Rapid Response™

COVID-19 Antigen Control Kit

REF GCCOV(Ag)-PN10 or GCCOV(Ag)-PN20 Product Insert

Configurations:
(PN10: 5 positive swabs, 5 negative swabs)
(PN20: 10 positive swabs, 10 negative swabs)

For *in vitro* diagnostic use only.
For prescription use only.
For professional use only.
Instructions for use must be carefully followed when performing the test. Failure to follow the instructions may result in inaccurate results.

Intended Use

The Rapid Response™ COVID-19 Antigen Control Kit is a ready-to-use external control kit for use with the Rapid Response™ COVID-19 Antigen Detection Test to ensure that the reagents and materials are working properly and that the test procedure is correctly performed.

Contents

The Rapid Response™ COVID-19 Antigen negative control swab is composed of negative control buffer dried onto a swab, with a blue shaft, containing a preservative.
The Rapid Response™ COVID-19 Antigen positive control swab is composed of a SARS-CoV-2 recombinant antigen extract dried onto a swab, with a red shaft, containing a preservative.
The preservative is 0.1% sodium azide.
The COVID-19 Antigen Control swabs are designed to be used to verify proper test procedure and performance of the Rapid Response™ COVID-19 Antigen.

Precautions

- For *in vitro* diagnostic use only.
- For professional use only.
- Do not use after expiration date.
- The Rapid Response™ COVID-19 Antigen Control Kit is only for use with the Rapid Response™ COVID-19 Antigen Detection Test. They have not been validated for use with other tests.
- The swab should remain in the sealed pouch until use.
- Do not use the swab if pouch is damaged.
- Do not re-use any contents in the product.
- Follow Good Laboratory Practices, wear protective clothing and use
- disposal disposable gloves when working with these controls. Do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The control swab and test device should be discarded in a proper biohazard container after testing.

Storage and Stability

Store as packaged in the sealed pouch either at refrigerated or room temperatures (2-30°C/36-86°F). The swab is stable through the expiration date printed on the sealed pouch. The swab must remain in the sealed pouch until use. Do not freeze.

Materials

Materials Provided	Materials Required but Not Provided
• 5 or 10 Negative control swab (blue) • 5 or 10 Positive control swab (red) • Product insert	• Disposable gloves • Timer • Rapid Response™ COVID-19 Antigen Detection Test

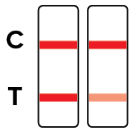
Control Kit Test Procedure

Allow the test materials to reach room temperature (15-30°C/59-86°F)
prior to testing. Do not open pouches until ready to perform the test.
For full instructions for use on how to use these controls, please refer to Rapid Response™ COVID-19 Antigen Detection Test Healthcare Provider Product Insert. The swab samples should be tested in the same manner as patient swab specimens.
We recommend controls be run once for:

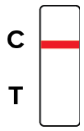
- Each new kit lot,
- Each new operator,
- Each new shipment,
- As required by site quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

If either or both external quality controls give invalid results, repeat the external controls with new swabs on the Rapid Response™ COVID-19 Antigen Detection Test.

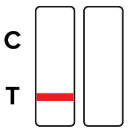
Results Interpretation



POSITIVE: If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive. Repeat testing is not needed for individuals with a positive result.



NEGATIVE: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes COVID-19 was not detected in the sample.
NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours or followed up with a molecular test.



INVALID: If the control line (C) is not visible within the result window after performing the test, the result is invalid. Some causes of invalid results include failure to correctly follow directions or the test was used beyond the expiration date. It is recommended that the control swab be re- tested using a new test device.

Manufactured for:
BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2
Canada
Technical Support: 1-888-339-9964