TESTING CAPACITY FOR A POTENTIAL SECOND WAVE OF COVID-19

Summary of conclusions

Prior to the covid-19 outbreak, the UK did not have accredited test houses for all the relevant standards for PPE and medical devices, but UK notified bodies had appropriate agreements with other accredited labs overseas (primarily in the EU, USA and China).

At the start of the pandemic, test houses worldwide faced high demands and queues for testing were very long – 3-9 weeks for surgical masks (IIR), 5-7 weeks for gowns, up to 5 weeks for FFP3 respirators. In some cases, countries have requisitioned their testing labs for their own medical devices/PPE.

The report examines UK testing house capacity and the additional arrangements that notified bodies have brought on with trusted laboratories overseas. It finds that:

- Although there was an acute shortage of testing for IIR masks to BS EN 14683, two UK testing houses have set up new facilities and one is planning to open new facilities in early 2021. There are two EU test houses (Eurofins and Kiwa) which have started offering these tests in Germany and Italy. Therefore, the UK is not likely to require further capacity for this standard;
- The UK has low capacity for testing FFP3 respirators to BS EN 149. These respirators were in very short supply in the early summer. The UK only has one accredited test house (and one other which is not accredited), both of which have expanded capacity on the basis of overtime and staff redeployment. This expansion is therefore unlikely to be sustainable long term if demand for testing is expected to remain high. One notified body is intending to expand capacity in China but has not done so yet[1];
- **Wait times internationally for testing surgical gowns to BS EN 13795 are currently very long (3 months to one year).** The two specific tests causing the delays require the ability to handle biological hazards (ISO 22610 and ISO 22612). The UK has no accredited test capacity for these tests and there is very little capacity internationally. A similar issue applies for coveralls. In general, the NHS has a very low demand for coveralls (ambulance service and specialist cleaning only) but there are many consignments of coveralls at Daventry awaiting testing;
- There are no long term standards for isolation gowns; the Essential Technical Specifications set out a pragmatic route for testing under the PPE Regulatory Easement that applies during the covid-19 crisis only[2],[3]. There are plenty of facilities for these tests, and current lead times are a few weeks;
- NHS England has set a target of 80% of isolation gowns to be reusable by the end of 2020. Most reusable gowns are expected to be fit for 50-100 uses and therefore, this target should

[1] Intertek has confirmed that this new facility in China has been audited and expects to receive accreditation by mid October. (Email 08-09-2020).

[2] These tests are liquid penetration (BS EN 13795 A.2.3, based on BS EN ISO 811) and wet and dry tensile strength tests, including tensile strength tests of seams, (A.2.5, based on BS EN 29070-3), or equivalents.

[3] HSE and MHRA have clarified that the tests set out in the Essential Technical Specifications for isolation gowns can also be used for isolation gowns being purchased by individual NHS Trusts under the PPE regulatory easement, (Trust communication document, to be sent out when the revised ETS are published).

reduce the need for testing of isolation gowns[4]. However, it will increase the demand for laundry pre-treatment (ISO 15797) which is required before testing, and which currently takes 5-10 weeks. Therefore, although the re-use of isolation gowns will, in the long run, reduce testing requirements, it may increase lead times for testing in the short term;

- To date there has been no problem with lead times for testing eyewear to BS EN 166 and medical gloves to BS EN 455-1-4, or aprons to BS 2782-6.

In the light of these findings, our recommendations are:

- Procurement teams should concentrate their efforts on purchasing products which have passed the appropriate tests and regulatory approvals. We recommend that DHSC[5] develops a list of trusted suppliers, and stockpiles items with long wait times for testing, particularly surgical gowns and FFP3 respirators[6]. **Given the low fit rate of certain FFP3 respirators[7], we recommend stockpiling those respirators that have been found to have a higher fit-rate**;
- **When purchasing equipment that requires regulatory approval, procurement teams must take into account lead times for testing;**
- If DHSC considers that the long lead times for testing surgical gowns and FFP3s could affect its ability to deliver, then there are a number of ways in which this could be addressed:
  a) by incentivising the market to invest in new facilities for the key tests by providing a guaranteed level of testing;
  b) by providing direct funding, probably as part of an open competition, for new facilities;
  c) by booking testing slots at existing laboratories well in advance and factoring this delay into procurement plans. This approach was suggested by Notified Body Intertek early in the crisis, but has potential risks, as individual Governments have sometimes requisitioned testing capacity for their own country's health systems[8].

  We have spoken to BSI about options a) and b). Their estimate to build facilities specifically for tests ISO 22610 and 22612 (required for surgical gowns) was £750k capital cost and approximately £100k per year. We have examined State Aid Rules, and have concluded that these would allow for direct Government support for testing under section 3.7 – "Investment aid for testing and upscaling infrastructures" of the "EU Commission's Temporary Framework for State Aid", put in place to support EU economies during the period of disruption caused by the coronavirus epidemic[9];
- When purchasing reusable isolation gowns that require testing, procurement teams should take into account the fact that laundry pre-treatment will extend lead times for testing by 5-10 weeks;
- HSE should develop clear, long term standards for isolation gowns that will apply after the end of the PPE Regulatory Easement;

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[4] NHS England has an aspiration to extend this target to surgical gowns in 2021, depending on the success of the isolation gown target and on funding for improved laundry facilities.

[5] And devolved equivalents?

[6] Clearly, stockpiling should be planned in such a way as to minimise the chances of equipment being stored beyond its expiry date.

[7] According to HSE experience and research, a really good FFP3 design might fit around 60% of the staff population. (Source HSE); NHS' typical stock respirators fit around 40% of the population. (Source HSE and NHS E&I).

[8] For example, Spain.

[9] Note that State Aid rules will cease to apply at the end of the transition period on 31/12/2020.

Typical waiting times for tests plus assessment of additional testing capacity added since April[10]:

Item	Test standard	Test times quoted in June	Test times quoted in August	Key test causing delays	Assessment of additional capacity brought online
Surgical masks (IIR)	BS EN 14683	3- 9 weeks	1- 4 weeks[11]	The "splash resistance test" ISO 22609:2004	4WardTesting (UK, operational) 2030 Labs (UK, operational) KIWA (EU, operational) Eurofins (EU, operational). SMTL is planning to bring new facilities online in early 2021.
Disposable Surgical gowns	BS EN 13795	5-7 weeks[12]	3-12 months[13]	The "wet penetration" (ISO 22610), "dry penetration" (ISO 22612) (no UK facilities, subcontracted to the US and China) and microbial cleanliness (ISO 11737-1) (limited UK facilities and often subcontracted abroad).[14]	None for ISO 22610 and 22612. Some additional UK capacity for ISO 11737-1 (SMTL).
Re-usable isolation gowns	ISO 15797 (laundering)		5-10 weeks for laundering[15], 7-	Laundering pre-treatment (ISO 15797).	There are limited laundry facilities in the UK able to offer this service, some are

[10] Note that these delays are delays quoted by our manufacturers, or from estimates that BEIS has requested from specific test houses. They are indicative only, not precise figures.

[11] Conversation with 4WardTesting, 02/09/2020.

[12] SMTL quoted 3-4 weeks for the tests, and a wait time of approximately 3 weeks (wait time given on the phone, 3-4 weeks for tests themselves in email dated 29-05-2020). Intertek estimated 25-30 days (5-6 weeks, assuming this means working days) (email to Lisa Coppola, 18-06-2020)

[13] Information from BTTG, 17-08-2020

[14] See footnote 2. SMTL subcontracts to the wet penetration test to Nelson Labs in the US, Intertek subcontracts to a Chinese lab.

[15] BTTG quote dated 18-06-2020