WoSSVC-RA-064

Risk Assessment Form

Use this form for any detailed risk assessment unless a specific form is provided. Refer to your Summary of Hazards/Risks and complete forms as required, including those that are adequately controlled but could be serious in the absence of active management. The Action Plan and reply section is to help you pursue those requiring action.

Name of Assessor:	Pam Saunders	**Post Held:**	Operations Manager
Department:	SMiRL	**Date:**	16/03/2020

Subject of Assessment: E.g.: hazard, task, equipment, location, people

Operation of **Roche LIAT Influenza Point of Care Unit**
with samples from patients with a flu type illness

Documented Guidance
Current HPS guidance recommends that Point of Care Equipment should not be used, unless a local Risk Assessment is conducted to show that analysis can be conducted safely. The purpose of this risk assessment is to provide guidance to individual units to show the risks associated and recommended precautions to take to minimise this risk to facilitate POC Influenza A/B and RSV analysis in Greater Glasgow and Clyde.

The PHE Guidance **COVID-19: safe handling and processing for samples in laboratories** which is linked in the HPS Guidance for laboratories (direct link below) has been updated:

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens

Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)

Agent: COVID-19
2019-nCoV infection is classified as an airborne high consequence infectious disease (HCID) in the UK.

Characterisation of COVID-19 is ongoing. Initial information shared by China and WHO indicates that 2019-nCoV is a beta-coronavirus that is genetically similar to SARS-like coronaviruses obtained from bats in Asia. Both SARS-CoV and MERS-CoV are ACDP Hazard Group 3 Pathogens; as such this virus COVID-19 should be treated as hazard group 3.

Ref: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-background-information/wuhan-novel-coronavirus-epidemiology-virology-and-clinical-features

Roche Cobas LIAT analyser:

Mechanical:
Minimal risks to user mechanical lid risk of minor injury.
Incorrect insertion of the testing cartridge into the analyser may damage the analyser.

Chemical:
Chlorine based disinfectant.
Each cobas® Liat® assay tube contains all assay reagents for a single test, minor irritation risk if tube split.

Biological:
- Accidental spillage or exposure to biological material e.g. Respiratory sample – biological waste
- Pipetting of specimen to cartridge
- Incorrect disposal of specimen waste

Electrical:
Roche Cobas LIAT power supply

Description of Risk
Describe the work that causes exposure to the hazard, and the relevant circumstances. Who is at risk? Highlight significant factors: what makes the risk more or less serious – e.g.: the time

As respiratory secretions are considered a source of infection any risk of splash or spillage must be minimised during collection

Ref: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens

Based on knowledge of other coronaviruses, infection with COVID-19 could occur by inhalation of aerosolised virus or by contact with droplets, contaminated surfaces or formites. Exposure to upper and lower respiratory tract specimens in the absence of appropriate biological safety measures is likely to represent the greatest risk of transmission in a laboratory setting, and thus the risk could be assumed the same for Point of Care Testing.

Roche Cobas LIAT
Decision re undertaken procedure

Flu POCT procedure should not be carried out on patients who are COVID-19, MERS or Avian influenzae positive

Influenza A/B and RSV testing with the Roche Cobas LIAT should NOT be undertaken lightly if the need for Respiratory testing is not immediate or COVID-19, MERS or Avian influenza are suspected forward a respiratory specimen to the laboratory for processing.

PPE
Appropriate PPE is made available including FFP3 face mask, gown, gloves, eye protection where appropriate. PPE should be as per patient management. 'Fit testing' of FFP3 mask if required. The minimum level of PPE to be worn for the procedure is that suitable for droplet precautions Disposable apron , Disposable gloves, Fluid-resistant Type IIR surgical face mask and goggles.

Procedure – Refer Work Instructions for detailed procedure

Risks associated with flu POCT procedure

Risk during sample collection is contamination from fluids from the patients respiratory tract e.g. couching sneezing by aerosolisation or direct contact with sample container

ITU sputum samples

- For sputum samples from ITU patients (aersol generating procedure (AGP), risk is minimised by wearing FFP3 mask, PPE - gloves and apron - as per HPS guidance. Staff perform hand hygiene and donning and doffing of PPE as described in work instruction
- Specimen container is labelled prior to entering patient area/bay to reduce external contamination of sample container
- Specimen collection as per work instructions
- Specimen container is decontaminated post collection – wiped with 70% Isopropanol wipe, prior to sending to laboratory, again to reduce external contamination.
- To minimise contamination, loading of LIAT cartridge is performed at patient bedside.
- LIAT cartridge is wiped externally 70% Isopropanol wipe and patient area is decontaminated after procedure.
- LIAT cartridge is then carried through to allocated room with LIAT analyser and procedure performed as per work instruction.
- LIAT cartridge is disposed into sharps bin and all other clinical waste (including PPE) is disposed as biological waste.

Gargle and NPS samples

- For gargle (non AGP) and taking of NPS, risk is minimised by wearing PPE (gloves and apron) and fluid-resistant Type IIR surgical face mask and goggles as per HPS guidance and staff perform hand hygiene as described in work instruction
- Samples not sent to lab unless clinically required
- Refer ITU sputum sample for minimising risks

Decontamination

External contamination:

- Wipe down exterior of the analyser with either 70% Isopropanol wipe or 5-10% chlorine disinfectant

Internal contamination from leaking assay tube:

- Dispose of assay tube in accordance with local disposal policy
- Contact the Virology Department 0141 201 8724

Summarise current controls In place	Describe how they might fail to prevent adverse outcomes.
• Work instruction and risk assessments in place to cover all procedures and equipment pertaining to Roche LIAT Influenza A/B and RSV test • Staff receive approved training prior to requesting and using Roche Cobas LIAT and can demonstrate competence and attend update session • Collection of sample in a container with a sealable lid • Roche Cobas LIAT – is a closed system	• Work instructions and risk assessments not in place • Procedures, Risk assessments & policies not reviewed • Staff not carrying out procedures as per training /SOP/Risk assessment and failure of staff to work in a safe manner • Changes in procedures which are not cascaded to staff or analyser used by untrained staff. • Ongoing/review of Competency not assessed • Staff not carrying out procedures as per training /Work Instruction/Risk assessment • Risk of spillage if a container with no lid used .
• Appropriate PPE is made available including FFP3 face mask/ fluid-resistant Type IIR surgical face mask , gown, gloves, eye protection where appropriate. PPE should be as per patient management. 'Fit testing' of FFP3 mask if required. • Wipe down external cartridge before removing from dirty specimen loading area • Wipe down external surface of sample container after collection	• Failure of healthcare staff to wear appropriate PPE correctly. • Touching, mouth, eyes or nose with potentially contaminated gloves. • Failure could risk contamination of clean area. Risking staff safety
• All respiratory secretions spills handled according local departments policy on disposal of clinical waste • Decontamination of all potentially contaminated surfaces of analyser, screen with chlorine based disinfectant wipes • All waste material handled according to the local departments policy on disposal of clinical waste (Category B waste).	• Failure to report accidents or spills • Ward staff/infection control failing to inform sample of patient with suspected coronavirus. • Failure of staff to follow decontamination procedure after analysis of each potentially infective sample • Failure to dispose of clinical waste safely

Existing Precautions

Level of Risk - Is the control of this risk adequate?
Give more than one risk level if the assessment covers a range of circumstances. You can use the 'matrix' to show how 'likelihood' and 'consequences' combine to give a conclusion. Also, be critical of existing measures: if you can think how they might fail, or how they could be improved, these are indications of a red or orange risk.

Risk Matrix

Likelihood	Impact/Consequences				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Very High High Medium Low

Current risk level: Medium

Given the current precautions, and how effective and reliable they are, what is the current level of risk? **Green** is the target – you have thought it through critically and you have no serious worries. Devise ways of making the risk green wherever you can. **Yellow** is acceptable but with some reservations. You can achieve these levels by reducing the inherent risk and or by effective and reliable precautions. **High (Orange) or Very High (Red) risks are unacceptable and must be acted on: use the Action Plan section to summarise and communicate the problems and actions required.**

Action Plan (if risk level is **High (Orange) or Very High (Red)**

Use this part of the form for risks that require action. Use it to communicate, with your Line Manager or Risk Coordinator or others if required. If using a copy of this form to notify others, they should reply on the form and return to you. Check that you do receive replies.

Describe the measures required to make the work safe. Include hardware – engineering controls, and procedures. Say what you intend to change. If proposed actions are out with your remit, identify them on the plan below but do not say who or by when; leave this to the manager with the authority to decide this and allocate the resources required.

Proposed actions to control the problem List the actions required. If action by others is required, you must send them a copy	**By Whom**	**Start date**	**Action due date**
Actions – involve the Clinical teams agreeing to Risk assessment and have instructions on the wards. Requirement for training needs to be evidenced			

Action by Others Required - Complete as appropriate: (please tick or enter YES, name and date where appropriate)

Report up management chain for action	NA
Report to Estates for action	NA
Contact advisers/specialists	NA
Alert your staff to problem, new working practice, interim solutions, etc	Ensure this risk assessment is available to GGC POC Co-ordinators

Reply
If you receive this form as a manager from someone in your department, you must decide how the risk is to be managed. Update the action plan and reply with a copy to others who need to know. If appropriate, you should note additions to the Directorate / Service Risk Register.

If you receive this as an adviser or other specialist, reply to the sender and investigate further as required.

Assessment completed - date:	17/03/2020	**Review date:**	17/03/2021