

From: Alexander Bourne [REDACTED]
Subject: Anitgen Testing Problems/Solutions
Date: 30 June 2020 at 11:56:26 BST
To: [REDACTED] [REDACTED]

s40

Dear Matt,

Thank you for your time on Saturday. I think it is important to clarify that it is the belief of all I have encountered that the policy on testing overall has been very good and achieved great things in a short period of time. The overall feeling is that now the panic is over, we should be able to get into a rhythm that allows for consistent production/processing and redundancy to allow for surge manufacturing and testing in the event of outbreak or the need for larger scale surveillance. I have summarised all of the points that I have picked up from interviewing the following people over the last few days. Their correspondence and supporting documents are attached for reference. Most didn't want to give names but I have described their positions.

[REDACTED], Life Sciences Group – manufacturers of viral transport media, inactivating transport media and funded by Innovate UK to research non-guanidine based inactivating transport media. s40
Alex Bourne, Hinpack Limited- manufacturer of specimen collection tubes in strategic partnership with VWR/Avantor.

[REDACTED] seconded to the DHSC, since moved on. s40
[REDACTED] in the Lighthouse network. s40
[REDACTED] the DHSC in several capacities. s40
[REDACTED] laboratory in Cambridge. s40
[REDACTED]. s40

A total of 8 lighthouse laboratory operators/technicians or logistical staff.

NB: This only concerns antigen testing.

Summary of Points

Purpose of Testing

1. There are two clearly definable roles for testing be it antigen or antibody for that matter:
 1. Clinical diagnosing of patients at point of care and key workers with a high level of exposure to the virus. 'The sniper rifle'- every test must be accurate and results delivered back to donor within a very short time frame 2-24 hours
 2. Mass surveillance in order to determine transmission levels/infection rates in the population/specific groups in order to determine policy and response. 'The Shotgun' – tests to be delivered en masse with a higher acceptable failure/void rate in order to determine large scale patterns.

Whilst these are covered off with the five pillar approach, a number of people find it difficult to operate within a single framework that incorporates lighthouse and individual NHS trust testing. The first group is absolutely immovable in their attitude to clinical testing and rightly so. However, it means that build the large scale mass testing of geographical areas, borders, risk groups etc. as it has led to a significant slowdown in decision making on the technical side. This in turn created a chicken and egg situation whereby the demand is not there to support increased capacity which would effectively 'move the labs along'.

1. There is also a feeling that a great deal of the population who are eligible to be tested don't know that they are and don't know how to go about it, especially in the key

worker groups in the private sector. I have experienced this personally while trying to get essential trades to provide a service or product for us but they refuse on the grounds that testing is impossible, leading to them being unwilling to unfurlough staff and bring them back to work. On 4 occasions I have booked companies staff in for testing myself to break a supply deadlock.

Laboratory Capacity

1. Centralised, large scale factory labs such as the lighthouse network are welcome but additional capacity in smaller laboratories has been underused. A distributed approach is the only way to get large scale testing underway and labs need help from regulators to do it. Additionally, there is to be an organisational problem around the allocation of samples to laboratories whereby consultants simply increase the number of deliveries to labs in order to meet government targets. This can result in significant void rates and makes operational flow and tempo difficult to achieve. There are several companies who have developed a product to solve this problem (sample tracking and allocation) but they have been ignored because they can't get through to the correct team.

Procurement

1. Throughout the pandemic, the procurement chain has been highly problematic and erratic. As manufacturers we are able to advise on how problems can be solved and requirements can be met, however, the procurement chain continue to take the view that it's better to ask what we have physically got rather than the effect they wish to achieve. This has resulted in duplication of effort, enormous frustration, little to no product development/improvement and huge cost to suppliers. I will use my example to illustrate the structural problems and organisational failures that are leading to a shortfall in capacity:

Product: Specimen collection tube for swab samples.

Problem: Existing tubes were not in plentiful enough supply, did not meet laboratory specifications for use and were leaking, which in turn resulted in a huge number of void samples.

Execution: We were contacted through our strategic partner to produce a specimen collection tube. The procurement team were not able to supply a specification nor a sample of the tube they required, so we designed based on a copy of an existing tube in the network. When we managed to get an example from the supplier my designers immediately noticed that the design wasn't fit for purpose as it leaked due to a manufacturing defect in the thread- we passed this information on to procurement who then admitted that they knew this to be the case and for us to crack on with the design anyway. To cut a long story short we were only made aware of technical requirements by way of casual conversations with people in the network and the end design came about by me driving to Alderley Park, inviting myself in and speaking to individuals who were using the tube to discover what they wanted. In the intervening period the procurement team changed our design 9 times which resulted in mistakes during our tool making that has in turn resulted in a 4-5 week delay in production. We were producing drawings within 3-6 hours of being asked for them and making all the necessary arrangements only to have them repeatedly changed. When the final drawing was agreed it took the procurement team 10 days to get approval from the individuals who had told me what they wanted in the first place. This in turn has resulted in significant delays in production.

Solution: Procurement needs to provide a clear specification of the product they require and include the manufacturers in conversation with the end user, be they laboratories, logistics or those administering tests. We have developed several products that cheap, easily scalable, can be

manufactured in the UK and solve a known problem, only for us to never hear a word after submitting them after being requested to.

1. Subject matter experts on the outside of the supply chain are being ignored by consultants in the procurement chain to the detriment of widespread testing rollout. Please see attached email from [REDACTED] outlining [REDACTED] experience (attachments 1a-1f) as well as other docs concerning her expertise. The subsequent knock on effects have been felt in manufacturing where we are unable to develop the products because nobody will make a call on specification. To make matters worse, subject matter experts inside the lighthouse network have been ignored or not consulted on what they need which has caused widespread delays. In my illustration of the tube above, the actual idea of what we adopted as a full process for design and supply was pointed out by a senior scientist from Astra Zeneca. We independently thought of the same thing, however because of the procurement chain's structure and methodology we ended up with a 5 week delay and many costly mistakes. I have attached some minor points from a major distributor, not for you to try and action but to illustrate the lack of information being disseminated amongst the people who can make this happen. s40

These are a few of the major points but I think it would be worth speaking to the new team to flesh out detail. I am available 24/7 and can come up to London if it makes conversations easier.

All the best and look forward to speaking to you soon.

Alex

Attachments

- 1a-1f. Email from [REDACTED] outlining [REDACTED] experience with VTM/ITM/saline. s40
2. Points from large distributor.