meridian BIOSCIENCE

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Important Product Information for US customers

For product inquiries or reporting complaints, technical problems or other product-related issues, please contact

Meridian Bioscience COVID-19 Support:
MBI-TechService@meridianbioscience.com
1-800-343-3858

Para consultas sobre productos o para informar quejas, problemas técnicos u otros problemas relacionados con el producto, comuníquese con

Meridian Bioscience COVID-19 Apoyo:
MBI-TechService@meridianbioscience.com
1-800-343-3858

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EN REF C-NCOV-03G

STANDARD

COVID-19 Ag Control swab

STANDARD™ COVID-19 Ag Control swab

For *in vitro* diagnostic use only.
For prescription use only.
For use under the Emergency Use Authorization (EUA) only.

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

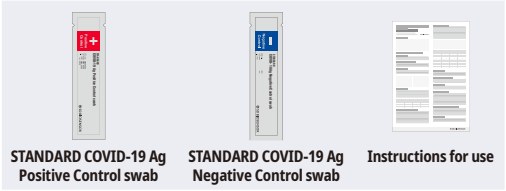
SD BIOSENSOR

INTENDED USE

STANDARD COVID-19 Ag Control swab is intended for use as an external quality control material to monitor the performance of STANDARD Q COVID-19 Ag Test 2.0. For use only with STANDARD Q COVID-19 Ag Test 2.0.

KIT CONTENTS AND ACTIVE INGREDIENTS

- STANDARD COVID-19 Ag Positive Control swab: 5 swabs packed in individual pouches (red colored label). Positive control swabs contain recombinant SARS-CoV-2 nucleocapsid protein, BSA (Bovine Serum Albumin) and excipients. The recombinant nucleocapsid protein works as an artificial antigen and it is used to verify if the system is working properly.
- STANDARD COVID-19 Ag Negative Control swab: 5 swabs packed in individual pouches (blue colored label). Negative control swabs do not contain active ingredients.
- Instructions for Use



STANDARD COVID-19 Ag Positive Control swab | STANDARD COVID-19 Ag Negative Control swab | Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- STANDARD Q COVID-19 Ag Test 2.0 (REF No. Q-NCOV-08G)
- Timer
- Disposable gloves
- Biohazard waste container

STORAGE AND STABILITY

Store the STANDARD COVID-19 Ag Control swab at 2-30°C/36-86°F. Kit materials are stable until expiration date printed on the outer box.

WARNING AND PRECAUTIONS

1. Bring the kit contents and specimens to operating temperature (15-30 °C/ 59-86 °F) before testing.
2. Do not reuse the control swabs.
3. Do not use the control swabs if the pouch is damaged or the seal is broken.
4. Do not smoke, drink or eat while testing.
5. Do not use the control swabs for sample collection from patients.
6. If there is evidence of microbial contamination in the reconstituted control in the extraction buffer, discard the control.
7. Wear protective clothing, mask, and gloves when handling specimens and reagents. Wash hands thoroughly after the tests are done.
8. Clean any spillage by immediately and thoroughly wiping up with a suitable disinfectant such as 1% sodium hypochlorite solution.
9. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
10. Dispose of all samples and materials used to perform the test as biohazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Do not use kit materials if expiration date has passed.
12. In the event of damage of packaging, contact the distributor of this product at Meridian Bioscience Customer Service Center MBI-TechService@meridianbioscience.com

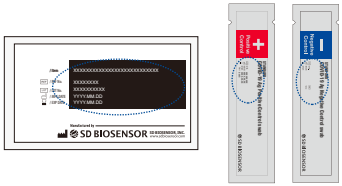
CIRCUMSTANCES FOR RUNNING QUALITY CONTROL TESTS

It is important to perform quality control tests with positive and negative control materials to ensure your system is working properly. It is recommended that positive and negative controls be run:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°-30°C (35°-86°F), and
- At periodic intervals as dictated by the user facility, country, state or local regulations and policies :
  - Control tests may be ran prior to performing each serial testing on patient specimens.
  - Serial testing of STNADARD Q COVID-19 Ag Test 2.0 should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals.

PREPARING A QUALITY CONTROL TEST

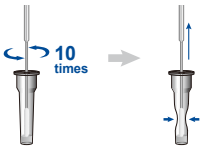
1. Bring the STANDARD™ COVID-19 Ag Test 2.0 and the STANDARD™ COVID-19 Ag Control swab to operating temperature (15-30°C / 59-86°F) at least 30 minutes prior to the test.
2. Carefully read the Instructions for Use for the STANDARD™ COVID-19 Ag Test 2.0.
3. Check the expiration date on the pouches of the control and of the test device. Do not use expired control or test devices.



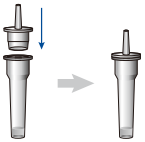
PERFORMING A QUALITY CONTROL TEST

1. Insert the positive or negative control swab into an extraction buffer tube which is in the STANDARD Q COVID-19 Ag Test 2.0. Stir the swab at least ten times while squeezing the sides of the buffer tube.

   Warning: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

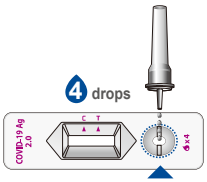


2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
3. Press the nozzle cap tightly onto the tube.



4. Apply 4 drops of the prepared control mixture into the specimen well of the test device.
5. Read the results in accordance with the Instructions for Use accompanying the STANDARD Q COVID-19 Ag Test 2.0.

   Warning: Read the results at 20 minutes. Do not read before 20 minutes or after 30 minutes. Even faint lines should be considered as a valid result.



INTERPRETATION OF QUALITY CONTROL RESULTS

STANDARD COVID-19 Ag Positive Control			
Result		Interpretation	Follow up
Test Line (T)	Control Line (C)		
Positive	Positive	Pass	-
Negative	Positive	Invalid	Retest*
No control line (C)		Invalid	Retest*

STANDARD COVID-19 Ag Negative Control			
Results		Interpretation	Follow up
Test Line (T)	Control Line (C)		
Negative	Positive	Pass	-
Positive	Positive	Invalid	Retest*
No control line (C)		Invalid	Retest*

* Use new test devices and new control for retesting. If the invalid control test result recurs, contact Meridian Bioscience Customer Service Center: MBI-TechService@meridianbioscience.com

LIMITATIONS

1. For *in vitro* diagnostic use.
2. For prescription use only.
3. This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA).
4. 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.
5. Do not use kit contents beyond the expiration date printed on the outside of the box.
6. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
7. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
8. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.
9. Adverse storage conditions or use of outdated reagents may produce erroneous results.
10. Alterations in physical appearance may indicate instability or deterioration of this product. If there is evidence of microbial contamination in this product, discard it.

FOR US CUSTOMERS ONLY-LIMITED WARRANTY:
SD BIOSENSOR warrants that this product will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL SD BIOSENSOR BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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Distribution in USA by
Meridian Bioscience, Inc.
Meridianbioscience.com
COVID-19 Support 1-800-343-3858

Manufactured by SD Biosensor, Inc.
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Please contact us for any complaints/inquiries/suggestions via email (MBI-TechService@meridianbioscience.com), Phone (1-800-343-3858) or website (Meridianbioscience.com).

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