

*For use under the Emergency Use Authorization (EUA) only  
in the United States*

*For in vitro diagnostic use*

**R<sub>x</sub> ONLY**



Sofia SARS Antigen FIA Control Set  
*Positive and Negative*

QUIDEL



### **INTENDED USE**

The Sofia SARS Antigen FIA Control Swabs are intended to be used as quality control samples representative of positive and negative test samples. These Controls may be used to demonstrate that the reagents and assay procedure perform properly.

### **SUMMARY AND EXPLANATION**

The Sofia SARS Antigen FIA Control Swab consists of non-infectious recombinant SARS-CoV-2 Antigen dried onto the swab. The Negative Control Swab consists of heat-inactivated Group C Streptococcus dried onto the swab.

### **PRINCIPLE OF THE TEST**

The Sofia SARS Antigen FIA Control Swabs are designed to be used as qualitative control samples in accordance with the Sofia SARS Antigen FIA Package Insert procedure.

### **REAGENTS AND MATERIALS SUPPLIED**

- SARS Positive Control Swabs (5): Swab is coated with non-infectious recombinant SARS-CoV-2 antigens.
- SARS Negative Control Swabs (5): Swab is coated with heat-inactivated *Streptococcus* C antigen.
- Package Insert (1)

### **WARNINGS AND PRECAUTIONS**

- For *in vitro* diagnostic use.
- Swabs are not for patient specimen collection; use only as a test quality control sample.
- Do not use contents beyond the expiration date printed on Foil Pouch.
- Use of Nitrile or Latex gloves is recommended when working with these controls.
- Dispose of used contents in accordance with Federal, State, and Local requirements.
- Testing should be performed in an area with adequate ventilation.
- Follow proper hand washing hygiene after handling these controls.
- The Control Swabs are designed for use only with the Sofia SARS Antigen FIA.
- Controls contain heat-inactivated microorganisms. However, handle as if capable of transmitting infectious disease.

## STABILITY AND STORAGE

Store the Sofia SARS Antigen FIA Control Set at room temperature 59°F to 86°F (15°C to 30°C). Do not freeze. The contents can be used until the expiration date printed on the Foil Pouch.

## QUALITY CONTROL

The Sofia SARS Antigen FIA Control Set may be used to demonstrate that the test kit reagents and assay procedure perform properly. Please refer to the Sofia SARS Antigen FIA Package Insert for quality control frequency recommendations.

## TEST PROCEDURE

Refer to the Sofia SARS Antigen FIA Package Insert.

## INTERPRETATION OF RESULTS

Refer to the Sofia SARS Antigen FIA Package Insert.

## LIMITATIONS OF THE PROCEDURE

The Sofia SARS Antigen FIA Control Swabs are qualitative reagents and are not to be used as quantitative calibrators. They should not be diluted or extracted with other reagents other than the Sofia SARS Antigen FIA reagents, and have not been validated for use with other assays.

The Sofia SARS Antigen FIA Control Swabs must be used at room temperature 59°F to 86°F (15°C to 30°C). Performance of the assay at other temperatures may yield invalid results.

## EXPECTED VALUES

The Sofia SARS Antigen FIA Control Swabs will produce negative and positive results when run according to the Sofia SARS Antigen FIA package insert instructions.

The failure to obtain a negative result with the Negative Control Swab or a positive result with the Positive Control Swab indicates that the test was not performed properly or that the test reagents were not functioning properly. Ensure the Positive Control Swab was run first, followed by the Negative Control Swab.

If either of the QC test results fail, repeat the test or contact Quidel Technical Support.

## ASSISTANCE

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com). If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference [quidel.com](http://quidel.com) to see more options for Support.

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Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	<a href="mailto:emeatechnicalsupport@quidel.com">emeatechnicalsupport@quidel.com</a>
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Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
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**REF** 20384 – Sofia SARS Antigen Control Set

**IVD**



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**REF**

Catalog number

**LOT**

Batch code

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Use by



Manufacturer

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Temperature limitation



Intended use

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**R<sub>x</sub> ONLY**

Prescription use only



Consult instructions for use

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**IVD**

For *In Vitro* diagnostic use



Contains sufficient for 5 determinations

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**CONT**

Contents/Contains

**CONTROL +**

Positive control

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**CONTROL -**

Negative control

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