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| Department/Location/Project: ED, ONC OP, MAU, Children’s ward, Maternity services | SOP Document Reference Number: **SOP/POCT/69/1** |
| Risk Assessor(s): Nicola Hodges | Highest Risk Rating Identified\*: 12 |
| Date of assessment: 25/02/2021 | Informed QM of any Risk Score >9 (NH, approval by quality manager): |

**\* Any identified risk which has a rating >9 must be communicated with the Quality Manager**

| **Description of risk** | **Existing control/ safe**  **System of work** | **Initial Risk**  **Rating**  **(S X L= RR)** | | | **What further action is required** | **Responsible person**  **and target date for completion** | **Final Risk**  **Rating**  **(S X L= RR)** | | |
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| There is an electrical hazard with a risk of electrocution to the staff using the analyser. | Analysers will be included in the wards PAT testing. Only trained staff should be using the analyser. Water is not to be used on the analyser only dampened tissue or wipes (see SOP). | 1 | 5 | 5 | **N/A** | N/A | 1 | 5 | 5 |
| Sample collection, a patient who fits the criteria for a rapid swab may not be able to give a sample due to mental capacity, health conditions, or refuse.  A risk to the patient and to other hospital patients from infection of COVID by not knowing the COVID status. | Patient would need to be managed clinically, there is only COVID tests available for patients via a swab sample. | 1 | 2 | 2 | N/A | N/A | 1 | 2 | 2 |
| Risk of incorrect results produced, un safe triaging of patients. This will affect staff and patients with a risk of transmitting COVID.  Incorrect results can lead to inappropriate use of hospital resources ie isolation side rooms. | The manufacturer states  sensitivity = 100%(Ct<30)  specificity = 98.38%  PPV = 95.10%  NPV = 96.37%.  We found (n=30) (all ct values):  PPV = 100%  NPV = 73.68%  Sensitivity = 68.75%  Specificity = 100%  Ct<30:  PPV = 100%  NPV = 93.33%  Sensitivity = 91.67%  Specificity = 100%  All positives must be confirmed with laboratory COVID test. | 3 | 4 | 12 | Retrospective validation of all positive results that are repeated in the laboratory. | N. Hodges  To be completed by 25/4/2021 | 2 | 4 | 8 |
| Samples pose a biological hazard to staff collecting and processing the sample for COVID. | The sample must be collected wearing PPE; face masks, eye protection, disposable apron, and gloves must be worn when handling the sample and performing analysis.  Sample is put back into sleeve and sealed in a sample bag once collected to transport to the analyser. The first stage of analysis deactivates the majority of the virus in the sample receiver. Removal of sample receiver does not entirely contained the liquid, so users must wrap glove around used segments when discarding.  Only trained staff should use the ID Now analysers. | 2 | 4 | 8 | N/A | N/A | 2 | 4 | 8 |
| Lack of COVID test kits for the ID Now has a risk of not being able to run a COVID test outside of the laboratory service (22:00 – 07:00)  A risk of an ID Now being out of use due to failure. This will reduce the capacity for Rapid COVID testing out of hours. | Daily review of tests performed is carried out, with a weekly stock count of test kits left to use.  Fortnightly deliveries of test kits to allow 80 a day in ED and 24 a day in ONC OP.  ED have 3 ID Now analysers allowing for one analyser to be out of action with minimal impact. If 2 analysers are out the laboratory will need to process swabs during 9am – 10pm, using the single ID Now outside of these times. | 2 | 3 | 6 | N/A | N/A | 2 | 3 | 6 |
| IT systems handling the results goes down or delay in set up will cause the results to not go into the electronic patient record. Also not report to SGSS but ultimately no electronic record of result to follow patient around the hospital. | Staff can obtain the result directly the ID Now analyser, this can be reprinted and stuck in the patient notes.  Movement of the results from the ID Now analyser to the EPR is live. Interruptions of data movement can be resolved with resending the results from the analyser and or data manager system (checked daily) | 1 | 3 | 3 | N/A | N/A | 1 | 3 | 3 |
| Risk of results not being reported due to an incorrect patient ID being used to run a patient sample.  Patient may need to have a repeat test as the first may be unidentifiable even on the ID Now analyser itself. | POCcelerator will be reviewed by the POCT team on a daily basis (mon-fri) any non-transmitted results will be followed up and corrected to allow the results to move into the EPR.  Over a weekend results could be delayed for over 2 days.  Only trained staff should use the analysers, the SOP states MRN number should be used to identify the patient. | 2 | 3 | 6 | N/A | N/A | 2 | 3 | 6 |
| Positive control not third party and not COVID virus (Flu A&B). No running evidence the analysers can detect COVID in a sample. A risk of reporting false negative results. | This will be resolved with IFU version 2 including a new COVID positive iQC, so a true positive iQC. | 2 | 4 | 8 | Upgrade software to run new positive iQC  Source a suitable external quality assurance scheme for all ID Now analysers | Nicola Hodges end of 2021  Nicola Hodges April 2021 | 1 | 4 | 4 |
| Negative results are not confirmed with laboratory PCR (as recommended in manufacturer manual). A risk of false negatives and thus infectious patients being placed on shared wards which may then require closing for deep clean if patient has subsequent positive COVID result. | Microbiology team are happy that positive results only are repeated. The laboratory does not have capacity to repeat all POCT COVID tests.  All symptomatic patients are simultaneously swabbed for COVID for the ID Now and Cepheid regardless of ID Now result.  All in patients have lab COVID tests at day 2, 3, 5  & 7 of stay.  Clinical presentation must also be considered for patient risk of having COVID.  The manufacturer states  sensitivity = 100%(Ct<30)  specificity = 98.38%  PPV = 95.10%  NPV = 96.37%.  We found (n=30) (all ct values):  PPV = 100%  NPV = 73.68%  Sensitivity = 68.75%  Specificity = 100%  Ct<30:  PPV = 100%  NPV = 93.33%  Sensitivity = 91.67%  Specificity = 100% | 2 | 4 | 8 | Retrospective validation of results that are repeated in the laboratory. To demonstrate the performance of negative results produced. See below:   |  |  |  |  | | --- | --- | --- | --- | | **Comparison data of 122 patients ran on both ID Now and Cephid** | | | | | |  | Lab platforms | |  | | ID Now | Pos | NEG | Total | | POS | 9 | 6 | 15 | | NEG | 0 | 105 | 105 | | Total test run in duplicate | | | 120 | |  |  |  |  | | PPV % | 60.00 |  |  | | NPV % | 100.00 |  |  | | Sensitivity % | 100.00 |  |  | | Specificity % | 94.59 |  |  | | N. Hodges  Completed August 2021 | 2 | 2 | 4 |

**Risk assessment matrix**

**Acceptable Risk**

Risk is tolerable as long as it is well managed and controlled. In addition to identified hazards, all incidents claims and complaints will be risk assessed according to the following process and investigated according to the severity or the consequence and likelihood of (re)occurrence.

**All Risk Assessments within the Trust will identify:**

1. The hazards within the Task/ area being assessed inherent in the work undertaken
2. who and how many people would be affected
3. how often specific events are likely to happen (may be based on frequency of previous occurrence):
4. how severe the effect or consequence would be
5. how controllable the hazards are.

Acceptable risk will be determined using the following traffic light system:

**Severity/consequence**

Given the (in) adequacy of the control measures, how serious the consequences are likely to be for the group, patient or Trust if the risk does occur (using the matrix).

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|  | **Consequence score (severity levels) and examples of descriptors** | | | | |
|  | **1** | **2** | **3** | **4** | **5** |
| **Domains** | **Negligible** | **Minor** | **Moderate** | **Major** | **Catastrophic** |
| **Impact on the safety of patients, staff or public (physical/**  **psychological harm)** | Minimal injury requiring no/minimal intervention or treatment.  No time off work | Minor injury or illness, requiring minor intervention  Requiring time off work for ≤3 days  Increase in length of hospital stay by 1-3 days | Moderate injury requiring professional intervention  Requiring time off work for 4-14 days  Increase in length of hospital stay by 4-15 days  RIDDOR/agency reportable incident  An event which impacts on a small number of patients | Major injury leading to long-term incapacity/ disability  Requiring time off work for >14 days  Increase in length of hospital stay by >15 days  Mismanagement of patient care with long-term effects | Incident leading to death  Multiple permanent injuries or irreversible health effects  An event which impacts on a large number of patients |
| **Quality/complaints/**  **audit** | Peripheral element of treatment or service suboptimal  Informal complaint/inquiry | Overall treatment or service suboptimal  Formal complaint (stage 1)  Local resolution  Single failure to meet internal standards  Minor implications for patient safety if unresolved  Reduced performance rating if unresolved | Treatment or service has significantly reduced effectiveness  Formal complaint (stage 2) complaint  Local resolution (with potential to go to independent review)  Repeated failure to meet internal standards  Major patient safety implications if findings are not acted on | Non-compliance with national standards with significant risk to patients if unresolved  Multiple complaints/ independent review  Low performance rating  Critical report | Totally unacceptable level or quality of treatment/service  Gross failure of patient safety if findings not acted on  Inquest/ombudsman inquiry  Gross failure to meet national standards |
| **Human resources/ organisational development/ staffing/ competence** | Short-term low staffing level that temporarily reduces service quality (< 1 day) | Low staffing level that reduces the service quality | Late delivery of key objective/ service due to lack of staff  Unsafe staffing level or competence (>1 day)  Low staff morale  Poor staff attendance for mandatory/key training | Uncertain delivery of key objective/service due to lack of staff  Unsafe staffing level or competence (>5 days)  Loss of key staff  Very low staff morale  No staff attending mandatory/ key training | Non-delivery of key objective/service due to lack of staff  Ongoing unsafe staffing levels or competence  Loss of several key staff  No staff attending mandatory training /key training on an ongoing basis |
| **Statutory duty/ inspections** | No or minimal impact or breech of guidance/ statutory duty | Breach of statutory legislation  Reduced performance rating if unresolved | Single breech in statutory duty  Challenging external recommendations/ improvement notice | Enforcement action  Multiple breeches in statutory duty  Improvement notices  Low performance rating  Critical report | Multiple breeches in statutory duty  Prosecution  Complete systems change required  Zero performance rating  Severely critical report |
| **Adverse publicity/ reputation** | Rumours  Potential for public concern | Local media coverage –  short-term reduction in public confidence  Elements of public expectation not being met | Local media coverage –  long-term reduction in public confidence | National media coverage with <3 days service well below reasonable public expectation | National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House)  Total loss of public confidence |
| **Business objectives/ projects** | Insignificant cost increase/ schedule slippage | <5 per cent over project budget  Schedule slippage | 5–10 per cent over project budget  Schedule slippage | 10–25 per cent over project budget  Schedule slippage  Key objectives not met | Incident leading >25 per cent over project budget  Schedule slippage  Key objectives not met |
| **Finance including claims** | Small loss Risk of claim remote | Loss of 0.1–0.25 per cent of budget  Claim less than £10,000 | Loss of 0.25–0.5 per cent of budget  Claim(s) between £10,000 and £100,000 | Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget  Claim(s) between £100,000 and £1 million  Purchasers failing to pay on time | Non-delivery of key objective/ Loss of >1 per cent of budget  Failure to meet specification/ slippage  Loss of contract / payment by results  Claim(s) >£1 million |
| **Service/business interruption Environmental impact** | Loss/interruption of >1 hour  Minimal or no impact on the environment | Loss/interruption of >8 hours    Minor impact on environment | Loss/interruption of >1 day  Moderate impact on environment | Loss/interruption of >1 week  Major impact on environment | Permanent loss of service or facility  Catastrophic impact on environment |

**Likelihood**

Given the (in) adequacy of the control measures for each risk, decide how likely the risk is to happen according to the following guide. Scores range from 1 for rare to 5 for very likely.

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| **Score** | **Descriptor** | **Description** |
| **1** | **Rare** | Extremely unlikely to happen/recur – may occur only in exceptional circumstances – has never happened before and don’t think it will happen (again) |
| **2** | **Unlikely** | Unlikely to occur/reoccur but possible. Rarely occurred before, less than once per year. Could happen at some time |
| **3** | **Possible** | May occur/reoccur. But not definitely. Happened before but only occasionally - once or twice a year |
| **4** | **Likely** | Will probably occur/reoccur. Has happened before but not regularly – several times a month. Will occur at some time. |
| **5** | **Very Likely** | Continuous exposure to risk. Has happened before regularly and frequently – is expected to happen in most circumstances. Occurs on a daily basis |

**Risk Score is determined by Severity x Likelihood**

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|  | **Consequence** | | | | |
| **Likelihood** | **1**  **Insignificant** | **2**  **Minor** | **3**  **Moderate** | **4**  **Major** | **5**  **Catastrophic** |
| **5 – Almost certain** | **5** | **10** | **15** | **20** | **25** |
| **4 - Likely** | **4** | **8** | **12** | **16** | **20** |
| **3 – Possible** | **3** | **6** | **9** | **12** | **15** |
| **2 – Unlikely** | **2** | **4** | **6** | **8** | **10** |
| **1 - Rare** | **1** | **2** | **3** | **4** | **5** |

