Orient Gene/Healgen Antigen Testing Guidelines

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1. INTRODUCTION

The distribution and administering of the Orient Gene / Healgen Antigen Tests are governed by the South African Health Products Regulatory Authority (SAHPRA), together with other Government Legislation and best practices, it is imperative to ensure the following important guidelines are read, understood, and implemented.

2. WHO CAN YOU SELL TEST KITS TO?

Orient Gene / Healgen Antigen Test Kits can be sold to anyone, provided it is not for on-shelf retail sales.

3. WHO CAN ADMINISTER THE TEST?

The Orient Gene / Healgen Antigen COVID-19 Test can only be administered by:

- Health Care Professionals,
- Trained Operators who are proficient in performing rapid test, or
- Clinical laboratory personnel.

4. STORAGE AND STABILITY

- The Test kit can be stored at temperatures from 2 - 30°C.
- Do not freeze any of the test kit components,
- Do not use the test device and reagents after expiration date,
- Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded,
- Close the kit box and secure its contents when not in use.
- “Extraction Buffer Viles / Buffer Solution” must not be decanted. Additional Viles can be purchased through BHA-Medical.
- Cassette must not be exposed to direct sunlight.

5. REPORTING

- The seller is required to retain and maintain information and records of clients.
- National Health Laboratory Service (NHLS) requires all COVID-19 tests to be reported via the NHLS Covid Screening Application (CSA) portal. Both positive and negative test results must be reported to the National Health Laboratory Service within 48 hours of testing.
- It is the responsibility of the administering individual/entity to report the results.
- Access to this portal can be attained by following the instruction below:

  i. Click on the following link: https://www.nhls.ac.za/sars-cov-2-rapid-test-reporting/
  ii. Click on the “Access Form” tab
  iii. Download, complete, sign the form and email it to: lis@nhls.ac.za.

6. PERSONAL INFORMATION LEGISLATION

- Collection of personal information must be strictly stored in accordance with the Protection of Personal Information Act (POPIA) and Promotion of Access to Information Act (PAIA).
- Personal information must only be used for the intended purposes.

7. CONSENT AND DISCLAIMER

- Prior to administering any test, the patient must sign a consent form and a disclaimer.
- The consent form must include among other points, authorization to undergo the test, agree for you to submit their personal information and results to the regulatory authority.

8. ADMINISTERING THE COVID TEST

Kindly refer to the Instructions For Use (IFU) for Detailed information.

Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used test strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the administrator of tests in accordance with local regulatory requirements. Dispose of test device and materials as bio-hazardous waste in accordance with local regulatory requirements is essential.

- Inadequate or inappropriate specimen collection and storage can adversely affect the results.
- Humidity and temperature can adversely affect results.
- Nasopharyngeal swabs will give the most accurate results.

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative test result does not at any time rule out the presence of SARS-CoV-2 Antigens in specimen, as they may be present below the minimum detection level of the test, or if the sample was collected or transported improperly.

Negative results from patients with symptom onset beyond 10 days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, should be performed.

Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive test results do not rule out co-infections with other pathogens.

When administering a test, it is imperative to ensure safety for both you and the patient, it is therefore important to ensure you adhered to the following:

Personal Protective Equipment Required:

- Disposable hazmat suits
- Disposable face mask
- Face shield
- Latex gloves
- Hand sanitizer
- Cleaning wipes
- Thermometers

Other Items Required:

- Timers
- Clock
- Plastic foot pedal dustbin with disposable bin bags,
- Medical waste disposal container
- Small plastic containers
- Plastic tables
- Plastic chairs

Stationery:

- Consent forms and disclaimer
- Pens
- Clip boards
- Unique identification numbers in duplicate
- Stickers (used for indicating the time a test has been performed)

Recommended Test process:

- Sanitize all the chairs, tables, pens etc,
- Sanitize the patient's hands,
- Check patients' temperature,
- Hand the consent form and disclaimer to the patient to complete and sign,
- Ensure all the details are completed correctly and the forms have been signed,
- Allocate a unique number onto the consent form and hand back to the patient,
- Patient to proceed to the tester with the consent form,
- Tester removes the test device from the sealed pouch and lays it on a flat surface. Administers the test.
- Tester inserts the cassette into the plastic container and
  i. allocates the same unique identification number on the consent form to the plastic container,
  ii. writes the time on a post-it sticker,
  iii. places the unique number, time sticker and consent form with the cassette and ensure that the plastic container remains level and is not moved until the 15 minutes have lapsed. Do NOT leave the cassette in direct sunlight.
- Tester disposes of gloves after each patient and sanitizes the entire workspace including chairs and tables. All swabs, papers, inserts, covers etc. must be disposed of in the plastic dustbin,
- After 15 minutes the result will be confirmed, advise the patient verbally, SMS or whatever means agreed upon.
- Remove the cassette from the plastic container and dispose it with stickers and paper in the plastic dustbin,
- Sanitize the plastic container for further use,
- Upon completion of all patients, all used PPE, dustbin contents etc must all be placed in the medical waste container and secured according to the procedure of the medical waste company,
- Ensure all consent forms are stored safely in a lockable cabinet,
- Ensure daily reporting to NHLS is completed.

9. CONTACT

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