Message

From: Chris Molloy [chris.molloy@md.catapult.org.uk]
Sent: 29/03/2020 3:13:10 PM
To: HILL, Sue (NHS ENGLAND & NHS IMPROVEMENT - X24) [sue.l.hill@nhs.net]
CC: FOWLER, Aidan (NHS ENGLAND & NHS IMPROVEMENT - T1520) [aidan.fowler1@nhs.net]; Kristen Mcleod [kristen.mcleod@officeforlifesciences.gov.uk]
Subject: Re: Visit yesterday

Thanks Sue,
As we discussed this is helpful. The measures were discussed, accepted and are understood.
We started with a deliberately conservative process to ensure quality and maximise safety. This is in a view to be able to streamline from there, and build confidence for our workforce, who are research scientists rather than seasoned clinical lab operatives.
Sudhanva discussed some very helpful approaches that could significantly increase our throughput, but we need to introduce these gradually with our staff, who are rightly starting with a hyper cautious approach to handling infectious human samples
Many of the optimisation steps are already in the plan but not yet in place - some of the liquid handling optimising steps / instruments will be in use from tomorrow
I shall call Ian later today
Just for clarity we are running controls in every plate. We agreed at the meeting yesterday to increase the number of NEGATIVE controls that we place on each plate. This will reduce patient sample throughput by 10% but for the initial period it is sensible to ensure comfort in the process. When we are at full pace we may be able to use a more manufacturing-style QA approach. We shall also run known -ve controls from the sample-to-the result.

I'll be pleased to discuss the detail of the report and share it with the emerging centres at AP and GLS, who shall visit MK this week

C

On 29 Mar 2020, at 09:58, HILL, Sue (NHS ENGLAND & NHS IMPROVEMENT - X24) <sue.l.hill@nhs.net> wrote:

Hi Both
There are a number of recommendations from yesterday's visit. Detailed report still being complied and will be completed by tomorrow morning
This is the high level feedback

Very manual process at the moment with some risks that need to be urgently mitigated
Automation needs to be put in place urgently for certain parts of the pathway
Systems and processes need to be improved across the whole end to end pathway
Controls within test pathway need to be included in every run
Ongoing validation of samples needs to be looked at in detail - we will be advising
Agreed process for validating changes that are being instituted in SOPs needs to be put in place
Staffing expertise - need more experienced staff (I will put a call out via the IBMS tomorrow for experienced biomedical scientists)

We will be arranging further visits to the facility over the next 10 days and beyond

I am hoping to have a clinical lead in place by tomorrow and have shared the name of a potential operational lead with Chris

Happy to discuss today or tomorrow when report produced

Sue

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Irrelevant & Sensitive

Sent from my iPhone