Explanatory notes

RTI #0740

COVID-19 false positives or false negatives. Eg. Test results which recorded positive which turned out to be negative an vice versa - correspondence, briefing notes etc to the DG.

This brief does not specifically relate to false results, but to an administrative error causing the correct scientific test results to be reported to 2 patients incorrectly. The scientific rigour of the testing was not called into question in this brief. A human error meant that a misalignment of the sample tray resulted in the positive results being attributed to the wrong patients. This administrative error was picked up and corrected, but not before 2 patients had been incorrectly informed that they had tested positive. Both patients were contacted approximately 4 hours after initially being contacted, advised of the administrative error and informed of their corrected negative test results.

All tests in this run were repeated, as is common practise when an error occurs. All test results were confirmed on the re-run.

Hot Issues Brief

Reporting Error for COVID-19 diagnostic testing

25 March 2020

Recommended Response:

- An error occurred in reporting results for a run of patient COVID-19 tests on 21 March 2020, potentially affecting five patients.
- Three patients were initially identified as negative, but subsequently identified as being positive for COVID-19. The patients were not informed of their negative result so would be unaware of the error.
- Two patients were initially reported as positive, but subsequently retested and identified as being negative for COVID-19.
- A third positive (sixth patient) was not released because it was identified as needing to be repeated due to a low-level initial result.

Issue:

- An error occurred in the reporting of results for a run of patient COVID-19 tests resulting in some results needing to be amended.
- All results related to the Metro South Hospital and Health Service (MSHHS).
- All results were corrected and re-run on 22 March 2020.
- Six patients were tested:
  - three patients were initially tested negative
  - two patients were initially tested positive
  - one patient, who was positive but a low-level result, was not reported as it did not meet the criteria for reporting and was repeated, therefore not affecting the patient.
- The two patients who initially tested positive were advised of the incorrect positive result but were subsequently advised of the negative result as soon as possible.
- The notification of the initial and subsequent results was managed by a Metro South Public Health Physician in discussion with the treating clinician.

Background:

- Forensic and Scientific Services is providing diagnostic testing for COVID-19 patients.
- Samples for testing are extracted into a liquid medium and loaded into a 100 well plastic ring using robotics. Each patient sample is loaded into an individual numbered well on the ring.
- The ring is manually placed into a carrier that clips into the machine that performs the analysis. The machine reads the result of each well. This is reported as a number by the software.
- In this incident, when the ring was loaded into the carrier it was misaligned. The machine was reporting each well out of place, that is, what the machine was reporting as well one was in fact well two.
- The scientist loading the ring omitted to identify the alignment and reported the results as shown by the machine. This resulted in the positives identified were out by one place compared with the work list.
- There were three positive patient results on this ring.
- One of the positive results was identified for re-testing prior to reporting as the result was low-level.
- Two of the results were strong positives. These two results were reported at approximately 2100 hours on 21 March 2020. The misaligned ring was identified the following morning (22 March 2020) after the positive samples had been reported.
- Two patients with positive results were notified of their results in error in the morning on 22 March 2020 between 0900 hours and 1030 hours.
- Two patients who were initially identified as negative, were not informed of their positive results until around 1330 hours on 22 March 2020. They had not been notified that they were initially tested as negative.

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Actions to date:

- The Clinical Microbiologist, clinicians, the COVID-19 Incident Management Team and the MSHHS Public Health Unit were notified immediately on discovery of the error, that is, at approximately 1200 hours on 22 March 2020.
- The MSHHS Public Health Unit notified the patients.
- All affected samples were rerun to confirm the correct result. The corrected result has now been reported. All patient results are now correctly reported.
- A clinical incident has been reported in Riskman ID #929993.
- It is not believed that fatigue contributed to this issue. Nonetheless, additional staff have been rostered to ensure that staff fatigue does not contribute to human error.
- Staff have been reminded to ensure that they follow all steps of the procedure and to ensure that rings are correctly aligned on the machines.

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