From the Permanent Secretary and Chief Executive of UKHSA
Sir Chris Wormald and Dr Jenny Harries

Department of Health & Social Care

UK Health Security Agency

Rt Hon Meg Hillier MP
Chair of Public Accounts Committee
House of Commons
London
SW1A 9NA

39 Victoria Street
London
SW1H 0EU
Permanent.secretary@dhsc.gov.uk
CEX.UKHSA@dhsc.gov.uk

Sent via email to: pubaccom@parliament.uk

22 July 2021

Dear Chair,

Re: Public Accounts Committee, Forty-Seventh Report of Session 2019-21, COVID-19: Test, Track and Trace (Part 1)

I am writing to provide the Committee with an update from the Department of Health and Social Care and NHS Test and Trace on progress against the outstanding recommendation 4 in the above-named report.

4) PAC recommendation*: The Department and NHST&T should set out clearly how and why mass rapid testing should be used in each of the settings where roll-out is planned, alongside clear targets and updates on progress in the various sectors. Any plans should take account of the approved purpose and accuracy of rapid tests, and how to manage the risks associated with false assurances the tests may provide. If LFD testing is not suitable in some circumstances, NHST&T should urgently bring forward other plans for identifying more asymptomatic carriers of COVID-19.*

I want to highlight to the Committee the work that has been undertaken so far and what we are doing to meet the requirements of the Committee's recommendation.

How and why mass rapid testing should be used in each setting and update on progress

Alongside the successful rollout of the COVID-19 vaccine, mass asymptomatic testing remains integral to the government's approach to combating the virus. This is because not all people who are offered the vaccine will take it up (including most children, for whom the vaccine is not yet authorised). Around one in three individuals with COVID-19 do not have symptoms but may still infect others, therefore, asymptomatic testing remains key to:

- Finding positive cases and breaking the chains of transmission;

- Supporting the safe reopening of society and accelerating the socioeconomic recovery by providing confidence in returning to school or work settings; and
- Building resilience for the future through the normalisation of preventive behaviours.

Asymptomatic testing was initially targeted at vulnerable individuals (for example, care home residents) or where infection levels were likely to be higher. This plan was set out in November 2020 and published on GOV.UK in the Winter Plan.[1] Page 17 provides the table to show the initial expansion of rapid testing workstreams which was delivered. The rationale for large scale rollout followed the testing pilot in Liverpool in November 2020, where 25% of 498,000 residents (around 125,000) took up lateral flow tests and 897 of these individuals tested positive for infection.

In December 2020, DHSC launched the Community Testing Programme. The programme provided English local authorities with funding and practical support, to deliver asymptomatic testing, tailored to the needs of their population. In recent months the role and priorities of Community Testing have evolved to support the removal of national restrictions, whilst the risk of transmission remains. The programme targets groups of people who are disproportionately impacted (i.e. at greater risk of infection, severe illness, transmission to others) and those who are under-served or under-represented (i.e. less likely to engage with the national testing offer). We also work with Directors of Public Health to target surge testing, ensuring that local stakeholder views are part of the decision making process; that Chief Executives are able to raise any concerns and share learning with a wider group of their peers; and data on viral transmission is shared to inform local outbreak planning. This ensures that teams across the country can respond quickly and effectively, whilst working in partnership with national government. On the 22 February, the roadmap was published[2] and set out plans on asymptomatic testing in more detail, including a table detailing the various channels deploying LFDs.

The population of England is now eligible for free, twice-weekly asymptomatic testing, accessed through their place of work, school or university, via GOV.uk or local pharmacy. The rollout of asymptomatic testing across these cohorts has been underpinned by public health advice and co-ordinated with lead policy Departments, where appropriate. For example, we have worked very closely with the Department for Education to roll out asymptomatic testing across all educational settings. A summary of each of the different channels and the rationale for the use of testing is below:

Use case	**Rationale**	**Latest published figures for number of positive LFD test results (up to and including 26 May 2021)**
Adult Social Care / Care Homes	Social care is focused on supporting some of those most vulnerable to COVID infection, many of whom will present with asymptomatic disease or nonspecific symptomology. There is a high risk of viral ingress into care homes through staff who represent community transmission rates and a high risk of serious illness and/or death in frail and elderly residents. Staff and residents/recipients of care are protected through rapid and/or early identification of infection.	23,898
NHS	Workers are in persistent close contact with a constantly changing number of potentially infectious people. Extending testing to those without symptoms will help protect them, the people they care for and those around them.	50,496

[1] COVID-19 Winter Plan - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/937529/COVID-19_Winter_Plan.pdf
[2] COVID-19 Response - Spring 2021 - https://www.gov.uk/government/publications/covid-19-response-spring-2021/covid-19-response-spring-2021

Higher Education	Help find positive cases and reduce the chains of transmission associated with those attending education settings and therefore maintain educational access.	3,915
Community Testing	To find and isolate positive cases within the community to support breaking the chains of transmission and reduce prevalence of the disease	60,437
Nurseries, primary schools, secondary schools and colleges	Help find positive cases and reduce the chains of transmission in education settings. To support the return of students into educational settings and to maintain access to education	49,197
Private sector employers	Support the return to work, for those who cannot work from home and to help keep businesses open	2,815
Public Sector employers	Support the return to work, for those who cannot work from home and to help keep organisations open to help keep the country open and support the roadmap	1,108
Universal Offer	Expanded eligibility requirements from April to enable anyone to access twice weekly testing utilises pharmacies and gov.uk as additional channels to help break the chains of transmission in rising prevalence	*Results received can be reported under any other use case via the self-report digital journey, therefore, we cannot report figures under this use case.*

Plans should take account of the approved purpose and accuracy of rapid tests, including how to manage the risks associated with false assurances the tests may provide

The approach adopted reflects the approved purpose of rapid testing, which has been authorised by the independent Medicines and Devices Regulatory Agency and is for use in large sections of the population to detect infection in asymptomatic individuals. Specifically:

> *A self-test device can be used by a member of the public with no previous experience of testing, in their own home or another community setting such as a place of work. The self-test device should be straightforward to use and give results which are easy to understand. The instructions for use provided with the self-test device must be easy to follow and be available in a range of languages and formats.*[3]

NHS Test and Trace regularly publishes detailed updated information on the accuracy of asymptomatic testing, the latest of which was which was published on 07 July 2021.[4] The evidence is robust and the MHRA has recently granted an extension to its authorisation based satisfactory review of action taken by the US Food and Drug Administration (FDA) who had issued a warning about LFDs manufactured by Innova Medical Group Inc in the United States. The MHRA conducted a risk assessment and decided that no further action was necessary.[5]

Alongside this, NHS Test and Trace actively monitors and manages various different risks which may occur with rapid point of care testing for SARS-CoV-2:

[3] MHRA issues exceptional use authorisation for NHS Test and Trace COVID-19 Self-Test device - https://www.gov.uk/government/news/mhra-issues-exceptional-use-authorisation-for-nhs-test-and-trace-covid-19-self-test-device

[4] Asymptomatic testing for SARS-CoV-2 using antigen-detecting lateral flow devices: evidence from performance data October 2020 – May 2021 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/999866/asymptomatic-testing-for-SARS-CoV-2-using-antigen-detecting-lateral-flow-devices-evidence-from-performance-data-Oct-2020-to-May-2021.pdf

[5] Following a satisfactory review, MHRA extends authorisation of NHS Test and Trace lateral flow devices - https://www.gov.uk/government/news/following-a-satisfactory-review-mhra-extends-authorisation-of-nhs-test-and-trace-lateral-flow-devices

- The risk of false positive results from an LFD test is reduced by the need to use a PCR test to confirm the result. This is kept under constant public health review as the overall prevalence of COVID-19 changes.
- We mitigate the risk of false negatives by advising an individual with a negative result that it is no guarantee that they do not have COVID-19 and they should continue to take the appropriate protections and cautions. We also use specialised testing regimes (e.g. in case of an outbreak in a care home, all staff must undertake seven days of LFD testing, even if they are not a contact) to further mitigate the risks in vulnerable settings.

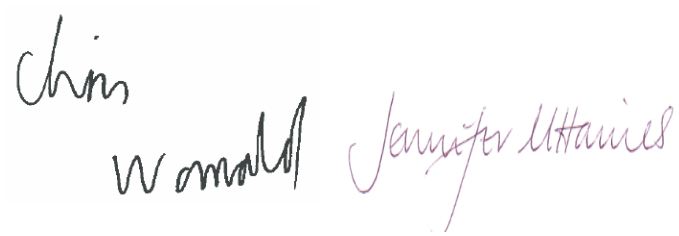
In addition, detailed post marketing assessment is carried out to ensure appropriate accuracy of tests against new variants.[6] We are aware that in some circumstances some people may find LFD tests more difficult to use than others e.g. SEND children find it harder to use for a variety of reasons. Where individuals have challenges using LFD testing, we identify what support can be provided to help them with this. For example, school children were asked to perform supervised testing on return to schools and support was provided to show them how to perform the test most effectively. We also provide similar support in residential care homes, where staff are able to assist visitors, this is particularly meaningful where the visitors may themselves be older or have particular needs, which may mean they would struggle to test themselves at home.

We continually look for ways to improve our offer and we are currently exploring saliva-based LAMP testing to support groups who struggle with swab-based testing. We are also conducting surveys on the behavioural response of individuals to LFD testing, to inform our approach in the months ahead.

Following the announcement on 5 July, the government lifted the remaining COVID restrictions on the 19 July. LFDs will continue to provide the government and the NHS with a way of finding positive cases that can help break chains of transmission in asymptomatic people. We are currently piloting the use of LFDs for events through our Events Research Programme (ERP),[7] and this may be an option for rollout in the event of a further wave of infections, to help keep society open.

The plan for the continued usage of mass rapid testing will be kept under review.

Yours sincerely,



Sir Chris Wormald and Dr Jenny Harries OBE

Department of Health and Social Care
UK Health Security Agency

[6] Technical report: In vitro and clinical post-market surveillance of Biotime SARS-CoV-2 Lateral Flow Antigen Device in detecting the SARS-CoV-2 Delta variant (B.1.617.2) - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/999867/in-vitro-and-clinical-post-market-surveillance-of-Biotime-SARS-CoV-2-Lateral-Flow-Antigen-Device-in-detecting-the-SARS-CoV-2-Delta-variant-B.1.617.2.pdf

[7] Events Research Programme: Phase I findings - https://www.gov.uk/government/publications/events-research-programme-phase-i-findings