

REF COV4100-1 **IVD** **Rx only** **EUA only**

INTENDED USE

The Accula™ SARS-CoV-2 Control Kit is intended for in vitro diagnostic use in quality control testing with the Accula™ SARS-CoV-2 Test.

SUMMARY

The Accula™ SARS-CoV-2 Control Kit provides positive and negative control swabs for use with the Accula™ SARS-CoV-2 Test. The positive swab is coated with DNA Based Synthetic Oligo near the limit of detection of the test. When used for quality control in the Accula SARS-CoV-2 Test, these controls are useful as an aid in verifying test and operator performance.

MATERIALS PROVIDED:

- 5 - SARS-CoV-2 Low Positive Control Swab: DNA Based Synthetic Oligo dried onto a swab near the limit of detection of the test.
- 5 - SARS-CoV-2 Negative Control Swab: untreated swab.
- Instructions For Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Accula SARS-CoV-2 Test (Catalog # COV4100)
- Accula Dock (Catalog # D2000) or Silaris Dock (Catalog # 1026)

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use under Emergency Use Authorization only.
- Federal Law restricts sale of this product to or on the order of a licensed practitioner.
- To be used in conjunction with the Accula SARS-CoV-2 Test and the Accula Dock or Silaris Dock.
- DO NOT use the Controls past their expiration date.
- DNA Based Synthetic Oligo is used to make the positive control swabs. However, control swabs and used cassettes should be handled as though they could transmit disease.
- Observe established precautions against viral hazards during use and disposal.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when handling samples.
- Do not use any damaged kit contents.
- Do not touch the heads of the Control swabs. Cross contamination may occur due to the high sensitivity of the test.
- Not for patient use.
- Follow proper infection control guidelines for handling all specimens, control swabs and related items. Properly dispose of all contaminated waste according to federal, state, and local requirements.
- Swabs stored in foil pouch at 15°C-30°C (59°F-86°F) are stable until the expiration date printed on the pouch.

STORAGE

- The Accula SARS-CoV-2 Control Kit must be stored at 15°C-30°C (59°F-86°F).
- The swabs should be kept in the pouch until testing.

INSTRUCTIONS FOR USE

- Use the Accula SARS-CoV-2 Control swabs as you would a patient sample in accordance with the procedure for the Accula SARS-CoV-2 Test (Catalog # COV4100). Read the instructions for use prior to utilizing the Accula SARS-CoV-2 Control Kit.

EXPECTED RESULTS

- The SARS-CoV-2 Positive Control should yield a positive SARS-CoV-2 result.
- The SARS-CoV-2 Negative Control should yield a negative result.

DISPOSING OF MATERIAL

- Discard of hazardous or biologically contaminated materials according to your institutions practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

REORDER NUMBER

Catalog No. COV4100-1 Accula SARS-CoV-2 Control Kit
Catalog No. COV4100 Accula SARS-CoV-2 Test Kit
Catalog No. D2000 Accula Dock or 1026 Silaris™ Dock

TECHNICAL ASSISTANCE

If External QC testing fails, repeat the test using new control swabs, reagents and test cassettes, or contact Mesa Biotech for assistance, mesabiotech.com or +1 (858) 800-4929 before continuing with further samples.

KEY TO COMPONENT LABELING



Instructions For Use



Positive Control



Use by
YYYY-MM-DD



In Vitro Diagnostics



Negative Control



Manufacturer



Contents



Product Catalog
Number



Single-use only.
Do Not Reuse.



Product Batch
Number



Temperature



Caution: Federal Law restricts
this device to sale by or on the
order of a licensed practitioner.



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