WHO Emergency Use Assessment SARS-CoV-2 IVDs PUBLIC REPORT

Product: BIOCREDIT COVID-19 Ag

Manufacturer: RapiGEN, Inc.

EUL Number: EUL 0650-160-00

Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety, and performance data. The EUL procedure includes the following:


BIOCREDIT COVID-19 Ag, with product codes G61RHA20 and G61RHA20C, CE marked regulatory version, manufactured by RapiGEN, Inc., 161 Saneop-ro 115 bon-gil, Gwonseon-gu Suwon-si, Geonggi-do 14119 Republic of Korea, was listed on 6 February 2023.

Intended use:

According to the claim of intended use from RapiGEN, Inc., “BIOCREDIT COVID-19 Ag is a rapid chromatographic immunoassay for qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasopharyngeal swab specimen collected by trained users in laboratory or point-of-care settings from patients suspected of COVID-19 within the first 7 days of symptom onset. This assay is intended to aid in diagnosing SARS-CoV-2 infection, and it is for in-vitro professional use.”

Specimen type that was validated:

Nasopharyngeal swab specimens.
Test kit contents:

<table>
<thead>
<tr>
<th>Component</th>
<th>20 tests (product code G61RHA20)</th>
<th>20 tests (product code G61RHA20C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test device (individually in a foil pouch with desiccant)</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Assay diluent tube (in a foil pouch) (0.4ml/tube)</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Filter cap</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Extraction tube caps</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Plastic tube rack</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sterilized nasopharyngeal swab</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Positive Control Swab</td>
<td>/</td>
<td>1</td>
</tr>
<tr>
<td>Negative Control Swab</td>
<td>/</td>
<td>1</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Items required but not provided

- Personal Protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
- Timer
- Biohazard container

Storage:

2-30°C.

Shelf-life upon manufacture:

24 months (real-time stability studies are ongoing).

Warnings/limitations:

Refer to the instructions for use (IFU).

Product dossier assessment

RapiGEN, Inc. submitted a product dossier for the BIOCREDIT COVID-19 Ag for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDX_0347)”. The information (data
and documentation) submitted in the product dossier was reviewed by WHO staff and 
external technical experts (assessors) appointed by WHO.

Post listing Commitments for EUL:

As commitments to listing, RapiGEN, Inc. committed to:

1. Assess the traceability of the materials used to validate the product (including 
estimation of LoD) with the WHO International Standard when available.
2. Partaking in an independent performance evaluation conducted by a laboratory 
   commissioned by WHO. Any such performance evaluation testing will be performed 
   using the protocol and technical criteria established by WHO.
3. Provide a supplementary clinical specificity study including at least 30 negative clinical 
   specimens. The submitted information is under review.
4. Provide the full shelf-life study report by 28 February 2024. If results at any of the 
   testing time points are outside the acceptance criteria, or the planned shelf-life 
   changes, the WHO is required to be notified.

Risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, RapiGEN, Inc. was asked to provide up-to-date 
information about the status of its quality management system.

Based on the review of the submitted quality management system documentation by WHO 
staff, it was established that sufficient information was provided by RapiGEN, Inc. to fulfil the 
requirements described in the “Instructions for Submission Requirements: In vitro diagnostics 
(IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 
antigens (PQDx_347)”.

Quality management documentation assessment is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting 
on adverse events, product problems, non-conforming goods and processes is critical 
component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:
1. Notification to WHO of any planned changes to a EUL product, in accordance with “WHO 
   procedure for changes to a WHO prequalified in vitro diagnostic” (document number 
PQDx_121); and
2. Post-market surveillance activities, in accordance with “Guidance for post-market 
surveillance and market surveillance of medical devices, including in vitro diagnostics” (ISBN 
978-92-4-001531-9).
RapiGEN, Inc. is also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in place in accordance with WHO guidance “Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics” (ISBN 978-92-4-001531-9).

**Scope and duration of procurement eligibility**

RapiGEN, Inc., with product codes G61RHA20 and G61RHA20C, manufactured by RapiGEN, Inc., is eligible for WHO procurement 12 months from the day of listing. The assay may be used for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, RapiGEN, Inc. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. RapiGEN, Inc. is required to notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

---


2 EUL renewal assessment is ongoing.
Labelling

1.0 Labels

2.0 Instructions for Use (IFU)
1.0 Product labels

1.1 Primary packaging

1.2 Secondary Packaging Product code G61RHA20
One step, rapid, immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab.

For in vitro diagnostic use

Package: 20 tests/kit
Store at 2-30°C (35.6-86°F)
Do not reuse.

Contents:
1) Test device (individually in a foil pouch with desiccant)×20
2) Assay diluent tube (in a foil pouch) (0.4 ml/tube)×20
3) Filter cap×20
4) Plastic tube rack×2
5) Sterilized swab for nasopharyngeal specimen collection×20
6) Instructions for use×1

Lot No.   :
Diluent      :
Exp. Date :
G61RHA20
1.3 Secondary packaging Product Code G61RHA20C
One step, rapid, immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab.

**BIOCREDIT COVID-19 Ag**

- **For in vitro diagnostic use**
- **Package:** 20 tests/kit
- **Store at 2-30°C (35.6-86°F)**
- **Do not reuse.**
- **Contents:**
  1. Test device (individually in a foil pouch with desiccant) × 20
  2. Assay diluent tube (in a foil pouch) (0.4 ml/tube) × 20
  3. Filter cap × 20
  4. Plastic tube rack × 2
  5. Sterilized swab for nasopharyngeal specimen × 20
  6. Positive control swab × 1
  7. Negative control swab × 1
  8. Instructions for use × 1

**CONTROL**

- **LOT No.:**
- **Exp. Date:**
- **G61RHA20C**

**Manufactured by:**
1.4 Buffer pouch
1.5 Sterilized nasopharyngeal swab
Rapigen

BIOCREDIT COVID-19 Ag Positive Control Swab

Control use only
DO NOT USE for specimen collection

Manufactured by Rapigen, INC.
165, Sanre-ro 155beon-gil, Gwoneun-gu, Suwon-si,
Gyeonggi-do 16648, Republic of Korea

Authorized Representative
MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St Ingbert, Germany

C-G61PC-E01(2021.06.15)
1.6 Negative Control Swab
1.7 Positive Control Swab
1. Noble Bioscience (NFS-1)

2. COPAN (534CS01)

3. Jiangsu HanHeng (Type A-04)

4. Jiangsu Changfeng (JSCF-ZR-3)

5. FA INC. (FANAB01)

6. Medico Technology (MFS-96000BQ)
2.0 Instructions for use

3 English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
### One Step SARS-CoV-2 Antigen Rapid Test

**Test Name:** COVID-19 Ag

**Purpose:** Detects the presence of SARS-CoV-2 antigens in nasal swab samples from patients suspected of having COVID-19.

**Specimen:** Nasal swab

**Test Procedure:**

1. Collect a nasal swab from the patient.
2. Mix the swab with the test buffer provided.
3. Apply the mixed sample to the test device.
4. Wait for 15 minutes.
5. Compare the test result with the control line.

**Positive Result:** One or more control lines appear.

**Negative Result:** No control lines appear.

**Result Interpretation:**

- **Positive:** Presence of SARS-CoV-2 antigens.
- **Negative:** Absence of SARS-CoV-2 antigens.

**Limitations:**

- The test is not intended for use in pregnant women.
- The test is not intended for use in children.
- The test is not intended for use in immunocompromised patients.

**Precautions:**

- Do not use expired products.
- Do not use the test device beyond the expiration date.
- Do not reuse the test device.

**Storage and Handling:**

- Store at room temperature.
- Do not freeze.

**Warnings:**

- Do not use unopened products.
- Do not use the test device if the integrity of the package has been compromised.

**Manufacturers:**

- **Rapigen**

**References:**

- World Health Organization (WHO), manufacturer's instructions.

**Interpretation:**

- **Positive:** Presence of SARS-CoV-2 antigens.
- **Negative:** Absence of SARS-CoV-2 antigens.

**Result Format:**

- **Qualitative:** Yes or No
- **Quantitative:** Not applicable

**Stability:**

- **Room Temperature:** 2-8°C
- **Expiration Date:** 2 years

**Quality Control:**

- **Control Line:** Preset control line for test accuracy.
- **Test Line:** Indicator for positive result.

**Discarding:**

- **Test Materials:** Dispose of all used test materials in appropriate waste containers.

**Interpretation of Results:**

- **Positive:** Presence of SARS-CoV-2 antigens.
- **Negative:** Absence of SARS-CoV-2 antigens.

**Limitations:**

- **Contraindications:** Use in pregnant women, children, or immunocompromised patients.
- **Precautions:** Not intended for use in immunocompromised patients.
- **Accuracy:** Limited accuracy in certain patient populations.

**Manufacturers:**

- **Rapigen**

**References:**

- World Health Organization (WHO), manufacturer's instructions.
**BIOCREDIT COVID-19 Ag**
One Step SARS-CoV-2 Antigen Rapid Test

### Description of materials provided

- Test Device
- Assay diluent tube
- Sterilized swab
- Filter cap
- Plastic tube rack
- Instructions for use
- External control swab (Only for G61RHA20C)
- Positive Swab
- Negative Swab

### Specimen collection

- Tilt the patient’s head slightly backwards.
- Insert a nasopharyngeal swab horizontally into the nasal cavity until resistance is met at the level of the turbinate, reaching the surface of the posterior nasopharynx.
- The distance is equivalent to that from the nostril to the ear of the patient, indicating contact with the nasopharynx.
- Gently rub and rotate the swab against the nasopharyngeal mucosa for 10-15 seconds to absorb secretion.
- Do not remove the swab until the tip of the swab is wet.

### Assay Procedure

1. Insert the swab specimen and swirl the swab 5-10 times.
2. Remove the swab while gently squeezing the head of the swab.
3. Close the assay diluent tube with a filter cap securely.
4. Place the assay diluent tube in the plastic tube rack. Remove the device from the foil pouch and place it on a flat and dry surface.
5. Invert the assay diluent tube and gently squeeze it to dispense 4 drops (120 - 150 μl) into a sample well on the device vertically.
6. Read the result within 10 - 15 minutes. Do not interpret the result after 30 minutes.

### Interpretation of Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>One red line “C” within the result window.</td>
</tr>
<tr>
<td>Positive</td>
<td>Two bands: black “T” line and red “C” line within the result window.</td>
</tr>
<tr>
<td>Invalid</td>
<td>No “C” line within the result window. It is recommended that the specimen be retested using a new test device.</td>
</tr>
</tbody>
</table>