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FROM: EDWIN POOTS MLA
Minister of Agriculture, Environment and Rural Affairs

DATE: 13 May 2020

TO: MINISTERIAL COLLEAGUES

AFBI TESTING FOR COVID-19

At the Executive meeting on Monday, 11 May, I undertook to look into the current position with regard to Covid-19 testing. I was very disappointed to learn that the testing had not yet begun, particularly given the enthusiasm which the Agri-Food and Biosciences Institute (AFBI) has demonstrated in offering to help. Indeed, my Department has consistently offered to assist in any way that we can, including making available additional PPE, making available the Greenmount Campus for HSC staff, and offering to assist with the epidemiology associated with COVID-19 testing.

Indeed, Minister Swann and I were very pleased to make the announcement that the AFBI laboratories would be used to test up to 1,000 samples per day. I know from speaking with colleagues that AFBI was delighted to be asked to work with the Regional Virus Laboratory (RVL) on testing. AFBI staff were keen to help with the fight against COVID-19 and to work together, with colleagues across Government, Queen's University, Belfast and Ulster University, to support the Health Minister and the Health Trusts. I am sure you will agree that they deserve our thanks for that.

Whilst disappointed that it has taken more time than it should have to reach this point, I intend that go-live COVID-19 testing will commence this week, with parallel testing alongside the RVL. All equipment, processes and a supply of test kits are in place ready to commence this work. This go-live date however remains subject to gaining approval from RVL.

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Having confirmed that we are ready, I think that it is important to address the process which has got us to this point, both because it demonstrates the hard work that has been taken forward, but also because it may help to clarify how the delays to date may have been avoided and to identify lessons to be learned by a number of the key players.

AFBI was keen to start the testing at an earlier stage, but there were a number of technical and systems issues which needed to be resolved with the RVL and Belfast HSC Trust as they set out their requirements. While the AFBI staff and laboratories are well equipped to undertake mass testing for animal health purposes, RVL needed to provide AFBI with their exact requirements in order to develop their processes and workflows. Accepting that this was vital in ensuring that rigorous processes and quality control measures were put in place, more urgency could arguably have been applied by some of those with whom AFBI was working.

A quality assurance timeline is included below, and this sets out the key issues at each stage.

- On 20 April the first QA sample panel from RVL arrived into the AFBI laboratories. This was not an official QA panel from RVL but it did allow AFBI staff to assess their operational workflows and to commence the internal quality and assurance processes. The results from this QA were finally received back from the RVL on 28 April.
- The RVL had planned to run the formal QA sample panel on Thursday, 23 April to enable the start of Go-live testing for end of April, but this was delayed.
- On 22 April, RVL changed the requirement of the processes to include full end to end automation of the testing workflow. Up to that point AFBI was only aware of the requirement from RVL for automation of the first part of the testing process. The new requirements were discussed in AFBI on Thursday, 23 April and action was taken immediately to relocate an additional robotic system from another AFBI laboratory to ensure that the RVL requirements were met. The equipment was moved on Friday, 24 April and was recalibrated and checked in its new location.
- The new robot was incorporated into the testing workflow from Monday, 27 April and the workflows and supporting documentation were redesigned to incorporate this new process. The process validation was repeated again to ensure the robotics were compatible and working within the workflow. This was required for quality and assurance purposes.
- The formal QA 50 sample panel was scheduled by RVL for 6 May, however on 5 May AFBI was informed by RVL that they had operational/IT issues at their end and would therefore only be sending half the panel. A panel of 25 samples was tested and on 8 May, AFBI was informed that RVL were satisfied with the results.
- The second part of the QA panel is due to be received from RVL on Tuesday, 12 May. Dependent on the successful completion of this panel, AFBI is aiming for a target of Go-Live on Thursday, 14 May, subject to approval from RVL.

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- All QA panels tested to date have been successfully passed and AFB/ RVL have not identified any major issues in process or methodology. There is no reason to assume at this stage that the Go-Live target date will not be achieved.

While there is little point focussing on each individual step in the process, it is important to state the obvious point that the approach will only work by a collective team effort. It is also worth stating that AFB has fully played its role throughout this process.

With regard to the Service Level Agreement (SLA), there have been two areas of work which caused the delay:-

Key Performance Indicators (KPIs)

A draft version of SLA dated 23 April, included a Key Performance Indicators (KPI) of 90% of Tests to be reported within 72 hours. This had been seen by RVL and the Trust. AFB was confident that this could be met. On 28 April the draft SLA was returned from the Belfast HSC Trust with an insistence on a 24 hour turnaround time. This was contrary to the 72 hour maximum turnaround time for which AFB had designed workflows and of which RVL were aware. AFB felt a 32-36 hour turnaround could be achievable with some changes to workflows, but a 24 hour or same day reporting (as being intimated by the Trust) of all received samples would not be achievable within the agreed staff work hours. Negotiations continued, requiring intervention by Professor Stuart Elborne (QUB) and an escalation to Expert Advisory Group on testing (EAG) and the KPIs were finally agreed on 4 May with the Trust Manager.

Indemnity Clause

On 22 April RVL raised the issue of DoH approval for indemnity wording within the SLA. This issue was discussed and AFB believed the wording had been resolved and the SLA was going to be signed by the Trust on 1 May. This turned out not to be the case as they raised further issues about the indemnity clause. On 7 May these issues were resolved within the Trust and they sent through the final version of the SLA to AFB for signing late on 7 May. The SLA was signed and sent back by AFB on 7 May.

In conclusion, I think it is important to acknowledge the excellent work which AFB has taken forward, together with colleagues from across the public sector. It is very disappointing for them and for everyone involved that the testing has not proceeded before now. Since the issues to which I have referred above now seem to have been resolved, it will now be important to proceed to live COVID-19 testing which is scheduled.

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I am sure we will want to put on record our gratitude for everyone involved in protecting the health of our people.

Personal Data

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