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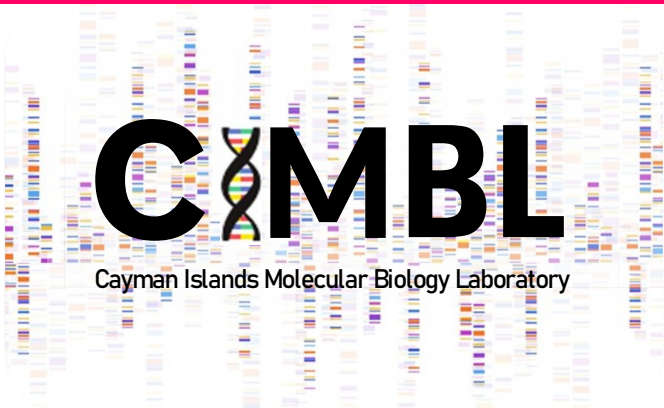

USER MANUAL

Cayman Islands Molecular Biology Laboratory

Cayman Islands Health Services Authority, 95 Hospital Road, George Town, Grand Cayman, Cayman Islands, KY1-1103

+1(345) 244-2711

Last Updated: 20JUN25

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CIMBL Mission Statement

The Cayman Islands Molecular Biology Laboratory (CIMBL), in collaboration with local and international stakeholders, shares a commitment to delivering high quality diagnostic services that prioritise patient care.

What is Molecular Diagnostics?

Molecular Diagnostics is a discipline of medical laboratory testing which uses proteomics and genomics to investigate genetic material (DNA, RNA, proteins, etc.) from humans, viruses, and microbes as biological markers of disease to aid in diagnostics and guide treatment. Molecular diagnostic techniques, such as Polymerase Chain Reaction (PCR) and Whole Genome Sequencing (WGS), represent a tremendous advancement in technology, which extends the range of information available to physicians, pharmacists, geneticists, Public Health and other healthcare professionals for the management of health and of outbreaks.

Our Mission

Our primary goals are providing diagnostic and Public Health services, to aid in the clinical management of patients, and to prepare for and respond to the threat of infectious disease. This is achieved by way of local testing for all epidemiologically significant organisms, and rapid pathogen identification - without the need to send specimens overseas, which reduces healthcare inequities for the people of the Cayman Islands.

In working with national and international partners, and in conjunction with the Cayman Islands Government, CIMBL provides scientific and operational support to build the national health security capability. CIMBL has adopted the *One Health* approach to ensure the local capability of molecular diagnostic services across the whole Cayman Islands. *One Health* is an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals and ecosystems *(WHO, 2025)*.

What We Do

Real-Time PCR | Whole Genome Sequencing | Pathogen Genomics

Real-Time PCR

Real-Time PCR is a molecular technique that is used to detect and measure a specific genetic target, i.e., DNA or RNA, in real-time. The process involves the repetitive amplification of a target genetic sequence of interest, for unambiguous identification of the target's presence. Detecting a genetic target can infer the presence of the organism associated with that target.

Whole Genome Sequencing

Whole Genome Sequencing (WGS) characterises the complete set of genetic material derived from an organism. The information derived from WGS is important for: **1.** Identifying and tracking infectious disease outbreaks (Pathogen Genomics) and predicting microbial response to antibiotics through Antimicrobial Resistance Genotyping (AMR). **2.** Investigating inherited disorders (Clinical Genetics). **3.** Characterising mutations that underpin the progression of cancers (Oncogenomics). **4.** Prediction of response to drug dosage (Pharmacogenomics).

Pathogen Genomics

Pathogen Genomics is defined as the process of examining the genetic material of disease-causing microorganisms. Pathogen sequencing is vital component of a modern Public Health response to infectious disease and is a key component of Genomic Epidemiology. Pathogen Genomics provides the capability to establish an early warning system for emerging infectious diseases and understand the relationship between locally and internationally circulating infectious disease. Whether it is related to keeping the food chain safe from outbreaks, allowing patients to receive appropriate treatment and halt infection transmission, or to inform our choice of the most effective vaccines to deploy for seasonal influenza spread, Pathogen Genomics plays a crucial role.

Contact Us

Address: CIMBL, Cayman Islands Health Services Authority (George Town Hospital), 95 Hospital Road, George Town, Grand Cayman, Cayman Islands, KY1-1103

Hours of Operation: Monday to Friday from 7:00am - 8:00pm

Closed - Weekends and Public Holidays

If a test is required outside normal laboratory hours, please contact the Laboratory Manager directly, through the HSA Telephone Operator, to facilitate on-call staff.

Email & Telephone:

1. CIMBL

Email: cimbl@hsa.ky | **Telephone:** +1-345-244-2711

2. CIMBL Laboratory Manager

Jonathan Smellie - jonathan.smellie@hsa.ky

* Direct Telephone Line Through HSA Operator: +1-345-949-8600 (*Press 0 for Operator*)

3. HSA Clinical Microbiologists

Dr. Camille Blake - camille.blake@hsa.ky (Ext: via *HSA Operator)*

Dr. Glendee Reynolds - glendee.reynolds@hsa.ky (Ext: via *HSA Operator)*

4. Public Health (Officers)

Timothy McLaughlin - timothy.mclaughlin@hsa.ky (Ext: 2651)

Saleicia Bailey - saleicia.bailey@hsa.ky (Ext: 2849)

Website: ***www.hsa.ky/medical-services/cimbl***

Location

Cayman Islands Health Services Authority (HSA) - George Town Hospital

Main Campus

← First Floor

1. Hyperbaric Chamber
2. Morgue
3. Molecular Biology Lab
4. Maternity Ward & NICU
5. Ambulatory Care Unit (ACU)
6. Accident & Emergency (A&E)
7. Radiology/X-Ray
8. Phlebotomy
9. MRI
10. Dialysis Unit
11. Information
12. Pharmacy
13. Urgent Care Clinic
14. Orthopaedics
15. Paediatric Clinic
16. Women's Health
17. Mental Health (Inpatient)
18. Nutritionist
19. Patient Financial Services (PFS)
20. Alex's Place
21. Lions Eye Clinic
22. Dental Clinic
23. Cafeteria (Barista Cafe)
24. Hibiscus Conference Rooms (A&B)
25. Information Technology (IT)
26. Forensics
27. Haematology, Oncology & Chemotherapy Unit
28. Merrens Dental Clinic *(37 Hospital Road)*

3 - **Molecular Biology Lab (CIMBL)**

Best Entrances for Specimen Delivery:

- Main Entrance at Front of Hospital
- (If Key Fob Access) Secure Entry Door between **2** and **3**

Specimen Ordering Procedure

Overview: Specimen Ordering Procedure

All specimens are expected to be accompanied with an order in CERNER or completed paper CIMBL Test Request Form. Patient samples/specimens are delivered to CIMBL from service users, via hospital staff, private couriers or the CIMBL Courier Service. Most of the specimens are initially delivered to HSA Pathology Laboratory Specimen Reception area and are sorted by discipline. From there, specimens are either collected by, or forwarded to the Molecular Laboratory (CIMBL) for specimen processing.

Specimen Information Requirements

All specimens that are sent to CIMBL must be appropriately labelled and be accompanied with a **CERNER label** and/or **TEST Request Form**. The Test Request Form can be found via the CIMBL website, *www.hsa.ky/medical-services/cimbl*.

If the requirements are not completely met, the specimen will be rejected.

Essential Information

- Investigation Required
- Patient's Full Name
- Date of Birth
- HSA Medical Record Number *or* Another Agreed Unique Identifier
- Responsible Clinician *(Including Location and Contact Details, if order is from an external clinic.*)

Desired Information

- Sex of Patient
- Specimen Details
- Patient's Location
- Date and Time of Specimen Collection
- Clinical Information

Useful Information

- Patient Contact Telephone Number

Specimen Acceptance & Rejection Criteria

Acceptation Criteria:

If none of the rejection criteria are applicable, then the specimen is deemed valid and can be accepted. Accepted/valid specimens will be processed as required by the relevant Standard Operating Procedures and Laboratory Policies.

Rejection Criteria:

Specimens will be rejected in the following circumstances:

- The minimum essential information is missing from the specimen or request.
- The specimen is unlabelled.
- The specimen and CERNER label/Test Request Form information differ.
- Specimen has leaked or has been compromised.
- There is insufficient specimen volume to perform the required investigations.
- The specimen was collected in an inappropriate container.
- The specimen type was inappropriate for the investigation requested.
- The specimen was transported or stored at an inappropriate temperature.
- The specimen has been haemolysed.
- The specimen collection date is outside of the specified acceptance timeframe for the required investigation.
- If no specimen has been received.
- If a specimen has been received without a Test Request Form.
- The specimen received is a duplicate order, which has already been performed on that day. *(The clinician will be contacted, and unless specifically instructed otherwise by the attending or consulting clinician, the duplicate order will be cancelled)*.

Exceptions to the Rejection Criteria:

- Certain specimens (also known as *un-repeatable*, *precious*, or *urgent specimens*) cannot be rejected without authorization from a Clinical Microbiologist or Laboratory Manager (unless they pose a significant risk to laboratory staff safety).

* ***Please Note:*** Clinicians will be contacted when a specimen is rejected.

CIMBL Specimen Identifier

Specimen containers or specimen bags for intended for delivery and processing at CIMBL should be labelled with a yellow 'CIMBL' sticker.

This sticker is to ensure direct delivery to CIMBL.

Please contact CIMBL to obtain CIMBL stickers.

Turnaround Time

Available Tests are categorized into three types based on Turnaround Time (TAT). The TATs are only monitored from Monday to Friday, as CIMBL is closed during weekends and bank holidays.

The following table shows the turnaround time for each testing category.

Testing Type	Collection to Receipt (T1)	Receipt to Report (T2)
Critical Tests	1 hour	4 hours
BioFire Tests	24 hours	4 hours
Routine Testing Services	24 hours	18 hours

Critical Tests:

- CIMBL BioFire Blood Culture ID PCR Panel
- CIMBL BioFire Meningitis/Encephalitis PCR Panel
- CIMBL BioFire Pneumonia PCR Panel

* *If a Critical Test is required outside normal laboratory hours, please contact the Laboratory Manager directly through the HSA Telephone Operator to facilitate testing.*
* *It is the responsibility of the physician initiating the procedure to ensure that CIMBL knows to expect the specimen.*

BioFire Tests - Other Than Critical Tests:

- CIMBL BioFire Respiratory PCR Panel
- CIMBL BioFire Gastrointestinal PCR Panel

* *All BioFire Tests - Other Than Critical Tests (listed above) can be expected to be processed on the same day if they are delivered before 6pm, or processed on the next day if delivered after 6pm.*

Routine Testing Services:

- CIMBL Respiratory PCR Panel
- CIMBL High Risk Human Papilloma Virus PCR Panel
- CIMBL Sexual Health PCR Panel
- CIMBL Arbovirus PCR Panel
- CIMBL Malaria PCR
- CIMBL Measles PCR
- CIMBL Mumps PCR
- CIMBL Monkeypox PCR

Placing A Specimen Order To CIMBL

HSA Staff:

- **CERNER** - All test names found in this User Manual are the same as the orderable test name in CERNER and the Test Request Form.
- In the event of CERNER downtime, tests will still be available to order through CIMBL Test Request Forms. Please see the CIMBL website to obtain a Test Request Form.

External Clinical Staff from Other Organisations:

- **Test Request Form** - All testing services that are offered by CIMBL are available to external Clinical Staff via orders placed through CIMBL Test Request Forms.

* *All specimens should be delivered to CIMBL within their own, individual specimen transport biohazard bags.*
* *Orders made via Test Request From will be placed as orders into CERNER.*

Receiving Results From CIMBL

All Tests Ordered Through CERNER: Results available through CERNER. Results will be disseminated via encrypted email to the appropriate Clinicians and stakeholders of the Patient's care in the case of CERNER downtime or when there is detection of a notable organism.

All Tests Ordered via Test Request Form: Results will be disseminated via encrypted email to the appropriate Clinicians and stakeholders of the Patient's care, and via CERNER. External Clinicians who have remote access to CERNER PowerChart can also view results ordered via Test Request From there.

Results: CERNER Access for External Clinicians

To be able to view and order test results for patients via HSA's CERNER system, Physicians must first be granted *Privileged Physician Access*.

* To apply for *Privileged Physician Access*, please contact the Office of the Medical Directorate via email, by sending your request to Darlene Whittaker (darlene.whittaker@hsa.ky) and Kayssie Mejia (kayssie.mejia@hsa.ky).
* Documents will need to be completed for the processing of the application. Once Privileged Physician status has been attained, please then contact *hscernerconcerns@hsa.ky*, and Cc the Office of the Medical Directorate, to attain CERNER access.

Interpretation of CIMBL Results

All results for all of the available PCR assays tested by CIMBL will either be 'DETECTED' or 'NOT DETECTED' in relation to one or more targets.

'**DETECTED**' denotes the presence of target.

'**NOT DETECTED'** denotes the absence of a target.

- If an assay has more that one target, each target will have its own, singular, 'DETECTED' or 'NOT DETECTED' result.
- In the case where a target has two names separated by a slash ('/'), this indicates that *either* one of the two targets is present. This is the case when the PCR assay is unable to distinguish between two targets. An example of this is '*Human Rhinovirus/Enterovirus*' on the CIMBL BioFire Respiratory PCR Panel. A 'DETECTED' result, would denote that the target for *either* Human Rhinovirus *or* Enterovirus was detected within the patient specimen.

Please Note: CIMBL does not provide cycle PCR threshold (Ct) values to clinicians.

Clinical Guidance

Free of Charge

Please contact CIMBL or the HSA Clinical Microbiologist with any queries related to the ordering of CIMBL tests or the interpretation of results. See the 'Contact Us' section of this User Manual for contact details.

Clinical Guidelines for Molecular Testing can also be found via the CIMBL website

Role of Clinical Microbiologists in Molecular Testing & Advisory Services

Clinical Microbiologists are available to provide essential oversight and advisory support to all Clinicians/ Laboratory Users in the selection, interpretation, and application of the molecular diagnostics available via CIMBL. Their involvement ensures tests are clinically appropriate, results are accurately interpreted, and patient care is optimised.

1. Test Selection and Specimen Guidance

Laboratory Users, where necessary and appropriate, are encouraged to seek clinical guidance prior to requesting molecular tests to ensure:

- The test requested aligns with clinical indications and current guidelines.
- The appropriate specimen type is selected.
- Specimens are collected, labelled, and transported under suitable conditions.
- Pre-analytical factors are met (i.e. regarding the correct specimen container, timing of collection, storage conditions, etc.).

2. Interpretation of Results

Clinical Microbiologists support Laboratory Users in interpreting complex or unexpected results by:

- Providing interpretative comments where appropriate.

- Advising on discordant or inconclusive findings.
- Recommending further or confirmatory testing where clinically necessary.
- Ensuring results are considered within the full clinical context.

3. Infection Management and Public Health Advice

Clinical Microbiologists also offer Laboratory Users guidance on:

- Appropriate antimicrobial therapies and treatment options based on the molecular findings.
- Infection prevention and control measures (i.e. isolation requirements).
- Public Health notification procedures for notifiable organisms or unusual findings.

When to Contact the Clinical Microbiologists

Laboratory Users *must* contact the Clinical Microbiologists in the following scenarios:

- Detection of high-consequence infectious agents or multi drug-resistant organisms.
- Unusual, incongruent, or clinically unexpected results.
- Urgent test requests outside routine hours (if applicable).
- Advice required on infection control or antimicrobial management.
- If referral to Public Health or specialist services is indicated.

Specimen Transportation to CIMBL

Specimens will be transported to the HSA and CIMBL via a dedicated CIMBL Specimen Courier Service.

- The collection of the specimens will be at the on-site location of the various Healthcare Providers.
- Each Healthcare Provider should have a dedicated, labelled specimen container for CIMBL specimens. This container should be located in a secure, yet accessible area for the courier.
- Whenever there is a specimen ready for collection, the Healthcare Provider should assign a driver for specimen collection/ pick-up. CIMBL will deploy a specified courier to collect the specimen and associated Test Request Form.
- The courier will scan the specimen to log it 'In Transit' to CIMBL.
- The Healthcare Provider will be notified when the specimens have been delivered to CIMBL.

Specimen transportation to CIMBL is available to Healthcare Providers who are registered for this courier service.

For Healthcare Providers who are not registered for this courier service, please contact the CIMBL Laboratory Manager to become registered.

Feedback

HSA Compliments/Complaints Procedures:

For Patients/Visitors/External Clinical Clients:

A **Patient Feedback Form** is located on the patient-facing HSA website (*www.hsa.ky/patients-visitors/patient-feedback*).

Patients, Visitors, and External Clinical Clients are encouraged to reach out to the **HSA Patient Experience Team** at patientexperience@hsa.ky or (345) 244-2736, whether they have a problem, question, complaint, special need, or wish to commend a department or an employee.

More information about **Patient Experience Services** are located though the link provided above.

For Internal HSA Clinical Staff:

Complaints can be recorded through the **HSA Incident Report Form**, which is located on the main page of the HSA Intranet (the internal, staff-facing website). There are several 'Types of Event' to choose from when recording an incident or event, including an 'Other' option, if the topic of the complaint is not covered within the list available.

Data Protection and Consent

The Cayman Islands Health Services Authority (HSA), through the Cayman Islands Molecular Biology Laboratory (CIMBL), performs testing as required for the Public Health Response. The HSA is the Data Controller of the patient data, by way of the *Cayman Islands Data Protection Act 2017*, and is responsible for the collection, storage, and handling of sensitive and personal data when a patient is registered with the HSA.

How We Receive Your Data

Receipt or collection of data by CIMBL is solely for the purpose of processing a specimen as directed by a Test Request Form or Test Order submitted via CERNER by or on behalf of the patient's Primary or Attending Physician. Most personal data that we process has been provided to the HSA directly from the patient, but personal data is also received indirectly from referral details from a patient's external Physician, through other Healthcare Providers, or through the patient's authorised representative.

How We Use or Process Your Data

During processing, specimens that are ordered through CERNER already have a unique specimen ID which is used to identify each individual specimen. After receipt or collection of a patient specimen by CIMBL, specimens are given an internal Laboratory ID for specimen processing.

The *HSA Data Privacy Notice: Privacy Policy* can be accessed via:

www.hsa.ky/privacy-policy

CIMBL Test Directory

Available CIMBL Tests, CPT Codes & Prices:

Prices Available Upon Request

Available CIMBL Tests	CPT Codes
CIMBL *BioFire* Respiratory PCR Panel	0202U
CIMBL *BioFire* Gastrointestinal PCR Panel	87507
CIMBL *BioFire* Blood Culture ID 2 PCR Panel *	87154
CIMBL *BioFire* Meningitis/Encephalitis PCR Panel *	87483
CIMBL *BioFire* Pneumonia PCR Panel	87633 (or 0528U)
CIMBL Respiratory Virus Rapid LFT	87637 (or 0241U)
CIMBL Respiratory Virus PCR Panel	87633
CIMBL High Risk Human Papilloma Virus PCR Panel	87624 (or 0429U)
CIMBL Sexual Health PCR Panel	87800 (or 0402U), 87481, 87511, 87529 (x2), 87798 (x4)
CIMBL Arbovirus PCR Panel	87798 (x6), 87662
CIMBL Malaria PCR	87798
CIMBL Measles PCR **	87798
CIMBL Mumps PCR **	87798
CIMBL Monkeypox PCR **	87593
CIMBL 16S Bacterial ID	87153

For Tests Marked with an Asterisk: (*) = On a case-by-case basis, the cost of these tests can be covered by Public Health. **(**)** = These tests are covered by Public Health.

CIMBL BioFire Respiratory PCR Panel

22 Targets

- Adenovirus
- Coronavirus 229E
- Coronavirus NL63
- Coronavirus OC43
- Coronavirus HKU1
- SARS-CoV-2
- Human Metapneumovirus
- Human Rhinovirus/ Enterovirus
- Influenza A Virus
- Influenza A Virus A/H1
- Influenza A Virus A/H3
- Influenza A Virus A/H1-2009
- Influenza B Virus
- Parainfluenza 1
- Parainfluenza 2
- Parainfluenza 3
- Parainfluenza 4
- Respiratory Syncytial Virus
- *Bordetella parapertussis*
- *Bordetella pertussis*
- *Chlamydia pneumoniae*
- *Mycoplasma pneumoniae*

Specimen Requirements

Required Specimen Type: Nasopharyngeal Swab

Container Type: Universal Viral Transport Medium (VTM or UTM)

Example of a Nasopharyngeal Swab

Collection Requirements

Nasopharyngeal Swabs are available through HSA Materials Management or upon request from CIMBL.

Accepted Swab Type: Polyester, Dacron, and other synthetic swabs tips, with plastic shafts.

Please Note:

- Do not use calcium alginate swabs, cotton or wooden-shaft swabs – these can inhibit and interfere with PCR.
- VTM should be dark pink/light red in colour and stored at 20-30°C until use. If the VTM colour has changed from dark pink/light red, it should not be used.

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL BioFire Gastrointestinal PCR Panel

22 Targets

- Adenovirus F40/41
- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus (I, II, IV, and V)
- *Campylobacter (C. jejuni / C. coli / C. upsaliensis)*
- ***Clostridiodes (Clostridium) difficile* (Toxin A/B) ****
- *Plesiomonas shigelloides*
- *Vibrio (V. parahaemolyticus / V. vulnificus / V. cholerae)*
  - *Vibrio cholerae*
- *Salmonella*
- *Yersinia enterocolitica*
- *Enteroaggregative E. coli (EAEC)*
- *Enteropathogenic E. coli (EPEC)*
- *Enterotoxigenic E. coli (ETEC) lt/st*
- *Shiga-like toxin-producing E. coli (STEC) stx1/stx2*
  - *E. coli O157*
- *Shigella/Enteroinvasive E. coli (EIEC)*
- *Cryptosporidium*
- *Cyclospora cayetanensis*
- *Entamoeba histolytica*
- *Giardia lamblia*

*** Upon detection of Clostridium difficile, reflex toxin testing is automatically performed.*

Specimen Requirements

Required Specimen Type: Stool

Container Type: Sterile Universal Transport Container

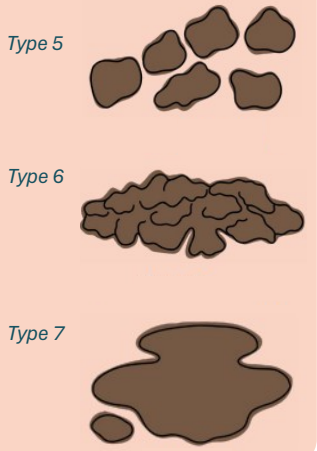
*The use of laxatives and stool softeners **72 hours prior** to specimen collection for a Gastrointestinal PCR test is **Not Permitted**.*

Collection Requirements

Accepted Specimen Type: Soft or Runny Stool.

- The Bristol Stool Chart/Scale can be used as a reference for accepted stool types guidance. Types 5, 6 and 7 are the only accepted stool types for this test.
- The specimen volume should equate to a minimum of 5mL.
- Wood is an inhibitor for PCR – the transference of the specimen using a wooden spatula (or a wooden tongue depressor) is not permitted.

Bristol Stool Chart (Excerpt)



Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C.

After 4 Days at 2-8°C: Too much degradation of viral nucleic acids will have taken place, and the specimen will be deemed non-viable.

CIMBL BioFire Blood Culture ID 2 PCR Panel

43 Targets

- *Acinetobacter calcoaceticus-baumannii* complex
- *Bacteroides fragilis*
- *Enterobacterales*
  - *Enterobacter cloacae* complex
  - *Escherichia coli*
  - *Klebsiella aerogenes*
  - *Klebsiella oxytoca*
  - *Klebsiella pneumonia group*
  - *Proteus spp.*
  - *Salmonella spp.*
  - *Serratia marcescens*
- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Pseudomonas aeruginosa*
- *Stenotrophomonas maltophilia*
- *Candida albicans*
- *Candida auris*
- Candida glabrata
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*
- *Cryptococcus (C. neoformans/ C. gattii)*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Listeria monocytogenes*
- *Staphylococcus spp.*
  - *Staphylococcus aureus*
  - *Staphylococcus epidermis*
  - *Staphylococcus lugdunensis*
- *Streptococcus spp.*
  - *Streptococcus agalactiae*
  - *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

Antimicrobial Resistance Genes

- Carbapenemases
  - IMP
  - KPC
  - OXA-48-like
  - NDM
  - VIM
- Colistin Resistance
  - *mcr-1*
  - ESBL
  - CTX-M
- Methicillin Resistance
  - *mecA/C*
  - *mecA/C* and MREJ (MRSA)
- Vancomycin Resistance
  - *vanA/B*

Specimen Requirements

Required Specimen Type: Positive Blood Culture

Container Type: Blood Culture Bottle

Safety SubCulture Unit 2

+

Please See List of Accepted Blood Culture Bottle Media for the BCID2 Panel in the Specimen Collection Guidelines section.

Collection Requirements

Accepted Specimen Type: Fluid from a Blood Culture Bottle that has been flagged 'Positive' for organism growth, that is being incubated within a blood culture instrument.

- A 500µl specimen (i.e., 0.5mL or the equivalent of 15 drops) of blood culture fluid should be transferred into a sterile 2mL tube via the *Safety SubCulture Unit 2* dispensing unit, to prevent contamination and needlestick injuries.

Transport and Storage Requirements

***Must* Deliver Specimen to the Lab Immediately:** Send specimen at ambient/ room temperature.

Please Note: HSA Pathology Laboratory & External Healthcare Providers *must alert CIMBL* of flagged positive blood culture bottles, that match the criteria for selection for the BCID2 PCR Panel. **Blood culture specimens should be sent directly to CIMBL for immediate processing.**

CIMBL BioFire Meningitis/Encephalitis PCR Panel

14 Targets

- *Escherichia coli* K1
- *Haemophilus influenzae*
- *Listeria monocytogenes*
- *Neisseria meningitidis*
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- Cryptococcus (C. neoformans / C. gattii)
- Cytomegalovirus (CMV)
- Enterovirus (EV)
- Herpes Simplex Virus 1 (HSV-1)
- Herpes Simplex Virus 2 (HSV-2)
- Herpes Simplex Virus 6 (HSV-6)
- Human Parechovirus
- Varicella Zoster Virus (VZV)

Specimen Requirements

Required Specimen Type: Cerebrospinal Fluid (CSF)

Container Type: Sterile, Plain Universal Transport Container/Tube

Examples of Acceptable CSF Container Types

Collection Requirements

Accepted Specimen Type: CSF in Sterile, Universal Transport Container/Tube (No Additives).

- **0.5mL - 1mL of CSF is required for processing.**

  The minimum amount required by CIMBL for processing is 200µL (0.2mL), however 0.5mL - 1mL is requested by CIMBL. In the chance that repeat testing needs to be performed on the specimen, this prevents a repeat of the spinal tap procedure.

Disclaimer: *For this Panel, PCR interference has been shown to occur when the Protein [Albumin] levels are greater than 4,000 mg/dL (40mg/mL). [Normal CSF Albumin Range – between 0.00 - 0.27mg/mL].*

Transport and Storage Requirements

***Must* Deliver Specimen to the Lab Immediately:** Send specimen at ambient/ room temperature.

Please Note:

* The Clinician performing the lumbar puncture (spinal tap) procedure *should make their best effort to* ***alert CIMBL*** **prior** ***to performing the procedure***.
* The specimen must be sent to CIMBL as soon as possible - within 1 hour draw time - for the immediate processing of the specimen.

CIMBL BioFire Pneumonia PCR Panel

33 Targets | **Coming Soon**

- Adenovirus
- Coronavirus
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A Virus
- Influenza B Virus
- Parainfluenza Virus
- Respiratory Syncytial Virus
- *Acinetobacter calcoaceticus-baumannii* complex
- *Enterobacter cloacae* complex
- *Escherichia coli*
- *Haemophilus influenzae*
- *Moraxella catarrhalis*
- *Klebsiella aerogenes*
- *Klebsiella oxytoca*
- *Klebsiella pneumonia group*
- *Proteus spp.*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Staphylococcus aureus*
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*
- *Chlamydia pneumoniae*
- *Legionella pneumoniae*
- *Mycoplasma pneumoniae*

Antimicrobial Resistance Genes

- Carbapenemases
  - IMP
  - NDM
  - KPC
  - VIM
  - OXA-48-like
- Colistin Resistance
  - ESBL
  - CTX-M
- Methicillin Resistance
  - *mec*A/C and MREJ MRSA)

Specimen Requirements

Required Specimen Type: Sputum or Endotracheal Aspirate, or Bronchoalveolar Lavage

Container Type: Sterile Transport Container/Tube (Universal Transport Container, or 15-50mL Tubes)

Examples of Acceptable Container Types

Collection Requirements

Accepted Specimen Type: Sputum-like Specimens (Endotracheal Aspirate or Sputum), or Bronchoalveolar Lavage (BAL)-like Specimens (BAL or mini-BAL).

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C.

After 4 Days at 2-8°C: Too much degradation of viral nucleic acids will have taken place, and the specimen will be deemed non-viable.

CIMBL Respiratory Virus Rapid LFT

4 Targets

- Influenza A
- Influenza B
- SARS-CoV-2
- Respiratory Syncytial Virus (RSV)

Specimen Requirements

Required Specimen Types: Nasopharyngeal Swab (NPS)

Container Type: Universal Viral Transport Medium (VTM or UTM)

Collection Requirements

Nasopharyngeal Swabs are available through HSA Materials Management or upon request from CIMBL.

Accepted Swab Type: Polyester, Dacron, and other synthetic swabs tips, with plastic shafts.

Please Note:

- Do not use calcium alginate swabs, cotton or wooden-shaft swabs – these can inhibit and interfere with PCR.
- VTM should be dark pink/light red in colour and stored at 20-30°C until use. If the VTM colour has changed from dark pink/light red, it should not be used.
- Please take into account that **reduced assay sensitivity for lateral flow devices (LFDs) can be expected when compared to PCR - especially for patients who present with low viral concentrations**. Although LFDs offer a faster and cheaper option for pathogen detection, PCR is considered the 'gold standard' for detecting respiratory viruses.

If no targets are '*Detected*' via the Respiratory Virus LFT, the CIMBL Respiratory Virus PCR Panel (19 Targets) will be run as a reflex test, unless stated otherwise.

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL Respiratory Virus PCR Panel

19 Targets

- Influenza A
- Influenza B
- Influenza A (H1N1) 2009
- Influenza A (H3N2)
- Respiratory Syncytial Virus (RSV)
- Parainfluenza 1
- Parainfluenza 2
- Parainfluenza 3
- Parainfluenza 4
- Human Adenovirus
- Metapneumovirus
- Bocavirus
- Human Rhinovirus
- Human Enterovirus
- Coronavirus 229E
- Coronavirus NL63
- Coronavirus OC43
- Coronavirus HKU1
- SARS-CoV-2

Specimen Requirements

Required Specimen Types: Nasopharyngeal Swab (NPS)

Container Type: Universal Viral Transport Medium (VTM or UTM)

Collection Requirements

Nasopharyngeal Swabs are available through HSA Materials Management or upon request from CIMBL.

Accepted Swab Type: Polyester, Dacron, and other synthetic swabs tips, with plastic shafts.

Please Note:

- Do not use calcium alginate swabs, cotton or wooden-shaft swabs – these can inhibit and interfere with PCR.
- VTM should be dark pink/light red in colour and stored at 20-30°C until use. If the VTM colour has changed from dark pink/light red, it should not be used.

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL High Risk Human Papilloma Virus PCR Panel

14 Targets

- HR-HPV Genotype 16
- HR-HPV Genotype 18

Other High-Risk HPV Genotypes:

- HR-HPV: 35, 58, 66
- HR-HPV: 33, 45, 51
- HR-HPV: 52, 59, 68
- HR-HPV: 31, 39, 56

Specimen Requirements

Required Specimen Type: Endocervical Swab (Pap Smear) **[x2]**

Container Type: Endocervical Collection Vial with Transport Medium used with one Sterile Cervical Broom or Brush **[x2]**

Two specimens are required for cervical screening. There is only one accepted specimen-type and container-type for each of these tests.

1. One specimen is for CIMBL *High Risk HPV (HR-HPV) Panel PCR*
2. One specimen is for HSA Pathology Laboratory Liquid-Based Cytology

Note:

For Liquid –Based Cytology Orders To HSA Pathology Laboratory:

* CERNER Order Name: *Pathology Gyn Request*
* CERNER Specimen Description: *'Pap'*

Collection Requirements

Order of Collection	Test Name	Container Details	Swab Type
Endocervical Swab #1	**CIMBL HR-HPV**	 BD SurePath Collection Vial (Blue Lid)	 *Cervical Broom*
Endocervical Swab #2	**HSA Pathology Laboratory LBC**	 Liqui-Prep Specimen Collection Vial, 10mL (Green Lid)	1. 2.  **or** *1. Cervical Broom , or 2. Cervical Brush*

Please Note:

- **A *separate* cervical broom or brush should be used for each cervical swab.**
- The endocervical swab for the CIMBL BD SurePath Collection Vial **must** be collected ***BEFORE*** the collection of the endocervical Swab for the Pathology Laboratory Liqui-Prep Specimen Collection Vial.

Transport and Storage Requirements

Specimen Delivery to the Laboratory: Send the specimen at ambient/room temperature, both sample types. The BD SurePath Collection Vial is viable up to 30 days at room temperature.

CIMBL Sexual Health PCR Panel

12 Targets

- *Neisseria gonorrhoeae*
- *Chlamydia trachomatis*
- *Mycoplasma genitalium*
- *Trichomonas vaginalis*
- *Ureaplasma urealyticum*
- *Ureaplasma parvum*
- *Mycoplasma hominis*
- Herpes Virus 1
- Herpes Virus 2
- *Treponema pallidum*
- *Candida albicans*
- *Gardnerella vaginalis*

Specimen Requirements

Required Specimen Type: **1.** Endocervical Swab (Pap Smear), ***or*** **2.** Genital Swab, ***or*** **3.** Urine Specimen.

Container Type: *One of the Following -*

1. *BD SurePath* Endocervical Swab Collection Vial, ***or***

2. Universal Viral Transport Medium Vial (UTM), ***or***

3. Sterile Universal Transport Container (Sterile Urine Cup).

Please Note:

- ** Please take into account that **a reduced assay sensitivity for urine specimens from female patients can be expected**, when compared to the same results from an endocervical swab or the genital swab for female patients (*Ward Medical Laboratory, 2015*).

Collection Requirements

Specimen Type	Container Name	Container & Swab Type Image	Patient Type
Endocervical Swab	**BD SurePath Collection Vial** ** *Using a Sterile Cervical Broom*		*Females Only*
Genital Swab	a. **Universal Viral Transport Medium** **or** b. **Aptima Unisex Swab** **or** c. **Cepheid ASWAB**	a.  b.  c. 	*Male or Female*
Urine	**Sterile Universal Container/ Urine Cup**		*Male or Female***

Transport and Storage Requirements

Endocervical Swab: Send the specimen at ambient/room temperature, for both sample types. BD SurePath is viable up to 30 days at room temperature.

Genital Swab/ Urine - If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C.

CIMBL Arbovirus PCR Panel

7 Targets

- Chikungunya Virus
- Dengue Virus
- Zika Virus
- Yellow Fever Virus
- West Nile Virus
- Mayaro Virus
- Oropouche Virus

This Orderable Test is comprised of two separate PCR Assays. Results for all targets, except Oropouche Virus, are available within 24 hours. Specimens for the Oropouche Virus PCR will be batched, and the PCR assay run on a weekly basis when possible.

Specimen Requirements

Required Specimen Type: Whole Blood

Container Type: Plain, Red Top, Whole Blood Collection Tube (No Additives)

- *A minimum of 5mL of Whole Blood (No Additives) is required for this testing service. The exception to this are specimens from neonates and infants.*

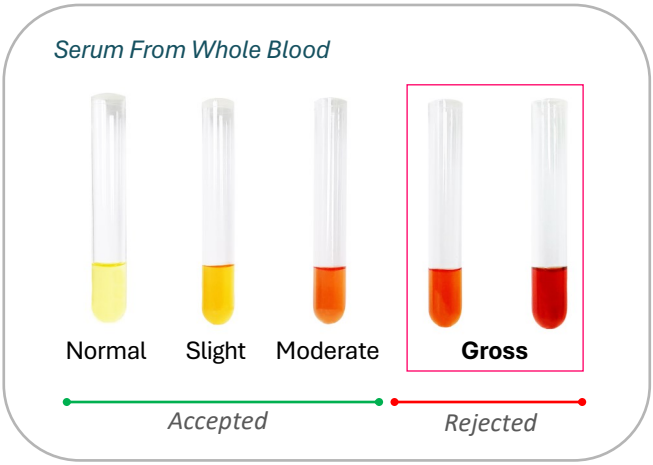
Example of a No Additive Whole Blood Collection Tube

Collection Requirements

Accepted Specimen Type: Whole Blood in red-capped, blood collection tube (No Additives)

- For arboviral infections within patients, RT-PCR has the greatest diagnostic sensitivity when specimens are collected within the window of viremia (i.e. when symptomatic).

Haemolysis Grading: Specimens with gross (excessive) haemolysis will be ***rejected*** and a new specimen will be required for testing purposes.



Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 6 hours.

- Whole blood must be spun down into serum **within 6 hours** of draw time. This is critical for the preservation of viral nucleic acids within the specimen.

CIMBL Malaria PCR

5 Targets | **Coming Soon**

- *Plasmodium falciparum*
- *Plasmodium vivax*
- *Plasmodium ovale*
- *Plasmodium malariae*
- *Plasmodium knowlesi*

Specimen Requirements

Required Specimen Type: Plasma (Anti-Coagulated Blood)

Container Type: Purple Top, Whole Blood Collection Tube (EDTA Additive)

Example of an EDTA Additive Whole Blood Collection Tube

Collection Requirements

Accepted Specimen Type: Whole Blood in purple-capped, blood collection tube (EDTA Additive)

A minimum of 5mL of Whole Blood is required for this testing service. The exception to this are specimens from neonates and infants.

For arboviral infections within patients, RT-PCR has the greatest diagnostic sensitivity when specimens are collected within the window of viremia (i.e. when symptomatic).

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL Mumps PCR

1 Target

- Mumps Virus (*Mumps orthorubulavirus*)

Specimen Requirements

Required Specimen Type: Buccal (Inner-Cheek) Swab

Container Type: Universal Viral Transport Medium (VTM or UTM)

Collection Requirements

Accepted Swab Type: Polyester, Dacron, and other synthetic swabs tips, with plastic shafts.

Please Note:

- Do not use calcium alginate swabs, cotton or wooden-shaft swabs – these can inhibit and interfere with PCR.
- VTM should be dark pink/light red in colour and stored at 20-30°C until use. If the VTM colour has changed from dark pink/light red, it should not be used.

Swabs are available through HSA Materials Management or upon request from CIMBL.

Collect buccal swabs as soon as Mumps disease is suspected.

* RT-PCR has the greatest diagnostic sensitivity when specimens are collected within the first 3 days of the onset of symptoms (i.e. parotitis; swelling of the parotid gland).
* Although mumps virus has been isolated from 7 days before to 9 days after parotitis onset, the highest percentage of positive isolations and the highest virus loads occur closest to parotitis onset and decrease rapidly thereafter.
* *Communicability:* 2 days before through 5 days after onset of parotitis.

CDC Pink Book - Epidemiology and Prevention of Vaccine-Preventable Diseases; Chapter 15: Mumps.

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL Measles PCR

1 Target

- Measles Virus (*Morbillivirus hominis*)

Specimen Requirements

Required Specimen Type: Nasopharyngeal Swab ***or*** Oropharyngeal Swab

Container Type: Universal Viral Transport Medium (VTM or UTM)

Collection Requirements

Accepted Swab Type: Polyester, Dacron, and other synthetic swabs tips, with plastic shafts.

Nasopharyngeal Swabs are available through HSA Materials Management or upon request from CIMBL.

Please Note:

- Do not use calcium alginate swabs, cotton or wooden-shaft swabs – these can inhibit and interfere with PCR.
- VTM should be dark pink/light red in colour and stored at 20-30°C until use. If the VTM colour has changed from dark pink/light red, it should not be used.

* RT-PCR has the greatest diagnostic sensitivity when specimens are collected **3 days prior to and 6 days post** the onset of symptoms (i.e. measles rash).
* *Communicability:* 4 days prior and 4 days post rash onset.
* Primary viremia 2-3 days after virus replication. Secondary viremia 5-7 days after exposure.

CDC Pink Book - Epidemiology and Prevention of Vaccine-Preventable Diseases; Chapter 13: Measles.

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL Monkeypox PCR

1 Target

- Monkeypox Virus (*Orthopoxvirus monkeypox*)

Specimen Requirements

Required Specimen Type: Skin Swab (Skin lesion material, including swabs of lesion surface, exudate or lesion crusts are recommended – collection will vary on phase of the rash).

Container Type: Universal Viral Transport Medium (VTM or UTM)

Collection Requirements

Accepted Specimen Type: Skin Lesion Material - Swab of Lesion Surface, Exudate, or Lesion Crusts.

Accepted Swab Type: Polyester, Dacron, and other synthetic swabs tips, with plastic shafts.

Please Note:

- Do not use calcium alginate swabs, cotton or wooden-shaft swabs – these can inhibit and interfere with PCR.
- VTM should be dark pink/light red in colour and stored at 20-30°C until use. If the VTM colour has changed from dark pink/light red, it should not be used.

Swabs are available through HSA Materials Management or upon request from CIMBL.

Transport and Storage Requirements

If Specimen Delivery to the Lab is Not Immediate: Store specimen at 2-8°C for up to 8 hours.

After 8 Hours at 2-8°C: It is recommended to freeze the specimen at -20°C to -80°C to prevent degradation of target nucleic acids which many be present in the specimen.

CIMBL 16S Bacterial ID

Target: Broad Range Pan-Bacteria

Molecular diagnostic techniques, such as PCR, aid in the diagnosis of bacterial infections by detecting bacterial genetic material. Broad range PCR assays are based on ribosomal genes and ribosomal DNA (rDNA). Bacterial rDNA consists of highly conserved nucleotide sequences that are shared by all bacterial species, interspersed with variable regions that are *genus* or *species* specific.

Some bacterial species are fastidious and are difficult to isolate, while others may not grow due to prior empirical treatment of patients with anti-microbial agents.

By using PCR primers that are targeted at conserved regions of rDNA it is possible to design broad-range PCRs capable of detecting DNA from almost any bacterial species. The identity of the bacterium is confirmed by sequencing of the PCR product, followed by comparison of the sequenced product with known sequences located in genomic databases.

* ***Please discuss any requests with a Clinical Microbiologist.***
* ***Positive results will also be telephoned to discuss their significance.***

Specimen Requirements

Required Specimen Type: *Any fluid or tissue specimens* from a normally sterile site that show signs of infection. Including, Positive (Flagged or Gram-Stained) Blood Culture Fluid, or Formalin-Fixed Paraffin Embedded (FFPE) Tissue.

Please Note: Samples from non-sterile sites, including sputum, bronchoalveolar lavage and skin biopsies, are not suitable for broad-range bacterial PCR and will not be processed.

Container Type: Sterile Transport Container/Tube, with no added fluids or media. (Universal Transport Container, or 15-50mL Tubes).

Examples of Acceptable Container Types

Collection Requirements

Minimum Volume Required: Blood Culture Fluid = 1mL, Other Fluids = 500µL, Tissue = 50mg, FFPE Tissue = 10 Rolls (10µm).

Transport and Storage Requirements

Due to the vast variety of specimens which can be sent for testing, the Laboratory cannot provide specific transport or storage guidance. Therefore, any specimen collected for this testing service should be transported **immediately** to the Laboratory.

Specimen Collection Guidelines

Accepted Specimen Type In Relation to CIMBL Test:

Specimen Type	Available CIMBL Tests	Containers
Whole Blood Specimen	· CIMBL Arbovirus PCR Panel	Example 
	· CIMBL Malaria PCR	Example 
Positive Blood Culture Specimen	· CIMBL *BioFire* Blood Culture ID 2 PCR Panel	Example 
Skin Lesion Swab	· CIMBL Monkeypox PCR	Example 
Buccal Swab	· CIMBL Mumps PCR	
Oropharyngeal Swab	· CIMBL Measles PCR	
Nasopharyngeal Swab	· CIMBL *BioFire* Respiratory PCR Panel · CIMBL Respiratory Virus LFT & PCR Panel · CIMBL Measles PCR	Example 
Sputum Specimens	· CIMBL *BioFire* Pneumonia PCR Panel · CIMBL Respiratory PCR Panel	One of:  or
Bronchoalveolar Lavage & BAL-like Specimens	· CIMBL *BioFire* Pneumonia PCR Panel · CIMBL Respiratory Virus PCR Panel	
Any Specimen From A Normally Sterile Site	· CIMBL 16S rDNA Bacterial PCR	
Cerebral Spinal Fluid	· CIMBL *BioFire* Meningitis/Encephalitis PCR Panel · CIMBL 16S rDNA Bacterial PCR	One of: 
Endocervical Swab	· CIMBL High-Risk HPV PCR Panel · CIMBL Sexual Health PCR Panel	
Genital Swab	· CIMBL Sexual Health PCR Panel	One of: 
Urine Specimen	· CIMBL Sexual Health PCR Panel	
Stool Specimen	· CIMBL *BioFire* Gastrointestinal PCR Panel · *C. difficile* Toxin Detection	

Specimen Collection Process:

Complete the specimen order via CERNER or via Test Request Form.

Ensure that the correct specimen container for is used.

Wear the appropriate Personal Protective Equipment (PPE) for the collection of the patient specimen.

Ensure the specimen is accurately labelled, is legible, and includes the required details (See page 5).

Secure the specimen lid to avoid any specimen leakage, and place the specimen into a biohazard bag.

Place the CERNER label or CIMBL Test Request Form into the separate, outer compartment of the biohazard bag, to avoid contamination.

Transport the specimen to CIMBL.

Whole Blood Specimen Collection Via Venipuncture

Only those trained in phlebotomy or venipuncture should collect this specimen type. Specimens with gross haemolysis will be rejected.

- Apply a torniquet approximately 3-4 inches above the selected site. Monitor the site to make sure tourniquet is not applied too tightly.
- Ask patient to make a fist.
- Cleanse the venipuncture site with an alcohol prep pad for 30 seconds and allow to air dry for 60 seconds.
- Hold on to the patient's arm, below the site of puncture. Firmly draw the skin taught to anchor the vein from rolling, and insert the needle at a 15-to 30-degree angle into the vein.
- If properly inserted, blood will flush into the catheter/tubing. Connect the vacutainer (red top, no additives) or use a syringe to draw the desired amount (at least 5mL, with the exception of neonates and newborns).

To Minimise Haemolysis:

- Avoid using line draws using IV devices; perform a venipuncture instead.
- Avoid vigorous mixing of tubes to prevent red cell damage.
- Avoid excessive pulling pressure when using syringes.
- Pre-warm skin puncture sites, rather than pinching the skin to increase blood flow.
- Fill tubes fully to prevent haemolysis.
- Deliver whole blood specimens promptly after draw to the laboratory.

How to Draw Blood: A Step-By-Step Guide (2024) , via www.nurse.org, and the WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy, Section 1.1.1. (2010).

Positive Blood Culture Specimen Collection

Once a blood culture bottle is flagged as positive, a 500µL specimen (0.5mL or the equivalent of 15 drops) of the culture fluid should be transferred into a sterile 2mL tube via the *Safety SubCulture Unit 2* dispensing unit *(See Image)*, for testing at CIMBL.

Bottle Type	Accepted Blood Culture Bottle Media
Aerobic	bioMérieux BacT/ALERT® SA
	bioMérieux BacT/ALERT® FA Plus
	bioMérieux BacT/ALERT® FA a
	BD BACTEC™ Standard/10 Aerobic/F
	BD BACTEC™ Plus Aerobic/F
	Thermo Scientific™ VersaTrek™ REDOX™ 1
Anaerobic	bioMérieux BacT/ALERT® SN
	bioMérieux BacT/ALERT® FN Plus
	bioMérieux BacT/ALERT® FNa
	BD BACTEC™ Standard Anaerobic/F
	BD BACTEC™ Plus Anaerobic/F
	BD BACTEC™ Lytic/10 Anaerobic/F
	Thermo Scientific™ VersaTrek™ REDOX™ 2
Pediatric	bioMérieux BacT/ALERT® PF Plus
	bioMérieux BacT/ALERT® PFa
	BD BACTEC™ Peds Plus/F
Mycology	bioMérieux BacT/ALERT® MPb
	BD BACTEC™ Media Myco/F Lytic

BioFire Blood Culture Identification 2 (BCID) Panel Instructions for Use, and Safety SubCulture Unit 2 from ITL BioMedical.

Nasopharyngeal Swab Specimen Collection

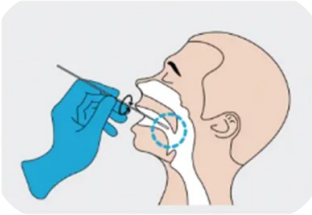
1. Tilt the patient's head back 70 degrees, and insert swab about 2cm into the first nostril, just parallel to the hard palate, until resistance is met at the nasal turbinate or nasopharynx.
2. Rotate the swab several times.
3. Specimens can be collected from both nostrils, but this is not necessary if the swab is already saturated with fluid from the first collection. If there is a deviated septum, collect the specimen from the opposite nostril.
4. Place swab tip first into viral transport medium (VTM) tube.
5. The swab should comfortably fit into the VTM tube, so that the cap may be screwed on tightly to prevent leakage. If there is protrusion of the swab from the top of the VTM tube, it may be necessary to break the swab at the top or to

CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing and the CDC Nasal Mid-Turbinate (NMT) Specimen Collection Steps.

Oropharyngeal Swab Specimen Collection

1. A tongue depressor may be used to avoid touching the swab tip to the tongue, teeth, and gums.
2. Insert swab into the posterior pharynx and tonsillar areas.
3. Rub swab over both tonsillar pillars and posterior oropharynx.
4. Place swab tip first into viral transport medium (VTM) tube.
5. The swab should comfortably fit into the VTM tube, so that the cap may be

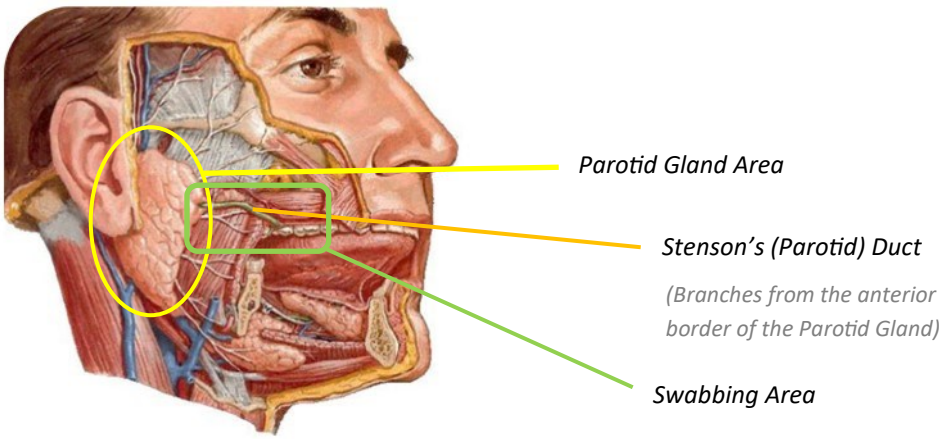
screwed on tightly to prevent leakage. If there is protrusion of the swab from the top of the VTM tube, it may be necessary to break the swab at the top or to breakpoint, in order to appropriately close the lid of the tube.



CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing .

Buccal Swab Specimen Collection

- Massage the parotid gland area for 30 seconds.
- Insert swab into the upper buccal cavity (upper cheek area) between the back molars and the cheek.
- Swab the area around Stenson's Duct (also known as the Parotid Duct).
- Do not allow swabs to dry out. Place swab tip first into viral transport medium (VTM) tube.
- The swab should comfortably fit into the VTM tube, so that the cap may be screwed on tightly to prevent leakage. If there is protrusion of the swab from the top of the VTM tube, it may be necessary to break the swab at the break-point, in order to appropriately close the lid of the tube.



CDC Mumps Specimen Collection.

Sputum & Sputum-like Specimen Collection

- The induction of sputum is not recommended. For patients who develop a productive cough, sputum can be collected.
- Educate the patient about the difference between a sputum-producing deep cough and oral secretions (saliva/spit).
- Have the patient rinse out their mouth with water and then produce expectorate via a deep cough directly into a sterile, leak-proof, screw cap collection cup or sterile universal transport container.

CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.

Bronchoalveolar Lavage & BAL-like Specimen Collection

This procedure should generally be performed in a hospital setting by a physician.

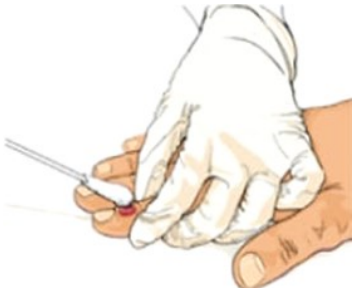
- The BAL procedure should be completed during a bronchoscopy, and includes bronchoalveolar washing to obtain a specimen for processing.
- Insert a bronchoscope into the patient's airway, instill a small amount of sterile saline to wash the airways, before suctioning up the specimen for analysis.
- Collect 2-3 mL of BAL or a BAL-like specimen into a sterile, leak-proof, screw cap collection cup or sterile universal transport container.

* Compared with sputum analysis, BAL allows for targeted sampling of the lower respiratory tract with less microbial contamination from the upper aero-digestive tract.

P. H. Patel et al., (2024) Bronchoalveolar Lavage [NIH: National Library of Medicine], NIH MedlinePlus Bronchoscopy and Bronchoalveolar Lavage (BAL), the CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing, and K. R. Davidson et al., (2020) Bronchoalveolar Lavage as a diagnostic procedure: a revied of known cellular and molecular findings in various lung diseases.

Skin Lesion Swab Specimen Collection

- It is recommended that full PPE is worn for the collection of a specimen from a suspected Monkeypox case.
- Swabs of skin lesion material, including swabs of lesion surface, exudate, or lesion crusts are the recommended specimen type. The swabbing procedure may differ depending on the stage of the rash.
- Unroofing or aspiration of the lesion (i.e., with use of sharps for collection) is not necessary or recommended due to the risk of sharps injury or exposure.
- To ensure adequate viral DNA is collected, avoid contamination of the specimen through additional contamination by gloved hands touching the specimen/swab.
- Vigorously swab each lesion (whether a swab is taken of the surface of a lesion or from the crust of a healing lesion), avoiding contamination of the area from gloved hands whilst ensuring adequate viral DNA is collected.
- Place swab tip first into viral transport medium (VTM) tube.
- If there is protrusion of the swab from the top of the VTM tube, it may be necessary to break the swab at the breakpoint, in order to securely close the lid of the tube.



CDC Guidelines for Collecting and Handling Specimens for Mpox Testing (2024), and Hologic, Inc. - Aptima Multitest Swab - Clinician Genital Lesion Specimen Collection Guide.

Cerebrospinal Fluid Specimen Collection

This procedure should be performed in a hospital setting by a physician.

- It is the responsibility of the physician initiating the procedure to ensure that CSF specimens are expected by CIMBL. If this test is required outside normal laboratory hours, please contact the CIMBL Laboratory Manager directly through the HSA Telephone Operator to facilitate testing.
- Generally, a spinal needle is inserted in the interspinous area between lumbar spinal vertebrae L4 &L5 or L3 & L4, and CSF fluid will flow if the subarachnoid space has been reached by the needle. Using a manometer connected via tubing to the spinal needle, the level at which CSF stops rising (opening pressure), should be documented, before disconnecting the tubing. CSF should then be allowed to flow freely/ drain passively from the spinal needle hub into CSF collection vials. After CSF collection, the stylet should be replaced into the spinal needle, and the spinal needle removed.

L.A. Jane, A. A. Wray, (2023) Lumbar Puncture [NIH: National Library of Medicine].

Endocervical Swab Specimen Collection

This procedure should generally be performed by a physician.

- Visualise the cervix using a speculum.
- Insert the cervical broom/brush into the cervical os, making sure that the broom/ brush extends beyond the visualised portion of the cervical os - which will increase the chance of successful collection of cells from the transformation zone.
- Take a specimen from the whole of the transformation zone (i.e. the endocervical zone, which is located at the junction of the ectocervix and the endocervix).
- Then obtain a specimen from the endocervix, by gently inserting the cervical broom/brush in to the endocervical canal. Rotate the broom 1-2 times only.
- Vigorously rinse the broom/brush in the collection vial, pushing it against the wall of the vial to release the material into the liquid.
- Delay Cervical Screening If The Patient Is: Menstruating, less than 12-weeks post-partum, less than 12 weeks after a termination of pregnancy or miscarriage, pregnant, or has vaginal discharge or a pelvic infection (treat the infection first, then take the endocervical swab on another occasion).
- If the patient has two cervixes, take a specimen from each cervix.

C. Mayer and H. Mahdy (2023) Abnormal Papanicolaou Smear [NIH: National Library of Medicine], and Scenario: Cervical Screening [NICE: National Institute for Health and Care Excellence].

Genital Swab Specimen Collection

This procedure should be performed in a clinical setting by a physician or nurse.

General Rules

* The swabbing procedure should be specific to that of presentation of symptoms. Please exercise clinical judgement and follow the set guidelines for each specific swab type.
* For each swab, regardless of swab type/brand, **carefully open the swab packaging - ensuring that you do not lay the swab down on any surfaces, or the soft swab tip does not come into contact with anything**. If it does, discard the swab and use a new swab.
* Specimen collection via patient self-swabbing is not accepted by CIMBL.

Accepted Swab Types:

- Universal Viral Transport Medium (Copan) **(A)**
- Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens **(B)**
- Cepheid ASWAB Dual Swab Specimen Collection Kit **(C)** *(Females Only)*

A

B

C

1. Universal Viral Transport Medium

1a. Vaginal Swab

- Hold the swab with one hand and gently spread the skin outside the vagina with the other hand. Insert the swab no more than 2 inches into the vaginal opening, and at an angle so that the swab is pointing towards the lower back.
- The patient should relax their muscles to insert the swab. If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue.
- Rotate the swab for 10-15 seconds, making sure the swab touches the walls of the vagina so that fluid is absorbed by the swab.
- Withdraw the swab without touching the skin, place the swab in the tube and close the tube lid securely. If necessary, carefully break the swab shaft to any remove excess, to be able to close the tube lid securely.

1b. Penile Swab

- With one hand, place your thumb and forefinger in the middle of the swab shaft to hold the swab.
- If the patient is uncircumcised, with your free hand, roll down the foreskin to expose the tip of the penis.
- Using the hand with the swab, roll the swab clockwise around the tip, and around the urethra (through which urine is passed).
- It is not necessary to put the swab deep inside the opening of the penis.
- Withdraw the swab without touching the skin, place the swab in the tube and close the tube lid securely. If necessary, carefully break the swab shaft to any remove excess, to be able to close the tube lid securely.

Cepheid Clinician-Collected Vaginal Swab Specimen Collection and Endocervical Specimen Collection (PDF), and Hologic Instructions for Using Aptima Multitest Swab Specimen Collection Kit for Penile Meatal Swab Specimen Collection.

2. Aptima Unisex Swab Collection Kit

2a. Endocervical Swab

- Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white swab included within kit), then discard this swab. *Note:* To remove excess mucus from cervical os, a large-tipped cleaning swab may also be used (not provided within kit).
- Insert specimen collection swab (the blue swab included within kit) into endocervical canal.
- Gently rotate swab clockwise for 10-30 seconds in the endocervical canal.
- Withdraw swab carefully; avoid contact with vaginal mucosa.
- Remove the lid from the specimen transport tube, immediately place swab within the tube.
- Carefully break swab shaft at scoreline, then re-cap the specimen transport tube tightly.

2b. Male Urethral Swab

- The patient should not urinate for at least 1 hour prior to specimen collection.
- Insert the specimen collection swab (the blue swab included within kit) 2-4 cm into the urethra.
- Gently rotate swab clockwise for 2-3 seconds in the urethra, then withdraw swab carefully.
- Remove the lid from the specimen transport tube, immediately place swab within the tube.
- Carefully break swab shaft at scoreline, then re-cap the specimen transport tube tightly.

Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens - Instructions for Use.

2c. Lesion Swab Specimen Collection and Handling

Note: Do not use disinfectants or cleaners on the lesion before the specimen is collected.

- With one hand, place your thumb and forefinger in the middle of the swab shaft to hold the swab.
- If needed, expose the base of the lesion to access the fluid.
- Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.
- Remove the lid from the specimen transport tube, immediately place swab within the tube.
- Carefully break swab shaft at scoreline, then re-cap the specimen transport tube tightly.

Hologic Aptima Multitest Swab Specimen Collection Kit (Vaginal Swab Specimen Collection and Handling, Penile Meatal Swab Collection and Handling, Lesion Swab Specimen Collection and Handling, Rectal Swab Specimen Collection and Handling) - Instructions for Use.

3. Cepheid ASWAB Dual Swab Specimen Collection Kit (GeneXpert Swab Kit)

3a. Vaginal Swab

- Please see instructions for *'1. Universal Viral Transport Medium, 1a. Vaginal Swab'* for Vaginal Swab instructions for this swabbing procedure.

3b. Endocervical Swab

- Before collecting the endocervical specimen with the Xpert Swab Specimen Collection Kit, remove excess mucus from the cervical os and surrounding mucosa using the large individually wrapped cleaning swab, then discard swab. If collecting multiple specimens, excess mucus only needs to removed once.
- Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
- Carefully insert the collection swab into the endocervical canal.
- Gently rotate the swab clockwise for 10-30 seconds in the endocervical canal to ensure adequate sampling, then withdraw the swab carefully.
- Remove the lid from the specimen transport tube, immediately place swab within the tube.
- Carefully break swab shaft at scoreline, then re-cap the specimen transport tube tightly.

3b. Penile Swab

- No instructions for Penile Swabs are given by the Manufacturer for this brand. Please follow the instructions for *'1. Universal Transport Medium; 1b. Penile Swab'* for this swab type.

GeneXpert Powered by CEPHEID INNOVATION - Xpert Swab Specimen Collection Kit Instructions for Use (302-6827, Rev A., July 2022), Cepheid Clinician-Collected Vaginal Swab Specimen Collection and Endocervical Specimen Collection (PDF).

Urine Specimen Collection

Advise Patients To:

- First clean hands with soap and water.
- Verify that the correct patient identifiers are labelled on the sterile universal container, or write them if necessary.
- Take off the lid from the sterile universal container, without touching the inside of the lid. Then place the lid face-up on a clean surface or tissue.
- Place the container to catch the first void of urine (the initial stream of urine), the inside of the container should not come into contact with any part of the body, clothing or external surfaces.
- Fill the container at least 1/2 of the way with urine. Briefly halt urination to remove the container, and then finish urinating into the toilet.
- Place the lid on the container and close it tightly. Wash hands with soap & water, and place urine in appropriate designated area.

Regarding Urine Specimen Collection for Female Patients:

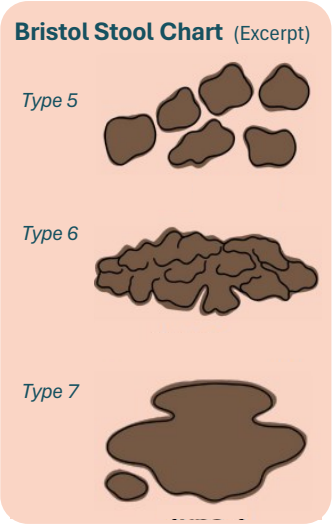
Urine specimens can be collected for women who have a suspected STI. This specimen type should be first-catch, but may detect up to 10% fewer infections when compared to cervical & genital swabs (*Ward Medical Laboratory, 2015*).

CDC 2021 Urine Specimen Collection Manual (February 2022), Wiedbrauk, D. (PhD) - The Importance of Obtaining First Catch Urine Specimens for Chlamydia trachomatis and Neisseria gonorrhoeae Testing - Warde Report [Warde Medical Laboratory, 2015, Volume 25, Number 1], and K. J. Aaron, et al., 2023 - Vaginal Swab vs Urine for Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis: A Meta-Analysis.

Stool Specimen Collection

CIMBL only accepts stool that is classified as 'Type 5, 6 or 7' as specified via the Bristol Stool Chart for testing.

- Use a clean, wide-mouth container, clean bedpan or clean plastic bag to collect the stool specimen from the patient.
- Try to avoid the mixture of water or urine with the stool specimen.
- Ensure the specimen container lid is well-sealed before placing the container into a biohazard bag for transportation.
- Certain drugs and compounds, like laxatives, will render the stool specimen unsatisfactory for testing. ***Stool specimens should be collected 72 hours before the administration of laxatives, otherwise collection must be delayed until the effects have passed.***



CDC DPDx - Laboratory Identification of Parasites of Public Health Concern; Stool Specimens - Specimen Collection, and Clinical Pathology Laboratories - Stool Testing Specimen Requirements (2024).

CIMBL 2025