

## Risk Assessment Form

HSF-CBIO-120

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:**  | Andy Kerry | **Post Held:** | Consultant Clinical Scientist |
| **Department:** | Clyde Biochemistry Dept | **Date:** | 19/03/2020 |
| Subject of Assessment: **E.g.: hazard, task, equipment, location, people** |
| Operation of **Abbott i-STAT handheld analyser** with samples from patients that fit the case description of novel coronavirus (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 at any time and biochemical analysis when the laboratory is closed in the Vale of Leven hospital where analysis is deemed essential and not being able to perform would be detrimental to patient care. Should i-STAT analysers be deployed in any clinical location in NHSGGC it is felt this guidance should be sufficient to cover their use, subject to consideration of any relevant local issues. This risk assessment is not intended to cover the analyser stored in QEUH haematology department for use in VHF patients. 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>There is, as yet, no evidence that viable virus particles are present in the blood of patients with COVID-19 and no evidence that aerosolisation of the blood would lead to infection in the HCW. Additionally, evidence of viraemia is low in patients with COVID-19.<https://jamanetwork.com/journals/jama/fullarticle/2762997?resultClick=1>A local risk assessment for routine use of the i-STAT already exists, see Appendix 1 |
| 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](https://www.gov.uk/guidance/high-consequence-infectious-diseases-hcid) (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](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.*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)**i-Stat Analyser****Mechanical:** No risks to user or patient. Incorrect insertion of the cartridge into the analyser may damage the analyser.**Chemical:** Chlorine based disinfectant. **Biological:*** Accidental spillage or exposure to biological material e.g. blood samples – biological waste
* Procedure use of safer sharp lancet sampling device – sharps risk
* Incorrect disposal of specimen waste

**Electrical:**i-STAT analyser power supply**Optical:**Class 2 laser product |
| 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 sample collection or analysis 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 fomites. 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.**Abbott i-STAT Analyser**PPEUnless the patient’s location or procedures being performed on them mandate AGP PPE, droplet PPE should be worn for the procedure as per HPS guidance and should be donned by both staff member taking the blood from the patient and staff member performing analysis on the i-Stat. That is:DROPLET (RESPIRATORY) PRECAUTIONS • Disposable apron; consider fluid-resistant disposable gown if apron provides inadequate cover for the procedure/task being performed • Disposable gloves • Fluid-resistant Type IIR surgical face mask and goggles or full face visor if splashes anticipatedLOCATION CHOSEN FOR SAMPLING AND ANALYSISVenesection will occur in the room/cubicle with the patient. Analysis should be performed in a suitable well ventilated location. If venesection and analysis are to be performed in different areas of the room the procedure may be safer with two participants both wearing PPE as per HPS guidance.The sample should be visually inspected for air bubbles. If required the user should expel any remaining air or air bubbles from the syringe by gently depressing the plunger, with a gauze swab 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. Following air-bubbles expulsion, homogenisation 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 syringe needle (if present) will require to be disposed in the sharps waste bin and any alcohol wipes or gauze swabs disposed of as biological waste in the patient room.A 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. Safe blood gas analysis in this patient group may require more than one staff member. The clinician taking the blood should wear PPE appropriate to the level required for being in the room with the patient and drop the sealed sample into a specimen bag carried by a second member of staff at the edge of the patient cubicle wearing appropriate PPE (apron, surgical mask, gloves and eye protection) who will go on to perform test cartridge analysis on the i-STAT. The risk during i-STAT analysis itself includes the risk of transmission from direct contact with the outside of the blood syringe as before which may have been contaminated by aerosolisation of the virus. There is also a risk to the local environment so samples and the syringe cap must not be placed directly on the workbench or surrounding area. They should be placed in a cardboard drug tray during the analysis stage to avoid direct contact with the bench, which can then be disposed of after use to biological waste. |

There is a small risk of blood splash or spillage during application of the blood sample to the test cartridge. This risk is reduced or removed by correct use of the analyser and only trained staff performing analysis on the i-STAT. It is recommended this procedure is carried out with the operator wearing PPE for droplet precautions (apron, surgical mask, gloves and eye protection).

**Procedure**

**Analysing the sample on the i-STAT**

* Prior to opening the bag put the patient’s details into the i-Stat as follows**:**
* Press the power button to turn on i-STAT
* Press **2** for i-STAT cartridge
* Scan operator ID
* Scan patient ID
* Scan cartridge
* Position patient demographic label next to i-STAT, to denote the i-STAT is in use

**Note: i-STAT should remain on a flat surface and not be moved during analysis.**

* Open specimen bag
* Mix sample 8 times between the palms of your hands
* Discard 3 drops of blood to waste with a gauze swab held at the opening of the tube to catch any blood expelled

**Application of Sample**

 This sequence **must** be followed:

* Place the cartridge in a cardboard drug tray

**Note: If application of blood is not immediate the sample must be remixed (8 times between the palms of the hands) before analysis.**

* Take the cap off the sample and place in the same drug tray. Apply blood to CG4 or CHEM 8 cartridge and seal cartridge.
* Recap sample and place on drug tray
* Insert cartridge to begin analysis.
* Once analysis is complete discard test cartridge immediately into sharps bin. A further test cartridge may be performed at this point if required, remembering to mix the sample 8 times between the palms of the hands before application.
* Once complete discard blood syringe and cartridge into sharps bin

**Note: If this sequence is not followed, there may be a risk of incorrect results being produced.**

**Post Procedure / Decontamination after analysis of sample from patient with COVID-19**

* Using clean gloves, clean machine with Clinell sanitising wipe. The device **must** be cleaned prior to use on another patient
	+ 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.
* Visible contamination - the device will need to be decontaminated immediately after use if there is visible contamination e.g. blood. For blood apply 10,000 ppm of chlorine solution for 10 minutes then wipe off with Clinell wipe
* Remove PPE and perform Hand Hygiene
* Once a day or as required, after decontamination, the i-Stat should be docked in MAU for upload of results to InfoHQ IT system for audit trail

|  |  |
| --- | --- |
| **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 i-STAT analyser protocol
* Staff receive approved training prior to requesting and using i-STAT analysis and can demonstate competence and attend update session
* Completion of Learnpro modules – including sharps
 | * Work instructions and risk assessments not in palce
* Procedures, Risk assessments & policies not reviewed
* Staff not carrying out procedures as per training /SOP/Risk assessment
* Changes in procedures which are not cascaded to staff
* Analyser used by untrained staff
* Ongoing/review of Competency not assessed
* Staff not carrying out procedures as per training/Work Instruction/Risk assessment
 |
| * Venesection being performed in line with GGC policies will help prevent needle stick incidents
 |  |
| * Appropriate PPE is made available including surgical or FFP3 face mask, apron or gown, gloves, eye protection where appropriate. PPE should be as per patient management. ‘Fit testing’ of FFP3 mask if required
 | * Failure of healthcare staff to to wear appropriate PPE correctly.
* Touching, mouth, eyes or nose with potentially contaminated gloves.
 |
| * All blood spills handled according local departments policy on disposal of clinical waste
* Decontamination of all potentially contaminated surfaces of analyser, screen and barcode scanner with chlorine based disinfectant
* All waste material handled according to the local departments policy on disposal of clinical waste (Category B waste).
* Use of sharps container for disposal of needle to prevent contamination and sharps injury by following GG&C infection control and safe dispoal of sharps policy
* Advise staff not to look into barcode scanner
 | * Failure to report accidents or blood spills
* Ward staff/infection control failing to inform sample of 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 dispose of sharps safely
* Eye damage could occur if laser beam is stared into
 |

**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:** | 19/03/2020 | **Review date:**  | 19/03/2021 |



## Risk Assessment Form

**Appendix 1** – Risk assessment for Routine use of iSTAT

**ID: HSF-CBIO-iStat**

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:**  | Karen Brazier | **Post Held:** | POCT Co-ordinator |
| **Department:** | Clinical Biochemistry | **Date:** | 01/05/2013 |
| Subject of Assessment: E.g.: hazard, task, equipment, location, people |
| Use of Point of Care Testing Ltd i-stat device |
| Hazards (Describe the harmful agent(s) and the adverse consequences they could cause) |
| Patients blood – BiohazardBarcode reader - Laser radiation  |
| 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. |
| Manual application of blood to cartridge, Class 2 laser product. Staff at risk includes ward nursing staff and BMS staff.The amount of time of exposure to each sample is minimal, and all staff must wear full PPE in accordance with their local policy. |

**Existing Precautions**

|  |  |
| --- | --- |
| **Summarise current controls In place**  | **Describe how they might fail to prevent adverse outcomes.** |
| Disposal samples into sharps bin.Clinical waste bin available for contaminated material.Spillages dealt with according to ward procedure.Infection control has also inspected the area. | If procedures are not followed correctly. Do not stare into beam. |

**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**

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** |
| N/A |  |  |  |

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

|  |  |
| --- | --- |
| **Report up management chain for action** | N/A |
| **Report to Estates for action** | N/A |
| **Contact advisers/specialists**  | N/A |
| **Alert your staff to problem, new working practice, interim solutions, etc** | N/A |

##### 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:** | 01/05/2013 | **Review date:**  | 27/06/16 |