CLS Medical Testing Laboratory User Manual

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Clarification reasons – no major changes.
DCR 188: Update contact details for Operations Supervisor, Clinical Consultant Microbiologist and Deputy Clinical Consultant Microbiologist as well as update to opening hours.
DCR 190: Update section 2.5 to reference current document numbers, update to include correct reference document for specimen transportation and update to include correct reference to COC (sample delivery form for Medical Testing
DCR 274: Update to include photo ID is required. Include updated uncertanty of measurement and correct form number.

Reason for Change:
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1 General Information

1.1 Introduction

Complete Laboratory Solutions (CLS) is the largest privately owned contract laboratory in Ireland and provides sampling, analysis and fully trained micro and analytical analysts on contract to clients in the food, environmental, medical device and pharmaceutical industries.

CLS operates two of their own accredited laboratory sites, located in Galway City for all things medical and pharmaceutical and Ros Muc for all things food and environmental.

In 2020 Complete Laboratory Solutions (CLS) launched PCR COVID-19 private testing as part of the expansion of the firm's clinical laboratory facilities in the west of Ireland. The service is available to both private industry and public health in Ireland. CLS' COVID-19 private testing service is designed to support proactive screening for COVID-19 and is relevant to all sectors including those that require employees onsite at present. CLS Medical Testing Laboratory is committed to providing this service to the highest quality to all of its users, by the use of procedures and methods which will ensure the highest quality of testing performed and will report results in a way which is timely, accurate, confidential and clinically useful.

On the CLS website www.cls.ie users can obtain information on how to contact us and the services that are available. This site also includes a link to those tests we offer that are on our INAB accredited scope. A copy of all laboratory documents referenced are available from the laboratory on request.

1.2 Quality Statement

Saotharlann Chonamara Teo, trading as Complete Laboratory Solutions (CLS) holds legal responsibility for any analysis performed by staff members in the laboratory's permanent facilities or in field measurement. We accept the responsibility to achieve our quality goals which will be reached through continual improvement, innovation, training, teamwork, quality systems monitoring and review.
The management and employees of CLS are committed to achieving and maintaining customer satisfaction by supplying the highest quality products and services.
This achievement will result in securing efficiency, a strong customer focus and enhancement of long-term sustainability and profitability within CLS. Our image reflects our mutual respect for each other, our customers and the attitude we take towards being a consistently high performing contract laboratory.

As we endeavour to continually improve quality through all phases of our operations, we are committed to consistently meet the requirements of the current management standards of ISO 15189, ISO 9001 and ISO 17025 to which we operate and to continuously improve its effectiveness. Our employees are familiar with this quality documentation and technical procedures.

We undertake to ensure sufficient resources are made available within CLS to achieve this.

We pledge to our customers and ourselves that we will strive to offer the highest services in our laboratory, and we are committed to acting in compliance with all statutory and regulatory requirements related to our activities and services and their environmental aspects.
We will act with honesty, integrity, responsibility and impartiality in all relationships professionally and personally and ensure that this and our competence is reflected throughout CLS.

CLS commitment to quality will be continuously monitored and reviewed to ensure that it remains relevant and effective to both the changing needs of our customers, interested parties and strategic objectives.

1.3 Location Of the Laboratory

CLS operates on two sites, site 1 is located in Connemara Co. Galway, site 2 is located in Galway city. The Connemara site is therein referred to as 'Ros Muc' and the Galway city site is therein referred to as 'MedPharma'

Site 1 address	Site 2 address
Complete Laboratory Solutions (CLS) Rosmuc, Co Galway, Ireland. H91 YK81	Complete Laboratory Solutions (CLS) IDA Business Park, Tuam Road, Co. Galway , Ireland. H91 H520
Telephone 091 574355	Telephone 091 574355

Information on the services provided and contact telephone numbers are available through the CLS website www.cls.ie

Covid 19 Testing mainly occurs at the Galway City Location. Please see map below for location, any queries can be answered by phone or on the website.

1.4 Clinical Services Offered by The Laboratory.

At present CLS collect and process nasopharyngeal swabs for SARS-CoV-19 only.

1.5 Opening Hours of The Laboratory

Department/ Activity	Opening Hours
Laboratory Diagnostic Service	Monday to Sunday 07:00 to 19:00
Out of Hours Service	Out of Hours Services are not provided

1.6 Contact Details

General Queries Contact	info@CLS.ie	
Clinical/ Technical Queries		
Position	**Name**	**Contact Information**
Clinical Consultant Microbiologist	Leonardo Nieto-Aponte	lnaponte@cls.ie
Deputy Consultant Microbiologist	Rosemary Curran	rcurran@cls.ie
Director of Microbiology	Anne O'Donnell	aodonnell@cls.ie
Operations Supervisor	Shauna Curtin	scurtain@cls.ie

**Clinical Advice:* *CLS provides via the Clinical Consultant Microbiologist, clinical advice on interpretation of results to interact with the GP or requesting doctor.*

2 Covid 19 Testing

2.1 Requesting a Covid 19 Test (Currently there is one sample type and one test available)

1. Medical clients are users of our testing service who operate their own medical services to the public. The medical clients are required to be registered users of the Full Health portal. For these clients, CLS can view the unique Full Health identifier for each sample required and can print this identifier label. The labels are placed onto the specimen containers which are sent to the medical clients, who in turn reconcile the sample with the patient using positive patient identification when taking the sample on site with the patient.

2. Company Clients are users who represent a body of employees. These clients are sent an electronic link to the Full Health portal whereby the employees fill out the request for testing and makes an appointment (within the Company stated guideline dates) with the CLS nurse for the samples to be taken. Photo ID is required to verify identity of users prior to samples being taken. For these clients CLS prints the label for the nurse to reconcile with the patient and apply to the sample tube. CLS prints the list of patients booked for appointments. Positive patient identification is done by requesting verbal confirmation of the surname, forename and date of birth onsite prior to taking the sample.

3. Public clients are members of the public who make direct contact with CLS for non-symptomatic testing for SARS-CoV-2. These clients are sent an electronic link to the Full Health who then fill out the request for testing and makes an appointment with the CLS nurse for the samples to be taken. For these clients CLS prints the list of patients booked for appointments and the laboratory ID label for the nurse to reconcile with the patient and apply to the sample tube. Photo ID is required to verify identity of users prior to samples being taken. Positive patient identification is done by requesting verbal confirmation of the surname, forename and date of birth onsite prior to taking the sample.

2.2 Request Forms

2.2.1 Electronic Test Request form, these can be accessed and completed on www.cls.ie website. The following information is required to completed the digital request form:

a) Patients Name
b) Gender
c) Date of birth,
d) location/contact details of the patient
e) Name and contact details of the requesting clinician or if a self referral the patients GP information needs to be completed.
f) Destination for the report and contact details.
g) Informed patient consent to test and to disclose relevant patient results to the CLS Clinical Consultant Microbiologist, GP, laboratory and other concerned bodies (HSE) is obtained on filling in the online request for testing.
h) Sample type
i) Test ordered
j) Date and time for sample collection
k) Patient clinical information

2.2.2 Alternative Test Request form, this is limited use only. Contact CLS support www.cls.ie.

2.3 Sample Container

A nasopharyngeal swab is required for a SARS-CoV-19 test request. CLS orders the supplies of the sample collection tubes and swabs therefore controls the use of these tubes within their expiry dates. The Viral Transport Medium (VTM) is formulated for collection, transport and long term freeze storage of viruses. The VTM only works if used prior to their date printed on the label. It is designed to maintain the optimum viability and virulence of the viral sample.

Viral transport tube with medium and Nasopharyngeal swab.

2.4 Sample Collection

Samples are collected by trained staff only, public patients do not collect their own samples.

Sample collection Guidelines as per the CDC.

Please note: Photo ID is required prior to sample collection.

Instructions for collecting an NP specimen (performed by a trained healthcare provider):

- Tilt patient's head back 70 degrees.

- Gently and slowly insert a minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
- Gently rub and roll the swab.
- Leave swab in place for several seconds to absorb secretions.
- Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection.
- If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
- Place swab, tip first, into the transport tube provided.

Accurate identification of the patient is essential. Photo ID is required to prove identity prior to swabs being taken. The sample collector must ensure that the patients details given by patient when they are getting swabbed match those on the request form. The sample collector asks the patient to:

1. state their name and
2. state their Date of Birth.

The unique FH number is placed on specimen container.

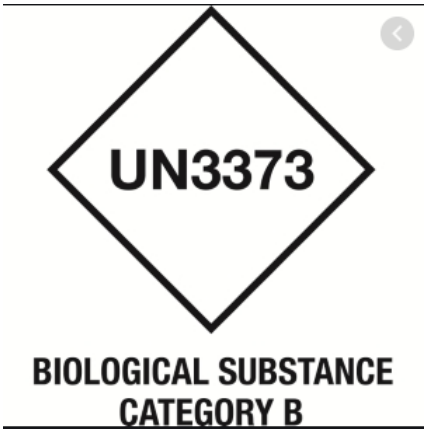
2.5 Specimen Transportation

The transport of specimens to the Laboratory must follow UN (UN 3373) regulations and guidelines in order to minimise the risk of infection to those who may come in contact with the specimens e.g. taxi drivers, couriers, postal workers, laboratory staff etc. Consignors of specimens must ensure that packages are prepared in such a manner as to meet the requirements for packaging and transport of biological material by road, rail or post in accordance with the ADR regulations. Transportation of samples including special handling needs are discussed with the user/client.
All specimen tubes must be tightly closed and placed in a transparent transport hazard bag for transportation to the laboratory. CLS collects and transports the samples accordance with 15189/M/SOP/005. Start time of sampling and signature representing the client must be noted on the Sample Delivery Form 15189/M/F/005 in addition to the time of receipt to the testing laboratory. Any delays in the transportation to the laboratory must be notified to the laboratory supervisor immediately.

Packing instruction for sample containers:

1. The packaging shall be leak proof, of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including transhipment between vehicles or containers and between vehicles or containers and warehouse as any removal from a pallet or over pack for subsequent manual or mechanical handling. Packaging shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.
2. The packaging shall consist of three components a) a primary receptacle; b) a secondary packaging; and c) An outer packing.
3. Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packaging. Any leakage of the contents shall not compromise the integrity of the outer packaging.

4. For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2mm; the letters and numbers shall be at least 6mm high.



2.6 Acceptance/ Rejection

The laboratory has set criteria for accepting and rejecting clinical samples. Unlabelled, wrongly labelled or inadequately labelled specimens will not be accepted. Samples where the sample container is broken or leaking are also rejected. Additionally, factors known to significantly affect the performance of the examination or the interpretation of the results can include expiry date on tubes where the functionality of the medium is only guaranteed prior to the expiry date printed on the label; tubes with sample being stored for >4 hrs at ambient temperature. The requester is informed if any samples are rejected.

2.7 Sample Storage

2.7.1 Samples

All portions of the primary sample are labelled and stored so that they are unequivocally traceable to the original primary sample. CLS refer to RCPATH guideline for sample retention times. (The Retention and Storage of Pathological Records and Archives' – 5th Edition Royal College of Pathologists 2015)

The recommendations that follow outline the minimum retention time for various clinical materials. Store respiratory specimens at 2-8°C for up to 72 hours after collection and during transport. If a delay in testing or shipping/transport is expected, store specimens at -70°C or below. (Extracted nucleic acid samples can be stored at -70°C or lower.)
There are separate storage facilities for:

- Clinical material

Storage facilities are in accordance with current legislation, regulations, and guidelines.

2.7.2 Safe disposal of materials used in the collection.

Sample collection materials are brought to the CLS laboratory contained in leak proof, good quality packaging. These items should be safely disposed of in the external biomedial waste bins on site following 15189/M/SOP/001 Biological Waste Disposal.

2.8 Turnaround Times

Turnaround time is given as the maximum number of working hours/days between sample collection and the issuing of a report under normal operating conditions. The turnaround time for Covid Testing is 24 hours. It should be noted that CLS do not provide an on- call service.

2.9 Reporting of Results

The reporting and communication of results is as follows:

- Not Detected (Negative test) results are uploaded to the Full Health portal by CLS and reports are generated and sent to users. See below table 1 for definition.
- Detected (Positive test) results are uploaded to the Full Health portal. The Consultant Clinical Microbiologist (CCM) is contacted to review the results. Once approved the GP is contacted who in turn contacts the user. The CCM then approves the positive results on the Full Health Portal and the report is sent to the user. Appropriate HSE contacts are advised by the CCM of the details of patient positive results. The laboratory contacts the HSE to update them with data requirement for statistical needs. See below table 1 for definition.
- Indeterminate results are uploaded to the Full Health portal by CLS and reports are generated and sent to users. See below table 1 for definition.

Table 1

Result	Comment
Detected	This PCR viral test identifies the presence of the SARS-CoV-2 virus that causes the COVID-19 disease. To protect yourself and others from COVID-19, continue to follow the advice from the HSE found on the HSE website or by telephoning HSELive on 1850 24 1850.
Not Detected	This result does not mean that you never had coronavirus. It just means that the virus was not found in the sample the laboratory tested. You could still get coronavirus in the future. If you feel unwell you should contact your GP. To protect yourself and others from COVID-19, continue to follow the advice from the HSE found on the HSE website or by telephoning HSELive on 1850 24 1850.
Indeterminate	Your result has been returned as INDETERMINATE for SARS-CoV-2 RNA. A repeat test is advised within 24-48 hours of original test if clinically indicated. To protect yourself and others from COVID-19, continue to follow the advice from the HSE found on the HSE website or by telephoning HSELive on 1850 24 1850.

2.10 Reference Ranges

Results are released as Detected, Not Detected, Indeterminate

2.11 Interactions/Interferences

SARS-CoV2 detection uses commercially available kits and technologies. With correct performance of the commercially available RNA preparation procedure based on the recommended methods and samples, it can generally be assumed that the RNA isolated from the patient sample does not contain any components that might interfere with the test system.

2.11.1 Analytical Sensitivity:

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Sensitivity: 1 cp/µl eluate.

2.11.2 Analytical Specificity (Kit insert)

- Positive agreement: 98.2%
- Negative agreement:100%

2.11.3 Measurement of Uncertainty

Uncertainty of measurement is a quantative indication of the analytical variability of a result. The uncertainty of measurement is calculated as 1.55Ct. The uncertainty may need to be taken into account when interpreting data.

3 Additional Information

3.1 Confidentiality/ Policy On Protection of Personal Information

Arrangements are in place to ensure that confidentiality of personal information is maintained. Each member of staff is contractually bound not to discuss or disclose any information of a confidential nature except in the proper course of their employment. Data protection policy is outlined on the CLS website www.cls.ie

3.2 Complaint Procedure

A complaint may be made by contacting the CLS website, Laboratory supervisor, Quality manager or any member of staff at the contact details given on the website. The Quality Manager will follow up complaints promptly and earnestly as per the procedures in the Quality Manual. This procedure is audited annually. All complaints outcomes are fed into the management review board meeting. Complaints can be made verbally or in writing to any member of laboratory staff.