1. Intended Use
The AbC-19™ Rapid Test is a single-use test for the detection of IgG antibodies against SARS-CoV-2. When the blood sample is tested, a line forms where the antigen is present if antibodies are present. The AbC-19™ Rapid Test is intended to be used by healthcare professionals.

2. Intended End User
The AbC-19™ Rapid Test is intended to be used by healthcare professionals.

3. Background
The SARS-CoV-2 virus is a member of the Coronavirus family (CoV). In human this virus family is capable of causing illnesses that range from the common cold to more serious conditions such as severe acute respiratory syndrome (SARS) and the COVID-19 disease. The SARS-CoV-2 virus is a member of the Coronavirus family (CoV). In humans this virus family is capable of causing illnesses that range from the common cold to more serious conditions such as severe acute respiratory syndrome (SARS) and the COVID-19 disease. The SARS-CoV-2 virus is a member of the Coronavirus family (CoV).

4. Limitations
AbC-19™ Rapid Test has been validated for use with blood samples obtained from finger-stick puncture. No other sample types should be used.

5. Storage and Handling
Store the AbC-19™ Rapid Test kit in a cool, dry place away from direct sunlight. Do not store or use above 40°C or below 0°C. Do not use the test with hands wet. Dry hands thoroughly prior to use. Do not place test kit outside of the packaging.

6. Warnings and Precautions
Do not use the AbC-19™ Rapid Test if the test is performed less than 14 days after the onset of symptoms, which is why the AbC-19™ Rapid Test may give a negative result for the presence of SARS-CoV-2 antibodies (IgG), if the test is performed less than 14 days after the onset of symptoms, which is why the AbC-19™ Rapid Test may give a negative result for the presence of SARS-CoV-2 antibodies (IgG).

7. Interference
Interference is possible if the sample contains high levels of ascorbic acid (vitamin C) or hemoglobin. These substances may interfere with the binding of the SARS-CoV-2 antibodies (IgG) to the test strip and may give a false-positive result.

8. Test Principle
Only a small amount of blood is required to perform the test. The AbC-19™ Rapid Test is used to detect SARS-CoV-2 antibodies (IgG) in blood samples obtained from finger-stick puncture. The test kit contains a test strip and a control strip. The test strip is used to detect the presence of SARS-CoV-2 antibodies (IgG) in the blood sample. The control strip is used to confirm the validity of the test.

9. Interpretation of Results
The AbC-19™ Rapid Test is read by visually inspecting the test and control strips. The test strip shows a result within approximately 5 minutes. A positive result is indicated by a line appearing on both the test and control strips. A negative result is indicated by a line appearing on the control strip only. An invalid result is indicated by a line appearing only on the test strip or no lines appearing on the test strip.

10. Performance Characteristics
Clinical specificity, sensitivity and overall agreement (accuracy)

<table>
<thead>
<tr>
<th>Clinical specificity</th>
<th>Sensitivity</th>
<th>Overall agreement (accuracy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.8% (95% CI: 99.6% - 99.9%)</td>
<td>99.9% (95% CI: 99.8% - 99.9%)</td>
<td>99.8% (95% CI: 99.6% - 99.9%)</td>
</tr>
</tbody>
</table>

**Symbol Key**
- **POSITIVE**: Result indicates a recent or previous infection by the virus.
- **NEGATIVE**: Result indicates no past or current infection by the virus.
- **INVALID**: Result invalid, test must be repeated using a new test kit.

**Interference**
A range of substances were tested using the AbC-19™ Rapid Test for positive and negative interference. No false positives or false negatives were recorded at the concentrations detailed in the table above.

**References**
**When to test?**

The AbC-19™ Rapid Test should not be used until at least 14 days after the onset of symptoms.

Symptoms of COVID-19 are:

- A high temperature
- A new continuous cough
- A loss or change to sense of smell or taste

**Before you start...**

Read the step-by-step instructions several times until you are confident you understand each stage.

**KIT MATERIALS**

- Materials Provided:
  - 1x Test
  - 2x Single-Use Lancets
  - 1x Blood Collector
  - Instructions
  - 1x Test Solution
  - 1x Waste Bag

- Additional Materials Needed:
  - Timer
  - Tissue

**HELPFUL TIPS**

- Perform the test at room temperature (15-25°C) in a well-ventilated area.
- When performing the test, be in a clean flat surface.
- Use the spare lancet if you have problems getting enough blood.
- DO NOT over-fill or under-fill the blood collector.
- DO NOT freeze the blood collector or puncture site when collecting blood.
- Once collected the blood will begin to clot, move to step 7 without delay.

**STEP 1: PREPARE**

1. Prepare by washing hands with soap and water. Do not use any hand creams or hand sanitiser.
2. Open foil pouch and remove test. Discard silica gel packet.
3. Blood should be collected from the ring or middle finger of the non-dominant hand.
4. The finger stick puncture should be performed on the side of the fingertip next to the nail. Apply gentle pressure to break the seal.
5. To perform the finger-stick puncture, first remove the protective cap from the lancet. Place the lancet tip on the side of the fingertip. Apply gentle and steady pressure for 2-3 seconds until a click is heard.

**STEP 2: SAMPLE**

1. Wait a few seconds for a drop of blood to form. If a drop does not form, gently touch the centre of the sample hole on the test with the tip of the non-dominant finger, then gently squeeze the bulb or push the blood collector into the puncture site when collecting blood.
2. Place the blood collector at a slight angle, gently touch the tip to the blood collector. The bulb will automatically be shown up the blood collector to the black fill line.
3. Wait for 2-3 mm space to appear under the blood collector.
4. Holding the blood collector vertically at a right angle, gently touch the tip to the blood collector. The blood will automatically be shown up the blood collector to the black fill line.

**STEP 3: COLLECT**

1. Wait a few seconds for a drop of blood to form. If a drop does not form, gently touch the centre of the sample hole on the test with the tip of the non-dominant finger, then gently squeeze the bulb or push the blood collector into the puncture site when collecting blood.
2. Place the blood collector horizontally at a slight angle, gently touch the tip to the blood collector. The bulb will automatically be shown up the blood collector to the black fill line.
3. Ensure a good size drop of blood has formed before collecting the blood. Ensure getting enough blood by repeating the puncture site when collecting blood.
4. If you have hearing or speech difficulties please call our helpline:

**STEP 4: RUN TEST**

1. Holding the blood collector straight, gently touch the centre of the sample hole with the tip and squeeze the bulb until a drop of blood is in the sample hole.
2. Place the test solution to the sample hole on the test, one drop at a time, until there is no solution remaining.
3. Wait a few seconds before reading the results.

**STEP 5: RESULTS**

1. After 20 minutes look at the viewing window to interpret your results. Your test will have...
2. Interpret the results immediately following the 20 minute wait time. Reading too late can give inaccurate results.
3. 2 Lines (T and C) = POSITIVE
4. No Lines or 1 Line (T) = INVALID
5. 1 Line (C) = NEGATIVE

**STEP 6: DISPOSAL**

1. Place all kit materials in the waste bag and seal. Do not recycle any used lancets before disposing.
2. IMPORTANT: The test and Rapid Test is not suitable for recycling.

**FURTHER ASSISTANCE**

For general enquiries or additional assistance when performing and interpreting the AbC-19™ Rapid Test please call our helpline:

- **England, Wales and Northern Ireland**: 119 (Text – 7191)
- **Scotland**: 119300 and 333762 (Text – 7019)
- **Engines**: 119300 and 333762 (Text – 7019)
- **Further assistance**: 119300 and 333762 (Text – 7019)
- **Use the spare lancet if you have problems getting enough blood.**