



USER MANUAL

V.3

Prepared By

Tara Brady

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Prepared for

RTP Testing



RTP Testing & RTP Supplies Ltd.

Castlepollard Enterprise Centre, Innova Business Park, Water Street,
Castlepollard, Co. Westmeath

044-966 2456/086 101 9824 | info@rtptesting.ie

www.rtptesting.ie



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1. Introduction:

RTP Testing (RTP Supplies Ltd. T/A RTP Testing)'s Laboratory is located at the Synergy Centre on the TU Dublin Tallaght campus. This is a very convenient location in terms of transport links as it sits minutes from the M50 motorway and connects to the travel clinic, where samples are taken, in 1 hour. At RTP Testing we offer PCR testing for COVID-19 surveillance specifically for travel testing and for the benefit of the patient and population. Our main customer base is consumer clients wishing to travel and requiring a negative travel cert to do so, and corporate clients in the form of film and production companies testing shooting location staff to ensure COVID-19 free sets.

The laboratory has adopted a quality management system for the purpose of the effective and efficient use and management of its resources. RTP Testing is committed to the highest standard of quality and has applied to INAB for accreditation to the ISO 15189:2012 standard. All staff are committed to the culture of quality. All employees share responsibility for identifying nonconforming issues or opportunities for continuous improvement across all areas of the business to ensure the laboratory meets the needs of its customers.

2. Location of the laboratory:

The Laboratory is located at Synergy Centre, TU Dublin - Tallaght Campus, Tallaght, Dublin, Ireland

3. Examinations performed:

PCR testing for SARS-CoV-2 Coronavirus that causes COVID-19. The lab uses The Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit with a sensitivity of 99,22% and specificity of 100% respectively.

(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>)

4. Opening hours of the laboratory:

Mon-Fri: 11:00 - 20:00

Sat: 14:00 - 18:00

Sun: Closed



5. Examination requirements:

RTP Testing conducts PCR tests that require an anterior nasal or oropharyngeal swab. Swabbing is conducted on site at our Mullingar clinic by our trained swabbing technicians. It is recommended that you avoid caffeine and nicotine for a minimum of 2 hours before your test.

Please notify your swabbing technician of any nasal sensitivities you may or of any other existing nasal medical conditions.

Please note:

Face coverings must be worn during the swabbing procedure – both before and immediately after testing.

Nose must be blown prior to swabbing.

Hands must be sanitised prior to swabbing.

6. Results:

The turnaround time for tests is 24 hours unless a retest is required, in which case the customer is informed. Any known/anticipated delays are communicated to users by email or phone. In the event of an emergency that RTP Testing must use its backup laboratory for testing, users are informed by email via customer service.

Results are generated electronically from our Laboratory Information System (LIS) as one of the following results: “SARS CoV-2 Positive (Detected) / SARS CoV-2 Negative (Not Detected) / SARS Cov 2 Inconclusive (unclear)” and emailed to customers.

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 is dependent on many factors such as:

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

A positive (Detected) result indicates that the sample tested is positive for SARS-CoV-2 viral particles which have been detected by the test method. 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 may not always give a clear ‘Detected’ or ‘Not Detected’ result. If you get an “Inconclusive” 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 two tests, to determine whether you have an early-



onset infection or the remnants of a previous infection. It is recommended that you restrict your movements until you have the result of the repeat swab, as the result may be due to an early new infection.

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

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

The COVID-19 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/>

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

7. Instructions for completion of the request form:

New Clients must complete all fields in the “New Client” form (online at www.rtptesting.ie or in the clinic) including

- Passport Name
- Contact Number
- Email
- Gender
- Date of Birth
- Address
- Test Type
- Test Location

All patients must consent to RTP Testing’s terms and conditions as published on the company website.

8. Instruction for preparation of the patient:

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



9. Instruction for Transportation of Samples:

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

10. Requirements for patient consent:

Patients are required to sign a consent as per below:

“Consent To Test

I consent and authorise RTP Testing 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 regarding 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 RTP Testing, 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 RTP Testing, nor any third party accepts liability for any missed flights/ferries/travel accommodation due to late or inaccurate results.

Sharing with HSE in line with Infectious Disease Regulations



During process and Sharing of Data by authorising RTP Testing to conduct a COVID-19 diagnostic test, I note that RTP Testing 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.

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.”

11. The laboratory’s criteria for accepting and rejecting samples:

- Sample collection is only conducted on-site by trained staff. RTP Testing 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 correctly are rejected.
- Samples that are in a broken leaking or empty container are rejected.

Any rejections are notified to users via email by the laboratory.

12. 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

13. 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:

- Our User Manual provides information about the examination including choice of examinations including type of sample, clinical indications, and limitations of examination procedures.
- RTP Testing provides clinical advice on the issuance of a positive result. The Laboratory notifies HSE and provides public health advice to patients who have tested positive.
- Our Consultant Microbiologist is available to provide advice on all issues relating to the interpretation of test results to meet the needs of users. The Consultant is contactable during



defined periods of time through the Laboratory Director, Lab Manager and/or Lab Technicians that are approved to issue results.

- To promote 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.

14. The laboratory's policy on protection of personal information:

RTP Testing is fully GDPR compliant with EU regulations.

15. The laboratory's Complaint/Feedback procedure:

The laboratory has a marketing/customer service department. Access to RTP Testing's complaint/feedback form is available under the Contact Us link on our website at www.rtptesting.ie or online at <https://docs.google.com/forms/d/1nbdWQf3svlF5k5mF1CgbD5sw-tfsexliPXqzwHln9Kg/edit>

An email can also be sent to tara@rtptesting.com.

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