

Quick Reference Instructions of TekiTrust™ COVID-19 IgG Rapid Test

✓ For use under an Emergency Use Authorization Only.

✓ For in vitro diagnostic use only.

✓ For prescription use only.

✓ This is for fingerstick whole blood.

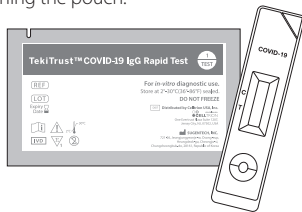
1. This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
2. The emergency 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.
3. The user should be trained in the procedure. Wear appropriate protective attire for your safety when handling patient samples.
4. Read the complete Quick Reference Instructions before performing the test. For technical assistances, please call 1-201-499-1844.
5. Due to the risk of false positive result, confirmation of positive result should be considered to use the second and different serology test.

Preparation before Test

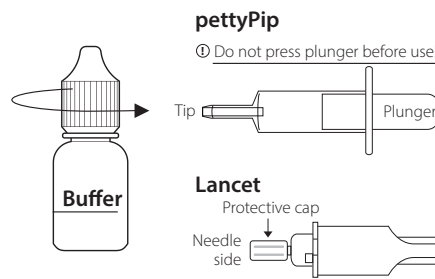
- Test components should be brought to room temperature for 30 minutes before testing.
- Test should not be used beyond its expiration date.

Test Procedure

1. Carefully read the Quick Reference Instructions for using TekiTrust™ COVID-19 IgG Rapid Test.
2. Open the cassette pouch and place on the flat surface. Use the test cassette immediately after opening the pouch.



3. Remove cap of buffer bottle and set it aside. Prepare a lancet, alcohol swab, pettyPip

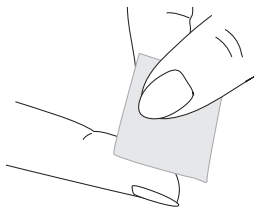


4. Before fingerstick, lower the arm to allow for better blood circulation to the finger.

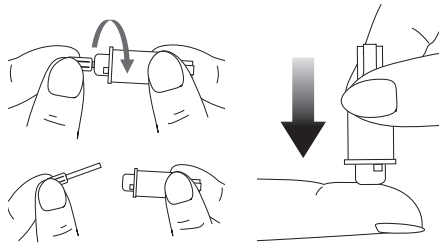


Test Procedure

5. Use the alcohol swab to clean the puncture site. Allow to dry.
Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.



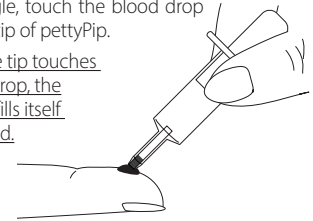
6. Turn the protective cap clockwise to remove it. **Never pluck away the protective cap.**
Push the sterile lancet firmly against the puncture site.



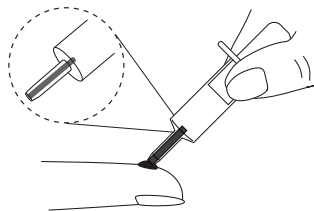
7. Place your fingers under the wing of the pettyPip and hold it horizontally. Take care not to cover the vent hole of the Plunger.

Make the blood drop form at the fingertip, then while holding the pettyPip tilted at an angle, touch the blood drop with the tip of pettyPip.

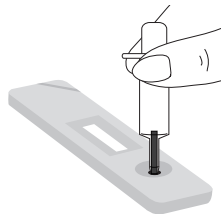
When the tip touches a blood drop, the pettyPip fills itself with blood.



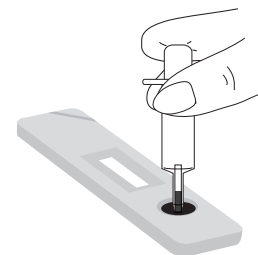
8. Please wait until the tip is completely filled with blood.
※ If the blood is not completely filled, the test results are invalid.



9. Grip the pettyPip vertical to the sample well with the end of tip touching the surface of sample well.
When the end of the tip touches the surface, blood begins to be absorbed into the sample well.



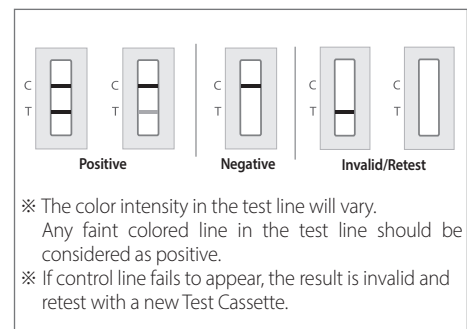
10. If blood remains in the tip, push the plunger slowly so that all blood is completely absorbed.



11. When blood is added, immediately add 3 drops of buffer onto the sample well of the Test Cassette.
Squeeze the tube lightly to allow the drops to come out.



12. Read the results after 10 min. The results are invalid after 30 min.
※ Do not read before 10 min.
※ Do not read after 30 min.



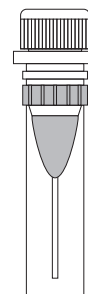
- ※ The color intensity in the test line will vary. Any faint colored line in the test line should be considered as positive.
- ※ If control line fails to appear, the result is invalid and retest with a new Test Cassette.

Quick Reference Instructions of TekiTrust™ COVID-19 IgG Rapid Test Control

Preparation before Test

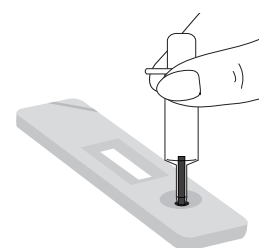
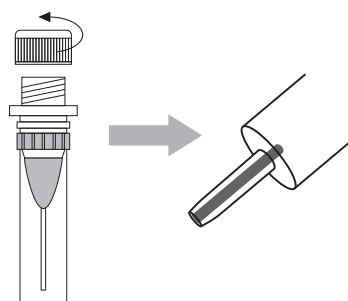
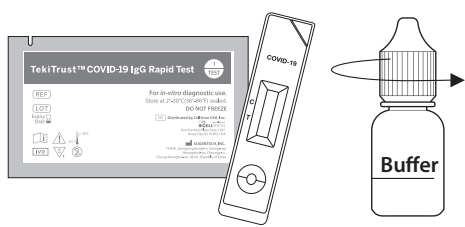
– Test components should be brought to room temperature for 30 minutes before testing

- 1 Carefully read the Quick Reference Instructions for using TekiTrust™ COVID-19 IgG Rapid Test Control.
 - TekiTrust™ COVID-19 IgG Rapid Test Positive control
 - TekiTrust™ COVID-19 IgG Rapid Test Negative control
- 2 Allow this product to reach room temperature. Gently mix by tapping the tube before use.

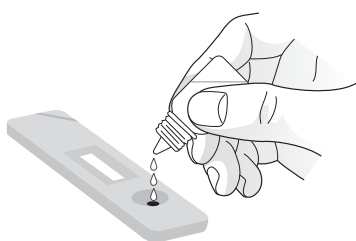


Test Procedure

- 3 Open the cassette pouch and place on the flat surface. Use the test cassette immediately after opening the pouch. Remove cap of buffer bottle and set it aside.
- 4 Remove cap of positive control or negative control and set it aside. While holding the pettyPip tilted at an angle, touch the control solution with the tip of pettyPip. When the tip touches the control solution, the pettyPip is filled with the control solution.
- 5 Grip the pettyPip vertical to the sample well with the end of tip touching the surface of sample well. When the end of the tip touches the surface, control solution begins to be absorbed into the sample well.



- 6 Immediately add 3 drops of buffer onto the sample well of the Test Cassette. Squeeze the tube lightly to allow the drops to come out.
- 7 Read the results after 10 min. The results are invalid after 30 min.
 - ※ Do not read before 10 min.
 - ※ Do not read after 30 min.



Expected Results

