

## Risk Assessment Form

**ID:**

HSF-CBIO-117

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.

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| **Name of Assessor:**  | Dr Iain Jones | **Post Held:** | Consultant Biochemist  |
| **Department:** | Clinical Biochemistry, Royal Alexandra Hospital | **Date:** | 16/03/2020 |
| Subject of Assessment: E.g.: hazard, task, equipment, location, people |
| Operation of GEM 4000 and GEM 5000 Blood Gas analyser with samples from patients that fit the case description of novel coronavirus (COVID-19)Blood gas analysis should only be done when deemed clinically necessary by the consultant in charge of the patient. Blood gas analysis is an essential element of the assessment and management of patients with signs and symptoms of respiratory disease and management of ventilated patients. These are all scenarios which may be seen in patients with COVID-19.**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 blood gas analysis in Greater Glasgow and Clyde where blood gas analysis is deemed essential and not being able to perform would be detrimental to patient care. https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimensLocal teams may be required to perform their own local risk assessment, using this risk assessment as guidance, following their own local patient pathway.  |
| Hazards (Describe the harmful agent(s) and the adverse consequences they could cause) |
| **Agent: COVID-19**Characterisation of COVID-19 is ongoing. Initial information shared by China and WHO indicates that [2019-nCoV is a beta-coronavirus](https://www.who.int/docs/default-source/coronaviruse/20200114-interim-laboratory-guidance-version.pdf) 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.The virus has been declared a global health emergency by WHO with infections and fatalities worldwide. At present there are 798 cases and 11 deaths in the UK.*Ref:* [*https://www.gov.uk/government/publications/wuhan-novel-coronavirus-background-information/wuhan-novel-coronavirus-epidemiology-virology-and-clinical-features*](https://www.gov.uk/government/publications/wuhan-novel-coronavirus-background-information/wuhan-novel-coronavirus-epidemiology-virology-and-clinical-features)The virus appears to be rarely identified in blood, with it being detectable in one study by PCR in 1% of patients with COVID-19 infection.*Ref: https://jamanetwork.com/journals/jama/fullarticle/2762997?resultClick=1***Blood Gas Analyser**This risk assessment applies to both the GEM 4000 and GEM 5000 blood gas analysers. The only difference is that use of the GEM 4000 analysers requires calibration with CVP material when the cartridge is changed- see section headed Risks During Analyser Maintenance.**Mechanical:** Moving components on blood gas analyser such as sample probe, reagent cartridge door, infra-red barcode Scanner. Failure to follow manufacturer’s instructions could lead to component jam or malfunction.**Chemical:** All reagents and chemicals are held within the reagent cartridge in a closed case system & not exposed. **Biological:**Accidental spillage or exposure to biological material e.g. blood samples. Blood sampled by analyser is stored in waste reservoir in blood gas cartridge which is a closed case system and disposed of in one unit as biological waste (Category B waste).Syringe with residual blood should be disposed in Sharps container (Category B waste).**Electrical:**Blood gas analyser power supply. |
| Description of RiskDescribe 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 taken, how often the work is done, who does it, the work environment, anything else relevant. |
| As blood is considered a potential source of infection any risk of splash or spillage of blood during blood gas analysis or collection could be infectious to the operator.Ref: <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens>. Updated 2 February 2020The procedure of blood gas analysis carries risks to those directly performing the blood gas analysis and those in the environment where the blood gas analyser is located. 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 fomites. As the virus is rarely detected in blood risks from splash and or aerosol may be low, but should be prevented where possible.**Risks during blood gas sample collection**MERS-CoV RNA has been detected in a variety of human specimens, including urine, faeces and blood, and it is reasonable to assume this could be the case for COVID-19. One study suggests COVID-19 is detectable in blood in 1% of individuals. There is a risk of splash or spillage of the blood which could be considered infectious, during sample collection procedure from the patient with contamination on the blood gas syringe/local environment. The sample should be visually inspected for air bubbles and the user should expel any air bubbles from the syringe by gently tapping the sides of the syringe allowing them to go to the top of the syringe for expulsion in order to avoid an air contamination and falsely altering the pO2 results. If required the user should expel any remaining air or air bubbles from the syringe by gently depressing the plunger, with a gauze swap held covering the opening of the tube to catch any blood expelled. The gauze should be disposed of as biological waste in the patient room. There is a risk of aerosolisation or spillage if this procedure is not performed correctly by untrained staff. The risk of aerosolisation is prevented by covering the opening of the tube with a gauze swab before any blood with bubbles is expelled into it. At a minimum droplet precautions are required, ie gloves + apron + surgical facemask + eye protection worn. The patient’s clinical condition or other procedures being performed upon the patient may mandate a higher level of PPE. This risk is also reduced by a trained member of staff taking the blood and capping the syringe once the sample is taken and air bubbles removed. Following air-bubbles expulsion, homogenization of the sample with the anticoagulant should be done to avoid formation of the clots. For optimal anticoagulation, rolling of the syringe between the palms, and then inverting it vertically is recommended The ABG syringe needle (if present) will require to be disposed in the sharps waste bin and any alcohol wipes or gauze swaps disposed of as biological waste in the patient room.Another risk during sample collection is contamination from fluids from the patient’s respiratory tract (e.g. by coughing or sneezing) by aerosolisation or direct contact to the outside of the blood gas syringe, with onward spread by direct contact with tube. The risk is greater if the clinician is working in isolation as a lone worker, with no direct route to the nearest blood gas analyser, requiring movement through multiple rooms, doors etc. Safe blood gas analysis in this patient group may require more than one staff member. This risk may be reduced by the clinician wearing the PPE appropriate to the level required for being in the room with the patient during sample collection and transport of the sample to an analyser, preferably to a blood gas analyser located in the same unit as the patient. Unless the gas analyser is within a cohorted area which can be accessed without changing PPE, then consideration of how to remove the sample from the room is needed. If airborne PPE is being used then handover by dropping the sealed sample into a specimen collecting bag carried by another staff member outside the room wearing gloves. Otherwise PPE can be doffed, fresh gloves put on, the sample placed into a sample bag and taken out of the room.**Risks during blood gas analysis**The risks of blood gas analysis itself include the risk of transmission from direct contact with the outside of the blood gas tube as before which may have been contaminated by aerosolisation of the virus. There is also a risk to the local environment so samples must not be placed on the workbench or surrounding area. |

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| **Description of risk continued...**There is a small risk of blood splash or spillage during analysis of blood gases. This risk is reduced if the specimen is capped after blood gas sample collection and analysis is performed by a trained member of staff. The operator should allow the sample probe to take the blood during sample aspiration and blood must not be forcibly injected into the analyser. It is recommended this procedure is carried out with the operator wearing PPE appropriate for droplet precautions (apron, surgical facemask, gloves and eye protection).It is recommended the blood gas syringe is transported capped to the analyser to reduce risk of blood splash or spill. Capping and uncapping the syringe is not described as an aerosol generating procedure according to HPS guidance <http://www.nipcm.hps.scot.nhs.uk/media/1395/2018-02-8-appendix-11-final.pdf> and to UK national guidance (<https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens>. However taking good practice into consideration it is recommended if practical that the analyser is situated in a well ventilated room with the doors closed. There is a risk of contamination if the cap is placed on the workbench. The cap should be placed immediately into a sharps bin.If blood gas aspiration is performed incorrectly by forced injection of the sample into the analyser, instead of letting the sample probe take the blood there is an increased risk of spill or splash. This risk is reduced or removed by correct use of the analyser and only trained staff performing blood gas analysis. It is recommended this procedure is carried out with the operator wearing PPE for droplet precautions (apron, surgical mask, gloves and eye protection).The patient’s blood within the analyser is held in sample waste section of the blood gas cartridge. This is a closed case system and not exposed. The cartridge is disposed at expiry or when no further reagent is available on board (whichever is sooner) and should be disposed of as clinical waste (Category B waste). The only risk would be if the cartridge was dropped forcibly on the floor in such a way as to break the cartridge. Once analysis has been completed the blood gas syringe must be disposed of into a sharps bin. The surface and screen of the blood gas analyser as well as the handle of the barcode scanner and the immediate worktop area must be decontaminated with a chlorine based disinfectant, in the form of a solution at a minimum strength of 1,000 ppm available chlorine or other approved cleaning agent safe for the analyser and effective against coronavirus, for example 70% alcohol wipes. 70% alcohol wipes are the preferred agent for cleaning the screen, and should be used for this purpose. Ref <https://hpspubsrepo.blob.core.windows.net/hps-website/nss/1942/documents/1_decontamination-of-blood-gas-analysers-v1.1.pdf>Visible blood spills must be cleaned with 10,000 ppm chlorine solution in line with health board policy.There is a risk to other healthcare staff operating the analyser afterwards due to transmission by direct contact with possible contaminated surfaces if the blood analyser is not decontaminated after each use following analysis.  After using the blood gas analyser staff should doff their PPE, dispose of this as clinical waste and decontaminate their hands, unless they and the analyser are already in an AGP cohort area.**Risks during blood gas analyser maintenance**Both GEM 4000 and GEM 5000 gas analysers will need maintenance. Once the blood gas cartridge has used all tests (a rare event happening every few weeks), the cartridge will need to be removed and should be disposed of as clinical waste (Category B waste). This should be done wearing PPE appropriate to the location the analyser is situated in (gloves, and apron unless the analyser is situated in a room where aerosol generating procedures are being performed on possible or confirmed patients with COVID-19.The GEM 4000, unlike the GEM 5000, requires calibration with CVP material 40 minutes after a new cartridge is inserted by a member of staff. This requires gloves and apron, unless the analyser is situated in a room where aerosol generating procedures are being performed on possible or confirmed patients with COVID-19.**Risks of blood gas analyser in an AGP hotspot**An analyser in an AGP hotspot will require additional decontamination steps are part of a terminal clean of the area. Additionally, if the analyser is close to the AGP procedures, consideration should be given to performing these steps more regularly as part of the routine cleaning on the environment.Steps for decontaminating the analyser on terminal clean of an AGP Hotspot:1. Power down and unplug the analyser (this will require priveleges sufficient to change cartridges on the analyser. Discuss with the Biochemistry Lab if these priveleges are required for more users).
2. To power down press **Menu>Actions>Shutdown** from pull down menu.
3. The analyser will prompt user to consider decision. **Press No** to return to the Start New Sample tab. **Press Yes** to continue shut down. Analyser will shut down on it’s own.
4. Unplug the analyser and UPS. The analyser is now ready for cleaning.
5. Use a clean, soft cloth with a chlorine based disinfectant in the form of a solution at a minimum strength of 1,000 ppm available chlorine and wipe the entire exterior of the instrument including the touch screen and power cord.
6. Use the cloth to wipe the barcode reader.
7. Use the cloth to wipe surrounding surface of bench area around the analyser
8. Place any used cloth or paper towel in biological waste.
9. Ensure analyser and power cord are dry before reconnecting the UPS and power cord.
10. Turn the analyser on by briefly pressing power button on the left side of the back of the analyser.
11. Blood gas analyser will begin its power-up cycle. **Note power must be restored within 60 mins of switching off, otherwise the PAK cartridge cannot be recovered.**
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| **Summarise current controls In place**  | **Describe how they might fail to prevent adverse outcomes.** |
| Only staff properly trained in blood gas sample collection and sample handling of biological samples are permitted to do so.Safe blood gas analysis for this patient group may require more than one staff member.Only staff who are trained in operating the blood gas analyser and certified with a barcode are permitted to do so. Appropriate PPE is made available including FFP3 face mask, gown, gloves, eye protection or gown, surgical facemask and gloves +/- eye protection where appropriate. PPE should be as per patient management. ‘Fit testing’ of FFP3 mask if requiredAll blood spills handled according local departments policy on disposal of clinical wasteDecontamination of all potentially contaminated surfaces of analyser, screen, barcode scanner and immediate worktop area with chlorine based disinfectant or 70% alcohol wipes.All waste material handled according to the local departments policy on disposal of clinical waste (Category B waste)Sample probe is not exposed and stored within the analyser. It is only exposed when blood sample is presented to the sample aspiration area. All internal components are contained, not exposed and can only access when analyser is in pause mode. | Failure of staff to work in a safe manner.Failure to adequately expel any air bubbles from blood gas syringe.Lone member of staff working when does not have direct access to a blood gas analyser.Blood gas analyser used by untrained staff. Failure of healthcare staff to to wear appropriate PPE correctly. Touching, mouth, eyes or nose with potentially contaminated gloves.Failure to report accidents or blood spillsWard staff/infection control failing to inform sample from patient with suspected coronovirus.Failure of staff to follow decontamination procedure after analysis of each potentially infective sample.Failure to dispose of clinical waste safely. Failure to work in a safe manner when sampling from the blood gas syringe, causing skin puncture. By-pass or override a safety device. Open covers when the system is in operation. Manufacturer fault. |

**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**

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| 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.

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| **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)

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| **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.**

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| **Assessment completed - date:** | 16/03/2020 | **Review date:**  | 13/03/2021 |