User Manual

1.0 Introduction

- This manual will be used as a training guide and will form part of all Induction, Quality System and Internal Auditor and any Quality System training sessions.
- The manual will be used as a reference document for all staff.
- The manual will be reviewed in the event of implementing other regulatory standards or systems in the Laboratory.
- This manual provides a Road Map for all procedures, checklists, forms, schedules and personnel responsible within the organisation.
- This manual will be used to ensure that Geo Med Diagnostics meet and exceed customer expectations on time, every time.
- A copy of the manual is issued to the laboratory and this copy is available to all staff on the controlled documents link.
- The Quality Policy will be maintained and approved as a separate document.

2.0 Mission Statement

Our Mission at Geomed Diagnostics is to provide quality laboratory services in a timely, accurate, and efficient manner and impart superior customer service in an environment that promotes compassionate care and contributes to co-worker satisfaction. We will strive to meet these goals by continuing to grow and adapt in order to consistently meet the needs of our community, patients, clients, and health system.

3.0 Accreditation Status

TBD

4.0 Patient Consent

All procedures carried out on a patient need the informed consent of the patient. This should be obtained as per 'National Consent Policy'. It is the responsibility of the clinician to explain the clinical procedure to be performed to the patient. For most routine procedures, consent can be inferred when the patient presents himself or herself with a request form and willingly submits to the collecting procedure e.g. Covid test.

5.0 Data Protection and Privacy Notice

We know that your privacy is important to you especially when it comes to matters concerning your health. This notice explains how we collect and use your information, who we share it with and your legal rights.
This notice applies to our use of your information in connection with COVID-19 testing services and all our related website, domains, and apps that may be accessed by our patients and employers (collectively the "Services").

WHO THIS NOTICE APPLIES TO

We collect and process information relating to individuals using the Services, including customers, employers, healthcare professionals and others.

INFORMATION WE COLLECT AND HOW WE GET IT

In the course of providing the Services, we collect or receive information in different ways and relating to various groups of individuals. This information may include your name, date of birth, address, mobile phone number and email address. We will collect and use information you provide to set up your account and/or to book a Covid-19 test. We will also collect payment information as part of our administrative, financial and operational process.

HOW WE USE THIS INFORMATION

We use this information for the purposes described below.

Providing the Services: We process your information as necessary to provide the Services requested.

Account set up and payment: We process your information in order to set up a profile for you on our platform and as part of our administrative, financial and operational processes, such as taking payment, issuing invoices, etc. where you pay for the Service directly.

Legal and regulatory: We process your information as required (a) for compliance with our legal and regulatory obligations (b) to detect, investigate, prevent, and address fraud and other illegal activity, security, or technical issues; (c) to protect our rights, property, or safety; (d) to

enforce any contracts we have with you; (e) to prevent physical injury or other harm to any person or entity, including you and members of the public; and (f) for regulatory compliance and investigations. For example, we may be legally required to share information with public health bodies.

SHARING YOUR INFORMATION

In the course of providing the Services, we share information with various third parties such as your relevant government departments and bodies (including public health bodies), our service providers or regulators (where legally required).

DATA TRANSFERS

In certain cases, we need to transfer your information to recipients outside the European Economic Area ("EEA"), such as where it is necessary to provide the Services.

Where we transfer your information, we do so in accordance with EU data protection law. We only transfer personal information to these countries when it is necessary for the services we provide you, or it is necessary for the establishment, exercise or defence of legal claims or subject to safeguards that assure the protection of your information. We may rely on different legal mechanisms to ensure the transfer is lawful. If the recipient is in a country that is not deemed 'adequate' by the European Commission, we may enter into the 'standard contractual clauses' with the recipient. These are contracts that contain standard commitments approved by the EU Commission protecting the privacy and security of the information transferred.

Please note that the privacy protections in some of these countries may not be the same as in your home country. We will only transfer information as permitted by law.

RETENTION

We may retain your information for as long as necessary in light of the purposes set out in this notice, including for the purposes of satisfying any legal, accounting, or reporting requirements and, where required for GeoMed Diagnostics to assert or defend against legal claims, until the end of the relevant retention period or until the claims in question have been settled. For example, we have specific legal obligations to retain medical information in accordance with our statutory requirements.

To determine the appropriate retention period for personal data, we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorised use or disclosure of your personal data, the purposes for which we process your personal data and whether we can achieve those purposes through other means, and the applicable legal requirements. For example, we retain any sample or DNA data you provide to us for the minimum period required to provide the Services, which will be less than two weeks after which it is safely and securely destroyed.

YOUR RIGHTS

You have a number of rights in relation to your information that we process. To exercise these rights, please contact us at info@geomed.ie.

6.0 Quality Policy

Geomed Diagnostics is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of the users.
In order to ensure that the needs and requirements of users are met, the Laboratory will:

- Ensure that the requirements of INAB and ISO15189 are met,
- Quality assurance and Quality Control programs are established, maintained and are effective in identifying problems.
- Monitor Quality Control, Quality Assurance, and Safety and Inspection Control practices to assure compliance with internal and external regulations.
- Develop and implement quality control programs to ensure reliability of testing procedures, proper function of laboratory equipment and compliance with INAB regulations and ISO 15189:2012; prepare and maintain applicable records.
- Participate in the development of new laboratory procedures and techniques; plan, develop and present workshops.
- Responsible for the oversight of the ancillary testing program including quality control, quality assurance, and development of policies and procedures.
- Interpret accrediting agencies standards or guidelines for ancillary testing program and translate requirement into policies and procedures; initiate corrective action as soon as deficiency is identified; complete checklist and other information sheets required and coordinate on-site inspection of sections for which responsible.
- Stay abreast of and execute latest technical and management developments including new lab procedures.
- Ensure that SOP's and manuals are available and have been reviewed annually by director, manager, supervisor or all other staff.
- Develop protocols for carrying out evaluation of candidate test methods, instruments, and quality control materials and procedures, and direct the evaluations, including the recording of data and maintenance of records to document performance.

7.0 Hours of operation

Day	Routine Hours	Emergency On-call Service
Monday – Friday	09:15 – 17:15	17:15- 00:00
Saturday/Sunday/Bank Holidays	No Routine Service	0800: 00:00

8.0 Postal Address

Geomed Diagnostics,

Shinagh House,

Bandon,

Cork

P72 TY31

9.0 Department contact and On-call Contact Details

Microbiology / Molecular	
Telephone	On-Call
021-7355430 ext. :111	083-0107071 or 021-7355430

10.0 Staffing

- Managing Director
- Technical Manager
- Consultant Microbiologist
- Heads of Departments
- Laboratory Analysts
- Laboratory Aides

11.0 Contact Details

Position	Name	Direct (internal)	Telephone (External)
Microbiologist	Dr Brian Carey		
Technical Manager	John Finn (Chief Medical Scientist)	110	023-8854100
Chief Scientist – Molecular	John Finn	103	021-7355430
Quality Manager	Evelyn O Sullivan (Acting)	106	023-8854100
Laboratory Office		111	021-7355430
Sample Reception		103	021-7355430
On-Call		111	021-7355430 083-0107071
Laboratory Accounts		107/109	023-8854100

12.0 Laboratory Request Forms, Specimen Collection & Result Reporting Times

This section outlines the information that is required to be documented on the laboratory request form and the specimen bottle of container, prior to the analysis of samples.

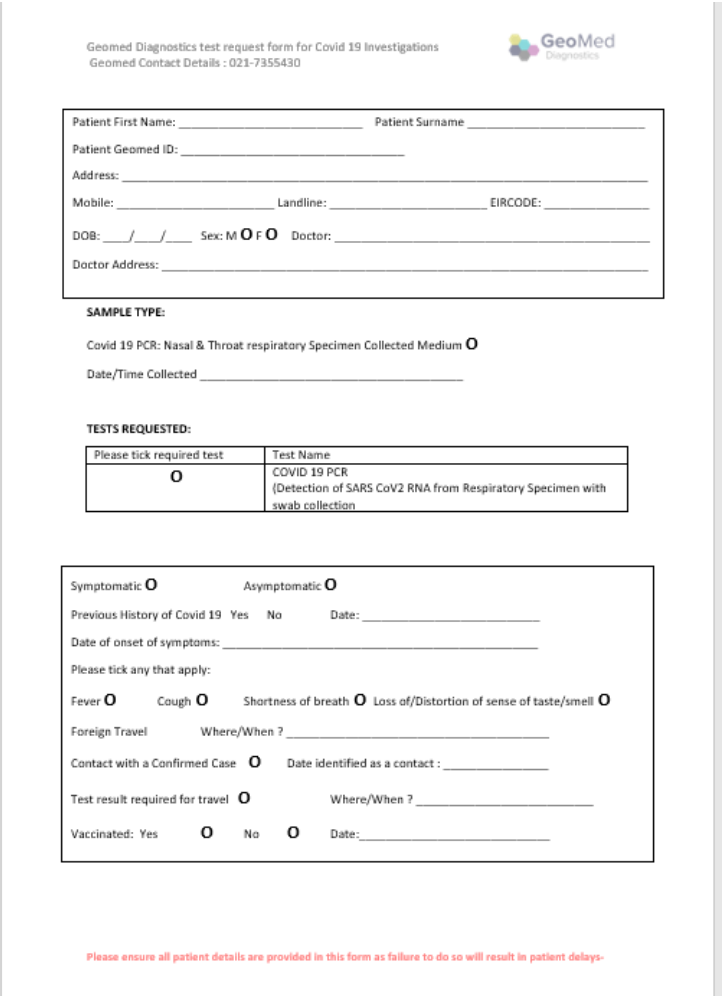
13.0 Laboratory policy on request form completion & Specimen Labelling

The purpose of this policy is to effect uniformity of requirements across the various disciplines in line with ISO and INAB standards. The policy ensures that:

- The information on both the request form and the corresponding clinical specimen are sufficient to unambiguously link the two together, thereby ensuring the correct results are always issued to the correct patient.
- The laboratory receives adequate information on the request form.
- The laboratory records accurate and complete patient and specimen identification for each request received. It is the responsibility of the requestor/person taking the sample to ensure that the laboratory is provided with complete and accurate patient identification details on both the request form and specimen container.

14.0 Request Forms

Request Forms as outlined below. It is important that the correct form is supplied for a particular test



Geomed Diagnostics test request form for Covid 19 Investigations

Geomed Diagnostics test request form for Covid 19 Investigations
Geomed Contact Details : 021-7355430

GeoMed Diagnostics

Patient First Name: _____ Patient Surname _____
Patient Geomed ID: _____
Address: _____
Mobile: _____ Landline: _____ EIRCODE: _____
DOB: ___/___/___ Sex: M O F O Doctor: _____
Doctor Address: _____

SAMPLE TYPE:

Covid 19 PCR: Nasal & Throat respiratory Specimen Collected Medium O

Date/Time Collected _____

TESTS REQUESTED:

Please tick required test	Test Name
O	COVID 19 PCR (Detection of SARS CoV2 RNA from Respiratory Specimen with swab collection

Symptomatic O Asymptomatic O
Previous History of Covid 19 Yes No Date: _____
Date of onset of symptoms: _____
Please tick any that apply:
Fever O Cough O Shortness of breath O Loss of/Distortion of sense of taste/smell O
Foreign Travel Where/When ? _____
Contact with a Confirmed Case O Date identified as a contact : _____
Test result required for travel O Where/When ? _____
Vaccinated: Yes O No O Date:_____

Please ensure all patient details are provided in this form as failure to do so will result in patient delays-

Geomed Diagnostics online request form

15.0 Completion of the Request Form

The following essential information must be documented in a legible manner on all request forms, including any back copies so that the identity of the patient is unequivocal:

1. Full name (First name & surname)

2. Date of Birth

4. Test request (including anatomical site for Microbiology)

5. Location for destination of report

7. Date & time of sample collection

The following information is desirable:

8. Consultant or GP's name

9. Relevant clinical information appropriate to the tests requested e.g. history of covid infection etc. The minimum clinical information supplied must include gender and date of birth for interpretative purposes.

It is the responsibility of the medical officer to ensure that the request forms and specimens carry all of the above information. Note: Most regularly used laboratory forms have more than one page. If using addressograph labels, they must be placed on all leaflets of the request form.

16.0 Clinical Details

The inclusion of brief clinical details including relevant medication and family history assists the laboratory in providing the most appropriate service for requesting doctors. All tests referred to the Microbiology department must include relevant clinical details and medications. Immune status, antimicrobial therapy in previous 72 hours and occupational or environmental risks are crucial to the processing of samples in Microbiology. Clinical details should include the following:

- Immune status
- Chemotherapy
- Radiation therapy
- Foreign travel
- Hx of Covid
- Vaccination / Booster status

The range and type of investigations carried out are governed by this information. If it is absent or incomplete, possible pathogens may be missed or overlooked. It is the responsibility of the requesting doctor to convey clear and pertinent clinical details if present.

17.0 Specimen Type

For testing a nasopharyngeal swab is collected and transferred into the viral transport media described below.

The remel Thermo Scientific™ MicroTest™ M4RT Tube with Beads, Lilac

Catalog number: TV4002V

Designed for the collection, transportation, maintenance and long-term storage of viral specimens, *chlamydiae, mycoplasma* and *ureaplasma*, From formulation to packaging, MicroTest products maintain the viability of organisms through freeze-thaw cycles while inhibiting antimicrobial contaminants and promoting safety.

MicroTest™ M4RT™ contains gelatin, gentamicin, and amphotericin B for the transport of viruses and *Chlamydiae*. MicroTest Tubes come with 3mL of liquid medium in a 15mL conical tube with 3 glass beads with accompanying disposable sampling swab

18.0 Specimen Collection

It is the responsibility of the person taking the sample to:

1. Ensure all appropriate sterile equipment is within date and all packaging is intact.

2. Explain procedure and rationale to patient, answering any questions.

3. Check patient identification, verbally confirming positive patient identification with the patient (where possible)

4. Ensure patient meets any special requirements e.g. fasting etc.

5. Take the sample into the appropriate specimen container for the tests required.

6. Dispose of all needles into sharps bin when finished sampling.

7. Dispose of all contaminated material into biohazard bin.

8. Label the specimen container fully.

9. Place in the bag attached to the form.

10. Ensure the form is properly completed.

Please note that any deviations or exclusions from, or additions to the documented collection procedure must be recorded on the request form by the sample collector

19.0 Labelling the Specimen Container

The following unique identifiers must be documented in a legible manner on the specimen container so that the identity of the patient is unequivocal:

1. Full name (First name & surname)

2. Date of Birth

3. QR code with accession number

Addressograph labels are permitted on all laboratory samples (see below). If using addressograph, please ensure that the label does not obscure the level of sample in the container. The label should not be wrapped around itself, hanging off the container as it makes it difficult to load samples on the various analysers. In the event that this not possible, please handwrite on the sample label. The above requirements are for both the safety of the patients and for medico-legal protection of laboratory staff.

20.0 Quality of Specimens, Specimen Bottles or Request Forms

Laboratory personnel must inspect each specimen prior to testing for:

- Presence of mandatory identifiers

In such instances, a second sample may be requested.

Issue	Action	Documentation
Specimen Issues		
Specimens unlabelled	Sample is not processed	Report is returned to clinician stating the problem & requesting repeat sample
Mandatory Identifier missing (i.e. full name,DOB)	Sample is not processed	Report is returned to clinician stating the problem & requesting repeat sample
Request forms issues		
No request form	Sample is not processed	Not applicable
Mandatory Identifier missing (i.e. full name,DOB)	Sample is not processed	Report is returned to clinician stating the problem & requesting repeat sample
No test requested	Sample is not processed	A comment will be applied to the final report stating “No request on form”
Specimen Quality Issues		
Age of sample		
Miscellaneous Quality issues	The relevant laboratory department will make a decision on whether or not the sample is suitable for testing. A second sample will be requested as appropriate.	
Sample leaking/soiled containers or forms	Sample is not processed	Report is returned to clinician stating the problem & requesting repeat sample

For urgent samples, the laboratory will contact the requestor and inform them of the reason for rejection.

21.0 Additional Testing Requests

If, on sending a specimen for testing and further testing is required, please contact the appropriate laboratory department to investigate the feasibility of using the initial specimen for analysis as age of specimen may impact on the validity of results. A request form should accompany all such requests but the lack of a request form should not impede the processing of an urgent result. In the event of analytical failure and where repeat testing is required, it may be necessary to request a fresh sample.

22.0 Health and Safety

All biological specimens should be considered as potentially hazardous and handled accordingly. However, special precautions are necessary for obtaining and handling specimens from patients infected (or thought to be infected) with high-risk pathogens. It is important to remember that carriers may be asymptomatic. Infection may be acquired by spillage of blood and other bodily fluids on to recently broken skin, accidental scratches, puncture wounds from needles, instruments or possibly by splashing into the eye, nostrils and lips of susceptible persons. Therefore, take care with all specimens for your own safety and that of others. Please remember that it is the responsibility of the person who requests laboratory examination of the specimen to ensure that both the form and the container are correctly labelled to indicate a risk of infection. Specimens that carry a risk of infectious disease should be clearly identified.

High risk categories include:

- Known HIV, Hep B & C etc.
- Suspect E coli O157 etc.
- Jaundice
- Patient from high risk group
- Known Covid-19

Potentially hazardous fluids/liquids that leak and soil containers or forms will be discarded without testing.

23.0 Delivery, Packing & Transport Requirements for all diagnostic specimens

It is the policy of the laboratory to treat all specimens as potentially infectious or high risk. Therefore, we advise taking universal precautions in the collection, packaging and the delivery of specimens being sent to the laboratory for analysis.

Packing of Diagnostic (Infectious) Specimens for Delivery to the Laboratory from external sources Specimens suspected or known to contain infectious pathogens should be packed and transported as follows:

1. Ensure the cap of the sample container is securely closed.

2. Wrap the container in tissue or cotton wool which will act as absorbent material in the event of any spillages.

3. Place the wrapped specimen inside the plastic container of UN approved Class 6.2 package type (available from the laboratory).

5. The transport bag should contain a label 'Infectious Substance'.

6. Place the name, address and contact number of the destination laboratory on the outside of the bag A licensed courier must be used for the transport of infectious specimens.

7. Couriers are required to notify the laboratory of any spillage, accident or damage to specimens.

24.0 External Quality Control Assessment Programme

The laboratory participates in relevant available third party EQA schemes. This includes schemes operated by:

- IEQAS – Irish External Quality Assurance Scheme

The laboratory is committed to participating in other QC schemes as they become available and are required to ensure comprehensive assessment of the test repertoire. Where third party EQA schemes are not available, inter-laboratory comparisons are used.

25.0 Reporting of results

- Where turnaround times (TAT) are stated, it refers to the time from when samples are received and stamped in sample reception until the time the result is issued from the laboratory so that it is available to the requestor.

- TATs do not take into account those cases where testing of samples need to be repeated for technical or quality control reasons.

- The times quoted are 'averages' and the laboratory will do their utmost to achieve them, circumstances permitting.

26.0 Result Reporting

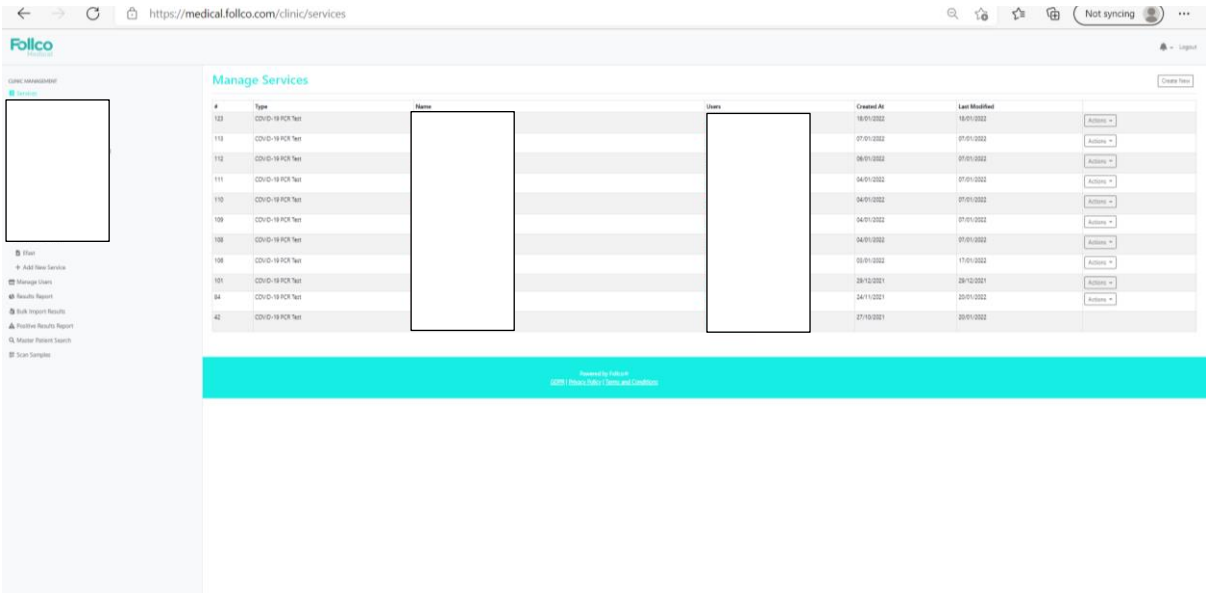
It is the responsibility of the healthcare professional who requests a laboratory test to ensure that the result is reviewed and appropriate action taken.

27.0 Laboratory Information Systems

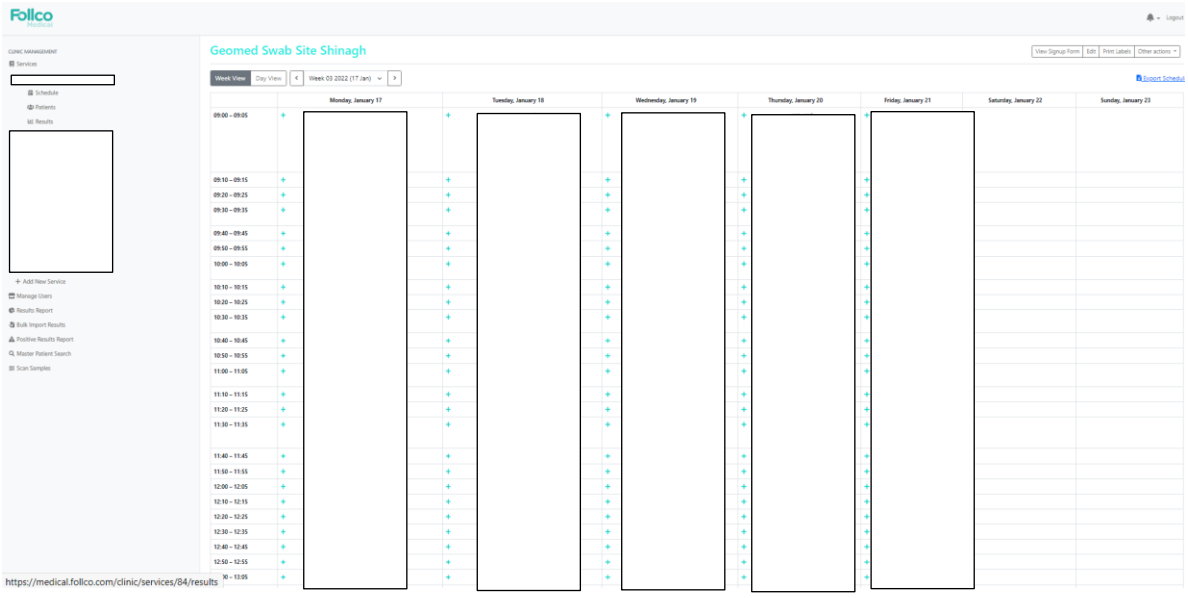
- Searching for patient and viewing results

Log into https://medical.follco.com/login

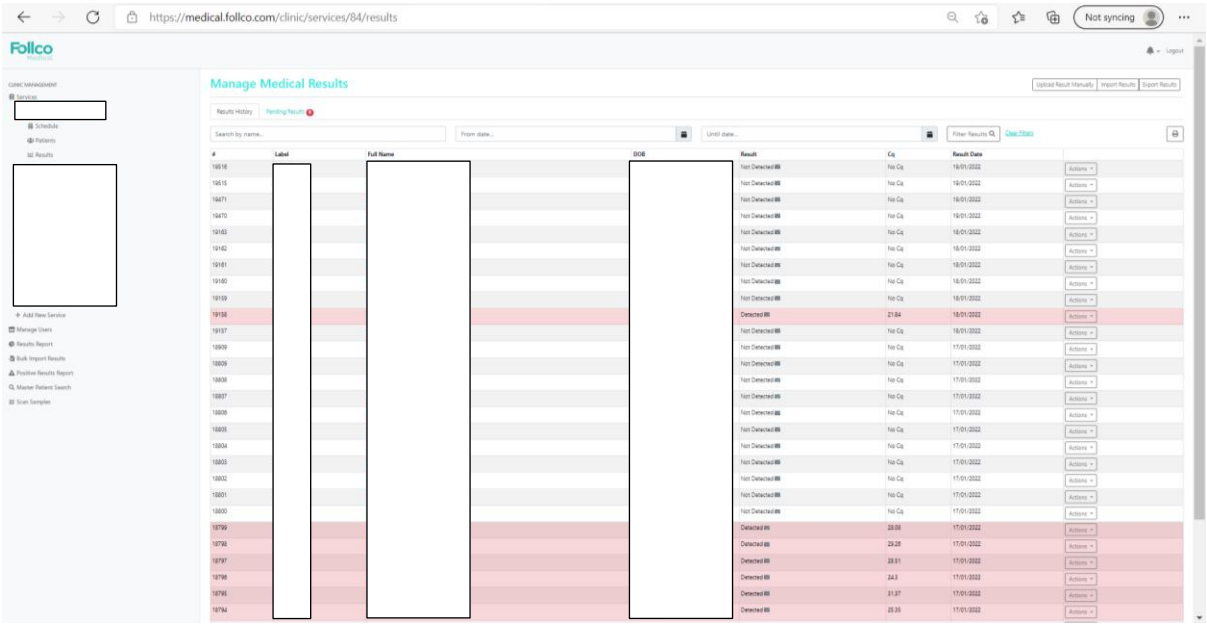
Enter assigned username and password, You are brought to the home page



Select clinician or source of sample



Select results



Search by name / date of date / use ctrl + F function

28.0 Laboratory Supplies

• The Laboratory supplies viral swabs, and request forms to all users of the service. Supplies can be obtained by contacting Specimen Reception at 023-885400 9:15am – 5.15pm, Monday to Friday.

29.0 Storage of Examined Specimens

Examined specimens are stored for archive and look-back purposes

Specimen Description	Storage Location	Minimum Retention Time	Responsibility
Viral swab samples	Molecular lab	Not detected 72 hours at $4^{O}C$ Detected -20^{O} Indefinitely	Chief Medical Scientist Molecular / Microbiology

30.0 Unexpected Results

Artefactual results may arise from difficulties or errors in, for example, sample collection, choice of specimen bottle, specimen transport or specimen storage. It is important that the Laboratory is informed as soon as possible if results appear to be inconsistent with the patient's condition or at variance with previous results.

31.0 Turnaround Times

All samples received prior to 2pm have a same day turn around. Samples received after this have a 24 hour turn around time.

32.0 Microbiology

32.1 Tests:

Swab – SARS-Cov-2 (Covid-19)

Sample Required: Nasopharyngeal Collection kits specific for this test (available from the laboratory) are required.

Covid-19 testing is performed twice daily from Monday to Friday with the following cut-off times:

• 13.30 - Results available 6.30 approx.

• 5.30 - Results available 21.30 approx.

Outside the above hours including weekends, testing is provided on a need based system.

Note: A negative PCR molecular test for SARS-Cov-2 does not preclude the presence of the target pathogen. Clinical discretion is advised when reviewing results from these tests.

33.0 Reference ranges & Uncertainty of Measurement

Uncertainty of Measurement is defined as quantification of the doubt about the measurement result. It is the policy of the laboratory at Geomed Diagnostics to determine the uncertainty for all examination methods used to report measured quantity values on patient's samples. The laboratory has a document listing the current uncertainties calculated for each test. These are available to all service users upon request.