pipette tips with aerosol barriers. Tips that are used must be sterile and free from DNases and RNases.
- Dispose of waste in compliance with the local, state, and federal regulations.
- Frequent cleaning of the wells of the PCR instrument plate is recommended to prevent contamination.
- To avoid contamination, use separated and segregated working areas.
- Check whether the PCR reaction tubes are tightly closed before loading on the PCR instrument to prevent contamination of the instrument from leaking tubes.

Product quality control

In accordance with ABL’s Quality Management System, each lot of the product is tested against predetermined specifications to ensure consistent product quality. Certificates of Analysis are available upon request.

Symbols

	Caution		Consult instructions for use
	Catalog number	**R*n***	R is for revision of the Instructions for Use (IFU) and n is the revision number
	Use by		Temperature limitation
	Manufacturer		Serial Number
	Country and date of manufacturing		

Contact Information

For technical assistance and more information, please see our Technical Support Center at Online: https://ablsa.odoo.com/fr_FR/issue; Email: support-diag@ablsa.com; Call +339 7017 0300 Or contact your ABL Field-Application Specialist or your local distributor. For up to date licensing information or product-specific disclaimers, see the respective ABL Assay User Guide. ABL User Guides are available at **www.ablsa.com/ifu** or can be requested from ABL Technical Services or your local distributor.

Manufacturer

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The customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the device. The information in this guide is subject to change without notice. DISCLAIMER: TO THE EXTENT ALLOWED BY LAW, ABL (S.A) AND/OR ITS AFFILIATE(S) WILL NOT BE LIABLE FOR SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH OR ARISING FROM THIS DOCUMENT, INCLUDING YOUR USE OF IT.

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