certior HEALTH	**Certior Health Limited User Manual**	Rev.No.	03
		Date	11 April 2022

Introduction

Certior Health Ltd Laboratory is located at Rosemount Business Park which is a stone's throw away from Blanchardstown and is well connected to the rest of the city through the motorway. As part of the diagnostic services of Certior Health Ltd. we provide PCR testing for COVID-19 surveillance for the benefit of the patient and population.

The laboratory has adopted a quality management system for the purpose of the effective and efficient use of its resources. All employees are committed to the culture of quality. All staff share responsibility for identifying nonconformities or opportunities for improvement, recording these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers. CHL is committed to the highest standard of quality and operates to the international standard ISO 15189:2012. It has been accredited for the standard by INAB (Irish National Accreditation Board) on the 9th Feb 2022.

Location of the laboratory;

The Laboratory is located at Unit 4G, Centrepoint, Rosemount Business Park, Dublin 11. D11F796

Examinations performed;

PCR testing for SARS CoV-2, the virus that causes COVID-19.

1. The lab uses the Primerdesign™ PROmate™ COVID-19 assay with a sensitivity of 91.3% and specificity of 100% (manufacturer data). CHL has found from it's verification of the assay that the lab obtained sensitivity of the assay is 97.43% and specificity is 95.75% excluding a fraction of High CT/Low Viral Load results from the large pool used for the study. This is based on the likelihood that persons with lower CT/higher viral loads are more likely to be infectious, and those with high CT are less likely to be infectious. It has been observed that people who have tested positive (Detected) remain positive on PCR for lengthy periods of time thereafter, with a weakly detectable result.
   [Ref: HSE guidance on the management of weak positive / high CT PCR results https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/outbreakmanagementguidance/PCR%20weak%20results%20guidance.pdf]

2. PCR tests with PCR ADAPT COVID-19 and found a sensitivity of 92.5% and specificity of 98.57% in our verification studies with NVRL and PROmate™. When very weak positive PCR samples (CT >35) were excluded, the sensitivity and specificity was 100%.

Opening hours of the laboratory;
Mon-Fri: 11:00 - 23:00.
Sat-Sun: 12:00 - 20:00.

Examination requirements;
Certior Health Ltd conducts PCR tests that require an anterior nasal swab/oropharyngeal swab conducted by our trained professionals. It is recommended to avoid nicotine, caffeine for at least 2 hours prior to testing.

Please notify your tester of any nasal sensitivities you may have including nose bleeds, sensitivity or any underlying nasal medical conditions.

A strong blowing of the nose prior to swabbing is required.
Hand sanitising must be performed prior to swabbing.
Face coverings must be worn prior to testing and immediately after.

Results
The turnaround time for tests is 4-8 hours unless a retest is required, in which case the customer is informed. Any known/anticipated delays are communicated to users via email by our customer service associates.

Results are reported electronically from the Laboratory Information System (LIS) as one of the following results: “SARS CoV-2 Positive (Detected) / SARS CoV-2 Negative (Not Detected) / SARS Cov 2 Unclear (Indeterminate)”

A negative (Not Detected) result indicates that the sample collected from the person did not contain SARS CoV-2 (the virus that causes COVID-19) at the time of specimen collection.
However, the validity of results are dependant on several factors such as:

- Timing of specimen collection in relation to onset of illness
- Transport conditions may impact stability of the sample
- Quality and type of sample

A positive (Detected) result indicates that the sample tested contains SARS CoV-2 viral particles which have been detected by the test. While this is indicative that the patient has been exposed to the virus it does not indicate whether they are currently ill or showing symptoms as some infections can be asymptomatic.

A test sample for SARS CoV-2, the virus that causes COVID-19, may not always give a clear ‘Detected’ or ‘Not Detected’ result. This may be due to (1) an Unclear or indeterminate result or (2) an invalid or inhibitory result.
If you get an unclear / indeterminate result you will be contacted by the lab to arrange for a retest 24-48 hours after your initial test. A time interval is required between the 2 tests, to determine whether you have a new onset infection or the remnants of an previous infection or a false positive result. It is recommended that you restrict your movements until you have the result of the repeat swab, as the unclear result may be due to a very early new infection.

If the test result is invalid or inhibitory, this means that the test could not detect if you have COVID-19 and you will be contacted by the lab to arrange for a retest as soon as possible.

For all patients who need to restrict movement please ensure government guidance is followed.

https://www2.hse.ie/conditions/covid19/restricted-movements/restricted-movements/

Virus can also be detected many weeks post infection. For all patients whose samples test positive for the virus please ensure that government guidance is followed regarding isolation and quarantine.

https://www2.hse.ie/conditions/covid19/testing/positive-result/

https://www2.hse.ie/conditions/coronavirus/self-isolation/how-to-self-isolate.html

Instructions for completion of the request form;

New Clients must complete all fields in the “New Client” form including

- Full name
- Email address
- Contact phone number

Clients then create a password and continue to the test request form.

Test request form includes

- Name (given & family) of the person
- Gender
- Date of Birth
- Address & County of Residence
- Passport ID number & country of issue
- Email for result issuance
- Mobile Number
- Test location

All patients must consent to Certior Health Ltd terms and conditions as published on the company website.

Instruction for preparation of the patient;

- Patients must arrive for their appointment at least 5 minutes in advance of their allocated appointment time
- Clients must bring proof of identification for inspection

Instruction for Transportation of Samples;

All samples are transported to the laboratory as per the ADR regulations..

Requirements for patient consent;

Patients are required to sign a consent as per below:

"*Consent To Test I consent and authorise Certior Health Ltd to conduct a COVID-19 diagnostic test involving the collection of an appropriate sample through a nose and throat swab. I Understand the Risks I understand that there are risks associated with undergoing any such COVID 19 test to include minor swabbing trauma such as nasal bleeding/irritation. I accept that, as with any COVID-19 test, there is the potential for a false positive or false negative COVID-19 test result. Not an Indication of Immunity. I understand that a positive/detected and/or negative/not detected test is not an indication that I am immune to COVID-19 and therefore I will continue to behave as if I might contract or transmit the infection. I Will Take Appropriate Action. I assume complete and full responsibility to take appropriate action with regard to my test results. I will provide my COVID-19 test result to my GP. I will seek medical advice, care and treatment from my medical provider if I have questions or concerns, or if my condition worsens. No Liability I understand that Certior Health Ltd or any third party does not accept potential liability arising from this COVID-19 test, to the extent that is permitted by law, to include but not limited to any potential liability arising from any minor swabbing trauma such as nasal bleeding/irritation and/or false positive or false negative test results. I understand that neither Certior Health Ltd nor any third party accepts liability for any missed flights/ferries/travel accommodation due to late or inaccurate results. Process and Sharing of Data By authorising Certior Health Ltd to conduct a COVID-19 diagnostic test, I note that Certior Health Ltd will be processing my personal data for the purposes of medical diagnosis and research, and will be obliged to share a positive test result and my personal data with the HSE. Sharing with HSE in line with Infectious Disease Regulations, I consent to my COVID-19 test result being shared with the HSE. Statistical and Auditing Requirements I understand that my test result may be used in a breakdown of percentages report which may be shared with third parties for statistical and audit purposes but I understand that this is not considered to be personal data as I will not be identified in any such report.*"

The laboratory's criteria for accepting and rejecting samples;

- Sample collection is only conducted onsite by trained staff. CHL currently does not accept patient collected samples for PCR testing.
- Samples that are not transported within 24 hours or stored refrigerated if this is not the case, are rejected.
- Samples that are not labelled with patient details and test details on the Laboratory Information System (LIS) are rejected.
- Samples that are in an improper/broken container are rejected.

A list of factors known to significantly affect the performance of the examination or the interpretation of the results;

- Blood in the sample from nasal bleed

Availability of clinical advice on ordering of examinations and on interpretation of examination Results (Advisory Services)

The laboratory has arrangements for communicating with users on the following:

- User Manual provides information about the examination including choice of examinations including type of sample, clinical indications and limitations of examination procedures.
- GoSafe provides clinical advice on the issuance of a positive result. The Laboratory notifies HSE and provides general public health advice to patients who have tested positive.
- The Consultant Microbiologist is available to provide advice on all issues relating to interpretation of test results to meet the needs of users. The Consultant is contactable during defined periods of time through Laboratory Director, Lab Manager and/or Lab Technicians that are approved to issue results. A list of key contacts (CHL/QCD/21) is available on QT9.
- Promoting the effective utilization of laboratory services, laboratory meetings between the Laboratory staff and Clinical Microbiologist, are held regularly regarding the use of the services and for the purpose of technical and clinical matters.
- The Consultant Microbiologist is available for consulting on scientific and logistic matters such as failure of samples to meet acceptance criteria when need arises.

The laboratory's policy on protection of personal information;

GoSafe48 is fully GDPR compliant with EU regulations.

The laboratory's complaint procedure;

The laboratory has a customer service team
Access to complaint/query form is available online or an email can be sent to customerservice@gosafe48.ie

Help desk is available from 9am – 9pm 7 days a week.