

# Quick Reference Instructions for Rapid Response™ Liberty COVID-19 IgG/IgM Rapid Test for the Detection of SARS-CoV-2 IgG/IgM Antibody

## For use under Emergency Use Authorization Only For Prescription Use only For In Vitro Diagnostic Use Only

### Important Note:

- Test should not be used beyond it's expiration date.
- Read the complete Quick Reference Instructions before performing the test for fingerstick whole blood.
- Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG and IgM assay.
- Refer to the package insert for specimen collection and handling for venous whole blood serum, or plasma.
- Allow test devices, reagents and specimens to equilibrate to room temperature prior to testing.
- Remove the *Rapid Response™ Liberty* COVID-19 IgG/IgM test device from its foil pouch immediately before specimen collection.



In the USA, this product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for detecting the presence of IgM and IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens. 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.

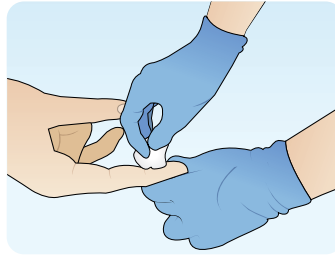
## SPECIMEN COLLECTION AND HANDLING FOR FINGERSTICK WHOLE BLOOD

### Materials required:

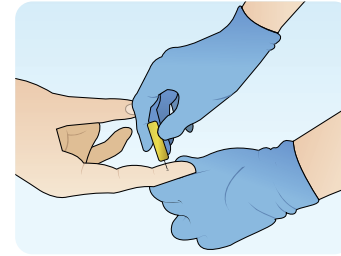
- Test device
- Assay buffer
- Blood transfer pipette
- Alcohol swab
- Sterile safety lancet
- Package insert
- Quick Reference Instructions (QRI)

### Materials required but not supplied:

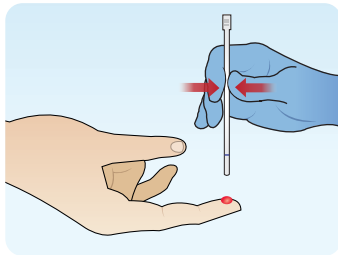
- Timer
- Pair of gloves



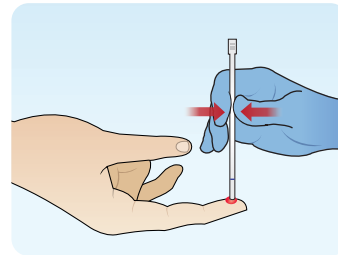
- 1** Clean the fingertip to be pierced with an alcohol swab.



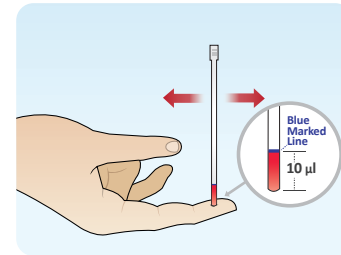
- 2** Squeeze the end of the fingertip and pierce the cleaned area using a blood lancet. Properly discard the blood lancet.



- 3** Press the top part of the provided blood transfer pipette.

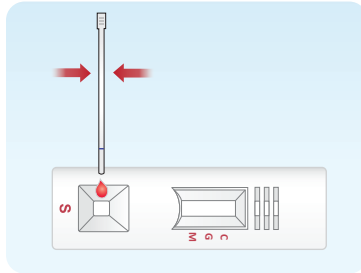


- 4** Touch the blood by the pipette tip while pressing the pipette.

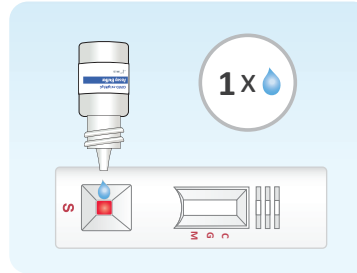


- 5** Fill the pipette with blood sample up to the **blue marked line** by releasing slowly.

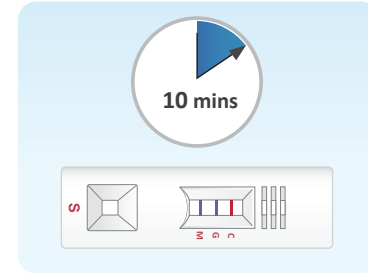
# Quick Reference Instructions for Rapid Response™ Liberty COVID-19 IgG/IgM Rapid Test for the Detection of SARS-CoV-2 IgG/IgM Antibody



- 6** Add the blood sample to the sample well "S" by pressing the top part of the blood transfer pipette.



- 7** Open the cap and invert the assay buffer bottle and hold vertically above the sample well. Add one (1) drop of the assay buffer solution to the sample well "S" immediately after sample loading.



- 8** Start a timer. Read the result at 10 minutes. The test result should not be read after 15 minutes.

## RESULT INTERPRETATION

**Positive**

**NOTES:**  
 - The color intensity in the test region will vary.  
 - Any faint colored line(s) in the test region(s) should be considered as positive.

**Negative**

**Invalid**

**NOTES:**  
 - Re-run the test using a new test device.

## EXTERNAL CONTROL TESTING PROCEDURES

User should refer to the instructions for use for the external control testing.

- Open a control vial containing the control reagents.
- Transfer the control solution from the control vial :
  - using a provided blood transfer pipette:*  
Press the top part of the provided blood transfer pipette and touch the control solution by the pipette tip while pressing the pipette. Releasing the press slowly to fill the pipette with sample up to the blue marked line (approximately 10 µL). Add the control sample to the sample well "S" of the test device by pressing the top part of the blood transfer pipette.
  - using a micropipette:*  
Transfer 10 µL of the control solution to the sample well "S" of the test device using a micropipette.
- Open the cap and invert the assay buffer bottle and hold vertically above the sample well. Squeeze the bottle gently to add one (1) drop of the assay buffer solution to the sample well "S" immediately after sample loading.
- Start a timer. Read the result at 10 minutes. The test results should not be read earlier than 10 minutes. Test results should not be read after 15 minutes.

## Expected Results:

**Positive Control**

**Negative Control**

**NOTES:**  
 If the test result for either the Negative Control or the Positive Control is not as expected, the test should be repeated using a new Test Device. If the test result for any of the controls is not as expected upon retesting, contact Technical Support.



BTNX, Inc.  
 Technical Support  
 Tel: +1-888-339-9964, Ext. 803  
 Email: support@btxn.com

Tel: +1-888-339-9964 Fax:  
 905-944-0406 Email:  
 info@btxn.com Website:  
 www.btxn.com