**Intended Use**
BIOCREDIT COVID-19 Ag Home Test Nasal is a rapid chromatographic immunoassay intended for the qualitative detection of nucleocapsid (N) protein antigen from SARS-CoV-2 in individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for home use with self-collected direct nasal (nares) samples using the sterilized nasal swab provided in the kit.

**Principle of Test**
BIOCREDIT COVID-19 Ag Home Test Nasal is a lateral flow immunochromatographic assay that adopted dual color system. The test contains colloidal gold conjugate pad and a membrane strip pre-tested by the expert. The test strips are specific to SARS-CoV-2 antigen on the line T. If SARS-CoV-2 antigen is present in the specimen, a visible black band appears on the test line (T) as antibody-antigen-antibody gold conjugate complex forms. The control line (C) is used for procedural control and should always appear if the test is performed correctly.

**Test preparation**
1. Prepare a flat and dry surface such as a desk. Clean the prepared area.
2. Wash your hands with soap or hand sanitizer for 30 seconds, then dry them off.
3. If more than one test will be used, you will need to clean the table and wash your hands before and after each test.
4. Make sure you have all the components required to use this kit. If there is any missing or damaged part, do not use the kit.

**Components required but not provided**
- Clock or timer, Tissues, Mirror, soap or hand sanitizer, disposable gloves
- Sterile cotton balls

**Sample collection using Nasal swab**
1. Wash your hands with soap or hand sanitizer, wear gloves (not included) and prepare timer (not included).
2. Remove the assay diluent tube from the pouch and remove the lid (The tube contains a colorless liquid). *When opening the assay diluent pouch with scissors, be careful not to cut the contents together.*
3. Install the assay diluent tube into the tube fixing hole of box.
4. Open the wrapper and remove the swab by holding the tube. Do not touch the soft, fabric tip of the swab with your hands.
5. Gently insert the swab into the nostril (about 2cm). Collect sample nasal from oval well by rotating the swab in a circular path for 10 times against the nasal wall. Slowly remove the swab.
6. Repeat the procedures above to the opposite nostril.
7. Take out the assay diluent tube which is installed in the tube fixing hole and immerse the entire tube line into the diluent. Rotate the tube for about 10 times with the head in contact with the bottom and the wall of the tube.
8. Leave the swab in the tube and break the swab stick at the break point. Make sure that the tip of the swab is inserted into the tube.
9. Thrown the broken plastic handle away in the disposal bag.
10. Press the cap tightly onto the tube to avoid any leaks (Do not separate the combined filter cap from the assay diluent tube).
11. Place the assay diluent tube in the tube fixing hole. **Result**

1. Read the test device from the aluminum pouch and place it on a flat surface.
2. Take out the tube from the tube fixing hole and mix by gently inverting for 10 times.
3. Hold the tube vertically and apply 3 drops of assay diluent into the sample well (S).
4. Check the results after 15 to 30 minutes.

**Interpretation**

<table>
<thead>
<tr>
<th>Result</th>
<th>Photograph</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td><img src="image" alt="Negative result" /></td>
<td>There is no control line in the result window. It is recommended to repeat the test samples.</td>
</tr>
<tr>
<td>Positive</td>
<td><img src="image" alt="Positive result" /></td>
<td>Two bands, black test line “T” and red control line “C” in the result window.</td>
</tr>
<tr>
<td>Invalid</td>
<td><img src="image" alt="Invalid result" /></td>
<td>There is no control line in the result window “C”.</td>
</tr>
</tbody>
</table>

**Even if the test line is faint, this should be interpreted as a positive result.**

1. Check the result window of the test device and see if there is a red line next to control line C or a black line next to test line T.
2. Negative result. The appearance of only the red line in control line C indicates a negative result.
3. Positive result. The appearance of only the test line T indicates a positive result.
4. Invalid result. The appearance of the control line C and test line T indicates a positive result.

**Clinical Performance**
BIOCREDIT COVID-19 Ag Home Test Nasal is a qualitative one-step, rapid, immuno-chromatographic assay for the qualitative detection of SARS-CoV-2 antigen from Nasal swab.

- Sensitivity: 93.15% (95% CI: 84.76% ~ 97.59%)
- Specificity: 100% (95% CI: 98.30% ~ 100%)
- Positive predictive value: 100% (95% CI: 97.87% ~ 100%)
- Negative predictive value: 97.15% (95% CI: 94.34% ~ 99.34%)

**Clinical performance**
- The results of the current test cannot distinguish between SARS-CoV and SARS-CoV-2 antigens.

**Precautions before test**
1. Be sure to read and understand the instruction for use before using the test.
2. Do not eat or drink 30 minutes before you use the kit. If you have a nosebleed, you should use the product after 24 hours.
3. If you have any bleeding on your nose, remove them all before testing.
4. Do not use a sterilized nasal swab to collect specimens from any part other than the nostril.
5. Do not use any other swabs other than the provided sterilized nasal swab.
6. Do not use with any liquid other than the provided assay diluent.
7. Do not dip the swab into the assay diluent or other liquid before rinsing the swab into the nose.
8. When opening the enclosed swab, do not touch the head.

**Precautions during test**
- After collecting specimens using the nasal swab, put it into the assay diluent tube immediately.
- The aluminum pouch which contains the test kit should only be opened before performing the test.
- Keep a sufficient distance from other people and conduct the test in a well-ventilated area and in a bright place.
- All kit components should be brought to room temperature (15~25°C) for 30 minutes prior to performing the test.
- Drop exactly 3 drops of sample extracts when performing the test.
- Failure to follow this instruction may adversely affect the results. Please hold the assay diluent tube containing the sample extract vertically and drop it slowly.

**Storage condition**
1. Store the kit between 2~30°C and keep away from direct sunlight.
2. Do not freeze the product.

**Package**
Refer to outer packaging
Quick guide

1 Preparation before test
Wash your hands

2 Components provided
- Instructions for use
- Assay diluent solution
- Sterilized nasal swab
- Test device
- Filter cap
- Waste disposal bag

3 Assay diluent solution
- Take out the assay diluent tube
- Remove the seal
- Insert the assay diluent tube into the tube fixing hole of the product box
* Caution when using scissors

4 Swab
- Take out the swab
- Collect specimen from both nostrils
- Insert the swab into the tube and rotate it for 10 times
- Break the swab as marked

5 Filter cap
- Insert the filter cap and push it firmly
- Insert the assay diluent tube into the tube fixing hole of the product box

6 Test device
- Take out the device
- Gently! Specimen mixing
- Dispense
- Wait 15-30 minutes and read result

7 Result interpretation
- Negative: One red control line "C" in the result window
- Positive: Two bands; a black line "T" and a red control line "C" in the result window
- Invalid: If the result is invalid, you will need to obtain another test

8 Waste disposal
- Negative: If the result is negative, dispose of it in the trash can used at home
- Positive: Put the used materials in the plastic bag provided for disposal
- If the result is positive, visit a screening clinic to request disposal.
* Do not dispose of it in the trash can used at home.

Band intensity
- If the black band appears (including smear) on the test line, contact the nearest screening clinic.

Refer to the back page for details.