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

Product: iStatis COVID-19 Antigen Home Test

Manufacturer: bioLytical Laboratories Inc.

EUL Number: EUL 0690-002-00

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 the 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:


Intended use:

According to the claim of intended use from BioLytical Laboratories Inc., “the iStatis COVID-19 Antigen Home Test is a single use, visually read, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from anterior nasal swabs that are self-collected by an individual aged 15 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first seven days of symptom onset to aid in the diagnosis of COVID-19 infection.

Persons who test positive with the iStatis COVID-19 Antigen Home Test should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.”
Specimen type that was validated:

Nasal swab specimens.

Test kit contents:

<table>
<thead>
<tr>
<th>Component</th>
<th>1 Test(T) (90-1122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Cartridge (Individually packaged, prepared with control (antibody capture) and test (SARS-CoV-2 nucleocapsid antibody) lines. For single use with anterior nasal swab sample.)</td>
<td>1</td>
</tr>
<tr>
<td>Nasal Swab</td>
<td>1</td>
</tr>
<tr>
<td>Vial Holder</td>
<td>1</td>
</tr>
<tr>
<td>Buffer Vial</td>
<td>1</td>
</tr>
<tr>
<td>Buffer Vial Cap</td>
<td>1</td>
</tr>
<tr>
<td>Package Insert</td>
<td>1</td>
</tr>
</tbody>
</table>

Items required but not provided:

- Personal protective equipment such as gloves, lab coat, or gown are recommended.
- Biohazard waste containers
- Timer

Storage

2-30 °C.

Shelf-life upon manufacture

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

Warnings/limitations

Refer to the instructions for use (IFU).

Product dossier assessment

BioLytical Laboratories Inc. submitted a product dossier for IStatis COVID-19 Antigen Home Test as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_0347)”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL:

As commitments to listing, BioLytical Laboratories Inc. committed to,
1. Assess the traceability of the materials used in validating the product (including estimation of LoD) with the WHO SARS-CoV-2 antigen International Standard when available.

2. Partake 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.

Risk-benefit assessment is acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, BioLytical Laboratories 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 BioLytical Laboratories Inc. provided sufficient information to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics detecting SARS-CoV-2 nucleic acid or antigen (PQDx_347)”.  

The 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

Certain categories of complaints and changes to the product 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 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).^1

---

Scope and duration of procurement eligibility

iStatis COVID-19 Antigen Home Test, product code 90-1122, manufactured by BioLytical Laboratories Inc., is considered eligible for WHO procurement for 12 months from the day of listing. The assay may detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. 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, BioLytical Laboratories Inc. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. BioLytical Laboratories 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.

Labelling

1.0 Labels

2.0 Instructions for Use (IFU)
1.0 Product labels

1.1 Test device pouch (front and back side)
1.2 Nasal Swab label
Disposable Specimen Collection Swab

- DISPOSABLE DEVICE, DO NOT REUSE
- DO NOT STORE AT EXTREME TEMPERATURE AND HUMIDIFIED PLACE
- PLEASE REFER TO THE INSTRUCTIONS FOR MORE INFORMATION

AnHui WenSheng Medical Materials Co., Ltd.
8th floor, No.3 workshop, No.1 Donghu Road.
BiYan Science & Technology Park, High-tech District,
Hefei, AnHui province, China

SUNGO Europe V.
Olympisch Stadion 26, 11780E Amsterdam,
Netherlands
2.0 Instructions for use

---

2 English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
INSTRUCTIONS FOR USE
COVID-19 ANTIGEN HOME TEST

TEST SET UP
1. Wash your hands thoroughly for at least 30 seconds before the test. Dry your hands before using the product and wear gloves if available.
2. Unpack the components from kit pouch.
3. Remove the cartridge from its packaging and lay flat on the table.
4. Tear off the foil seal of the Buffer Vial and place the vial into the vial holder.
5. Remove the swab from the sterile packaging, being mindful not to touch the soft pad with your hand.

NASAL SAMPLE COLLECTION
6. Gently insert the swab with soft pad no more than 3/4 inch into the LEFT nostril. Then, slowly rotate the swab at least 5 times in a circular path for 15 seconds. Once complete carefully remove the swab from the LEFT nostril.
7. Place the swab directly into the RIGHT nostril, repeating the process of rotating at least 5 times in a circular path for 15 seconds.

TEST PROCEDURE AFTER NASAL SAMPLE COLLECTION
8. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times. Further rotate the swab another 5 times while squeezing the sides of the extraction vial.
9. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab.
10. Insert the Buffer Vial Cap to the vial containing the sample and push firmly to close onto the vial.
11. While holding the top of the vial with one hand flick the bottom of the vial with the other to thoroughly mix the solution.
12. Slowly turn the vial vertically upside down, pinch the vial, and add 3 drops to the sample well on the cartridge. The first drop may contain bubbles, but this will not affect the test results.

READ TEST RESULTS
- CONTROL
- TEST
- SAMPLE

NEGATIVE
Your result is negative if only control line is present. This means virus that causes COVID-19 was not found in your sample.

POSITIVE
Your result is positive if both control line and test line are present. This means the virus that causes COVID-19 was found in your sample. If positive, please immediately reach out to your healthcare provider for additional testing and follow local self-isolation guidelines.

INVALID
Your result is invalid, if no control line is present. Even if a test line is present but no control line, the result is considered invalid. Control line must appear to indicate that the test has been performed correctly. This may be the result of incorrect test procedure, repeat with new test.

DISPOSAL
I know. iStatis.
Discard all the test kit components in to the trash bin.
**COVID-19 Antigen Home Test**

Single-use lateral flow immunoassay for the detection of nucleocapsid proteins from SARS-CoV-2

**INTENDED USE**

The iStatis COVID-19 Antigen Home Test is a single-use, visually read, lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from anterior nasal swabs that are self-collected by an individual aged 15 years or older or can be collected by an adult for children under 15 years of age. This test is intended for use in individuals with symptoms of COVID-19 within the first seven days of symptom onset to aid in the diagnosis of COVID-19 infection. Persons who test positive with the iStatis COVID-19 Antigen Home Test should seek follow up care with their physician or healthcare provider for additional testing and public health reporting may be necessary. Positive results do not establish infection or can exclude other infections with viruses. Persons who test negative on a test with symptoms consistent with COVID-19 infection may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

**BACKGROUND**

Coronaviruses (CoV) are a large family of viruses that can infect humans and animals. In humans, coronaviruses cause illnesses ranging from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). SARSCoV-2 is named in accordance with the International Committee on Taxonomy of Viruses (ICTV) naming strategy for viruses infecting humans. It is a member of the genus Beta coronaviruses, which is a group of viruses that cause the respiratory illness disease characterized by fever, cough, and shortness of breath.1

In more severe cases, COVID-19 can cause pneumonia, SARS, kidney failure, and death.2

There is a higher chance of false negative results with home tests than with laboratory-based molecular tests. This means that there is a higher chance that the test will give you a negative result when you have COVID-19.

The test may not be appropriate to use in individuals with severe respiratory symptoms (e.g., shortness of breath, difficulty breathing) or during pregnancy. Do not use this test for the diagnosis of COVID-19 in individuals who have symptoms of COVID-19 and are pregnant. If you have any questions about whether to use this test for COVID-19 in pregnant individuals, please consult with your healthcare provider.

If you test positive with the iStatis COVID-19 Antigen Home Test for COVID-19, you should self-isolate and seek follow up with your healthcare provider as additional testing may be necessary.

**What is the Diagnosis Limit?**

The iStatis COVID-19 Antigen Home Test Limit of detection (LoD) was determined by testing limiting dilutions of SARS-CoV-2 positive COVID-19 virus (Delta Variant) in pooled human nasal samples to determine the lowest concentration of SARS-CoV-2 that can be reliably detected.

**What is the Limit of Detection?**

The iStatis COVID-19 Antigen Home Test Limit of detection (LoD) was determined by testing limiting dilutions of SARS-CoV-2 positive COVID-19 virus (Delta Variant) in pooled human nasal samples to determine the lowest concentration of SARS-CoV-2 that can be reliably detected.

**If I have an invasive test result?**

An invasive test is performed to confirm the presence or absence of a respiratory illness caused by SARS-CoV-2. If you test positive for COVID-19 by an invasive test, additional testing cannot be used to confirm the diagnosis. If you test negative for COVID-19 by an invasive test, additional testing cannot be used to confirm the absence of SARS-CoV-2.

If you test positive with the iStatis COVID-19 Antigen Home Test you should self-isolate and seek follow up with your healthcare provider as additional testing may be necessary.

**BIBLIOGRAPHY**


2. www.biolytical.com

**Technical information for further assistance, contact the Technical Support +1 604 478-5474 or sales@biolytical.com

**For in vitro diagnostic use only**

**Manufactured by:**

Biolytical Labs Inc.

5010 N 106th St

Milwaukee, WI 53226 USA

www.biolytical.com

Phone: +1 414 478-5474

Fax: +1 414 478-5471

Richmond, BC, Canada V6Y 2A2

Phone: +1 604 478-6748

Fax: +1 604 478-2599

© 2022. All rights reserved.