EVALUATION CHECKLIST
For Clinical Laboratories performing Sampling and PCR testing for COVID-19

PRE-ANALYTICAL REQUIREMENTS

Triage and Patient reception

Criterion	Met	Not Met
TRIAGE/ SCREENING AREA		
There is a dedicated area for screening of COVID-19 patients **located outside the facility**; alternatively this area has a **specific entry site** separate from other facility entry sites.		
A **clinical triage** is set for early identification of patients with acute respiratory infection (ARI) to prevent the transmission of pathogens to health care workers and other patients.		
These **equipment** are present in the Triage area:		
• Screening questionnaire		
• Algorithm for triage		
• PPEs		
• Hand hygiene equipment (alcohol rub)		
• Infrared thermometer		
• Waste bins and access to cleaning/disinfection		
Triage area is secured by **glass** or **plexiglass** to protect healthcare workers who perform *preliminary screening* from patients to be screened.		
If this is not in place, they keep at least **1m distance** from patients to be screened and use the following **PPEs**: medical mask, gown (+apron), gloves and eye protection (goggles or face shield).		
Adequate space for triage is ensured.		
Patients to be screened arrive to the facility upon a **'previously scheduled appointment'.**		
If patients to be screened arrive spontaneously to the facility, they are provided **'waiting tickets'** by order of arrival and are asked to leave and come back at a later time if the Triage area is full.		
Medical masks are distributed to all patients to be screened while waiting for Triage.		
Patients with ARI symptoms are immediately **moved to an isolation room away from others**.		
At least **1m distance** is ensured between patients to be screened.		
At least **1m distance** is ensured between waiting room chairs; alternatively **back-to-back chairs** are set.		
Rapid triage is conducted.		
Contact and geographic information, history of clinical symptoms, recent travel, and possible exposure to suspected or confirmed COVID-19 patients are collected and filled in the **screening questionnaire**.		
There is **clear signage** for symptoms and directions.		
Family members are not allowed to enter the triage area to prevent overcrowding.		
Triage area is well aerated and regularly cleaned and disinfected.		
Triage area does not contain unnecessary objects (toys, books, newspaper, magazines...)		
Healthcare workers providing *physical examination* of patient with ARI symptoms in the consultation room use the following **PPEs**: medical mask, gown, gloves and eye protection.		
Healthcare workers providing *physical examination* of patient without ARI symptoms in the consultation room use the **PPE** according to standard precautions and risk assessment.		

Standard and Additional Precautions

Criterion	Met	Not Met
Laboratory staff are trained for **hand** and **respiratory hygiene precautions** and usage of PPE according to risk.		
There is a dedicated area for **Dressing/ Undressing** before and after specimen sampling and handling.		
Laboratory staff are familiar with Dressing/ Undressing phases and sequential steps.		
Sequence of Donning PPE is followed: Hand hygiene applied→ gown worn → mask/respirator applied → goggles/ face shield worn → first and second pair of gloves worn.		
Sequence of Doffing PPE is followed: First pair of gloves removed → goggles/face shield removed → gown removed → mask/respirator removed → second pair of gloves removed → hand hygiene applied.		
All used PPEs and paper towels are discarded inside a **waste container (yellow biohazard bag)** in the anteroom if available otherwise on the way to the door.		
Written procedures are available for standard and additional precautions.		

Specimen Sampling

Criterion	Met	Not Met
INPATIENT/ OUTPATIENT SETTING:		
For *nasopharyngeal or oropharyngeal aspirates or washes, nasopharyngeal or oropharyngeal swabs*, the healthcare worker uses the following PPEs: **medical mask**, **eye protection** (goggles or face shield), clean, non-sterile, long-sleeved **gown (+apron)** and **gloves**.		
INPATIENT SETTING:		
For aerosol-generating procedures (e.g., *tracheal intubation, non-invasive ventilation, tracheostomy, cardiopulmonary resuscitation, manual ventilation before intubation, bronchoscopy*), the healthcare worker uses the following PPEs: **respirator** (N95, FFP2 or equivalent standard), **eye protection** (goggles or face shield), clean, non-sterile, long-sleeved **gown** (+**apron**) and **double pair** of **gloves**.		
At least the **apron** and the **gloves** are changed between two consecutive patients to be sampled.		
Procedures are performed in an **adequately ventilated room** OR **negative pressure rooms** with at least 12 air changes per hour OR **controlled direction of air flow** when using mechanical ventilation.		
A **triple packaging** ensures specimen protection during transportation.		
The external surface of the transport box is wiped with a disinfectant and handled to the person assigned for specimen transportation.		

Biosafety Precautions

Criterion	Met	Not Met
Initial processing of all specimen take place in a validated **class II Biological Safety Cabinet (BSC)**, e.g. manual opening of container of respiratory sample, tube vortexing, etc.		
Appropriate **personal protective equipment** (**PPEs)** are used when working with clinical specimens.		
Double pair of disposable gloves and a **respirator (N95, FFP2 or equivalent standard)** are used.		
Diagnostic laboratory procedures (nucleic acid amplification tests) follow **Biosafety Level 2 (BSL-2)** guidelines implemented by the institution.		
Limited number of personnel is allowed to be present in the Biosafety Level 2 (BSL-2) area.		
Technical procedures are performed in a way that minimizes generation of aerosols and droplets.		
The **class II Biological Safety Cabinet (BSC)** is cleaned after use with a virucidal detergent-disinfectant as per manufacturer's recommendations (in compliance with the concentration and contact time).		
Written procedures are available for all biosafety rules and technical operations.		

Acceptable Specimen

Criterion	Met	Not Met
The following specimen are accepted:		
Nasopharyngeal or oropharyngeal aspirates		
Nasopharyngeal or oropharyngeal washes		
Nasopharyngeal or oropharyngeal swabs (synthetic)		
Broncheoalveolar lavage		
Tracheal aspirates		
Sputum		

Specimen Rejection Criteria

Criterion	Met	Not Met
The following specimen are rejected:		
Specimens not kept at 2-8°C (≤5 days) or frozen at -70°C or below.		
Incomplete specimen labeling or documentation.		
Inappropriate specimen type.		
Insufficient specimen volume.		

Transport and Storage conditions

Criterion	Met	Not Met
The personnel who transport specimens from suspected or confirmed COVID-19 patients are trained in **safe handling** practices and **spill decontamination** procedures.		
Specimen are labelled and transported as **'Biological Substance Category B'.**		
Specimen from URT (nasopharyngeal and oropharyngeal swabs):		
- Collected in VTM (viral transport medium) or Saline tubes.		
- Stored at 2-8°C for up to 5 days (VTM).		
- Stored at 2-8°C for up to 72 hours (Saline).		
Specimen from LRT (bronchoalveolar lavage, tracheal aspirate, nasopharyngeal aspirate, nasal wash or sputum)		
- Collected in a sterile container		
- Stored at 2-8°C for up to 48 hours**.**		
If a delay in extraction is expected, specimens are stored at -70°C (dry ice) or lower.		
Extracted nucleic acids are stored at -70°C or lower.		
A **triple packaging** ensures specimen protection during transportation.		
- Primary container: absorbent packaging material, water-tight and leak-proof		
- Secondary container: durable, water-tight and leak-proof ; contains absorbent material (cushions)		
- Outer container : protects contents from physical damage and water while in transit		
When a specimen is received from an external laboratory, the external surface of the transport box is disinfected.		

ANALYTICAL REQUIREMENTS

Criterion	Met	Not Met
Laboratory personnel is familiar with the **protocol** and **instruments** used.		
Written procedures are available for **nucleic acid extraction** and **PCR amplification** protocols.		
Separate areas and **dedicated equipment** (pipettes, microcentrifuges) and **supplies** (microcentrifuge tubes, pipette tips, gowns and gloves) are maintained for assay reagent setup and handling of extracted nucleic acids.		
Work flow is from the clean area to the dirty area.		
The test is performed using an **in vitro diagnostic (IVD)** medical device **EUA-FDA** or **CE marked.**		
The IVD medical device is on **the list of MOPH registered devices**.		
The test has at least **2 targets** (one for universal coronavirus detection and one specific to SARS-CoV-2).		
Assay controls are run concurrently with all test samples		
PTC – positive template control with an expected Ct value range		
NTC – negative template control added during rRT-PCR reaction set-up		
HSC – human specimen extraction control extracted concurrently with the test samples		

POST-ANALYTICAL REQUIREMENTS

Criterion	Met	Not Met
Validation of results :		
Validation is performed by a certified pathologist/scientist experienced in PCR testing.		
Discordant results between the two PCR targets prompts repeat testing on a new sample.		
Interpretation of results :		
Correlation is made with the patient's clinical history, and by taking into account the analytical sensitivity and specificity of the IVD used as per manufacturer's stated performance characteristics.		
In case of Positive RT-PCR result: On the final report, an interpretative comment recommends that **"the result needs to be confirmed at RHUH (the National Reference Laboratory for COVID-19 testing)."**		
In case of Negative RT-PCR result: On the final report, an interpretative comment warns that **"a negative result doesn't exclude the possibility of COVID-19, especially in early disease"** and recommends **"follow-up with a medical health-care provider, continue to adhere to safety and isolation precautions, and eventually repeat testing in case of high disease suspicion".**		
The final report mentions the sample origin.		
The final report mentions the name of the test, the method used and its analytical sensitivity (LOD).		
The final report mentions the name and the address of the referral laboratory if the specimen is outsourced.		
The laboratory follows the national reporting requirements :		
The laboratory reports all results (negative and positive) to **MOPH (Epidemiologic Surveillance Unit)** as per circular nb. 47 (10/3/2020), and/or via the electronic platform as per circular nb. 52 (16/3/2020).		

Annex 1:

Sampling, Processing, Storage and Transport of Whole Blood/Serum/Urine of COVID-19 suspected or confirmed patients (for Hematologic/ Serologic/ Biochemical testing and Urine analysis)

Criterion	Met	Not Met
For highly suspected and confirmed COVID-19 patients:		
The laboratory technician uses the following PPEs during *blood sampling*: **medical mask**, **eye protection** clean, non-sterile, long-sleeved **gown (+apron)** and **gloves**.		
Hematology (EDTA, Citrate) and chemistry samples collected using vacutainer system.		
Specimen taken have **dedicated centrifuge.**		
Centrifugation operations are done using nacelles or airtight rotors.		
The associated technical operations (centrifuge balancing, position, filling and opening of tubes, removal of supernatants, etc.) are performed under **Class II Biological Safety Cabinet.**		
Specimen are stored at 2-8°C for up to 48 hours**.**		
If a delay in processing is expected, they are stored at -70°C (dry ice) or lower.		

Annex 2:

Waste Decontamination and Disposal

Criterion	Met	Not Met
Waste generated by the management of clinical sampling (regardless of COVID-19 status) are discarded in a **strong, leak-proof autoclavable container** under the **Class II Biological Safety cabinet.**		
This 'Highly Infectious' waste container is **autoclaved for 30 min at 121°C.**		
If no autoclave is available in the laboratory, 'Highly Infectious' waste container is filled with a 2 cm-height **virucidal detergent-disinfectant** or any other disinfectant active against COVID-19 such as 0.5% sodium hypochlorite, peracetic acid, hydrogen peroxide, 70% ethanol or alcohol or glutaraldehyde, quaternary ammonium and phenolic compounds.		
The disinfectants are used as per manufacturer's recommendations (in compliance with the concentration and contact time).		
Waste final disposal follows validated procedures implemented by the institution.		