



Department
of Health &
Social Care



UK Health
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13 June 2022

By email: pubaccom@parliament.gov.uk

Dame Meg Hillier MP
Chair, Committee of Public Accounts
House of Commons
London SW1A 0AA

Dear Chair,

RE: Public Accounts Committee, Government's contracts with Randox Laboratories Ltd

We undertook to write in response to queries raised at the above hearing which took place on 18th May 2022.

Randox's Annual Accounts

The Committee asked us to confirm whether we asked Randox to see their unpublished accounts either before or during the NAO Inquiry. We can confirm that we did not.

As part of our pre-contract due diligence, we use information from Companies House and Dun and Bradstreet to facilitate assessment of a prospective supplier's ability to deliver the contracted services. During the contracting process we work with suppliers to agree a contract and pricing structure that delivers best value for the taxpayer. The cost of PCR testing services provided by Randox was very significantly reduced in the October 2020 variation to their contract, reflecting

efficiencies made both by the supplier and NHS Test and Trace as part of normal commercial procedure.

Payments to Randox

The Committee asked us to provide further details on payments made to Randox. We can confirm that the Department did provide detailed information about payments to Randox when requested to by NAO, although this was not presented in the form of a monthly schedule. Information about payments was set out in two bundles of evidence containing the Purchase Orders from March 2020 onwards and we have attached to this note an Excel document which shows the BACs payment date for each invoice paid, or credit note netted off against payment.

A summary of payments by month (£) is as follows:

2020	247,603,476
Mar	55,000,000
Jul	21,409,707
Sep	45,800,964
Oct	26,655,056
Nov	98,737,749
2021	241,243,423
Jan	48,475,647
Feb	85,497,578
Mar	26,226,175
Apr	13,551,574
May	5,259,014
Jun	29,817,023
Jul	11,144,092
Aug	21,272,319
Total	488,846,898

Recall of Swabs

The Committee asked us to provide more details on the recall of the swabs from Randox and whether that undermined the government's pledge to test everyone in care homes in the summer of 2020.

I (Jenny Harries) have reviewed the *PHE Risk Assessment on the use of non-sterile Randox swabs for SARS-CoV2 testing dated 09 September 2020*.

Background

In order to ensure Randox was integrated into the wider laboratory testing network, which would allow other laboratories to process Randox test where there were

capacity constraints, we initiated a process to bring the test sample collection kits within the overall testing procurement process. This work highlighted that some of Randox's tests did not have all appropriate documentation.

On 15 July 2020, an announcement was made by the government to care homes that they should stop using Randox tests after concerns were raised that the tests did not meet required safety standards. All care homes were contacted to arrange replacement testing kits from other stock within the testing programme in the short term. Randox sourced new swabs and provided replacement testing kits at their own expense. This was followed by a recall of 740,000 Randox test kits on 12 August 2020.

A specific recall process was stood up with a dedicated booking portal and free return labels to ensure no costs were passed on to care homes.

Risks to health from using the Swabs

Between 10-13 July 2020 swabs were tested and the results showed the presence of multiple species of microbe on substantial proportion of the swabs. These microbes included strains of *Bacillus*, *Staphylococcus* and *Trichosporon*.

On 23 July 2020 tests were carried out on 304 swabs, this involved a 14-day incubation period.

On 5 August 2020 PHE advised that while the testing gave an indication of bacterial contamination, additional testing in the PHE Food Water and Environment microbiology laboratory would be required to confirm the actual risk of transfer to a patient. The tests carried out included a dry swab which simulates being rubbed onto a mucosal surface (nose or throat).

On 24 August 2020 the results of the further tests indicated that there was a very low level of transfer of organisms from the Randox swab. There was no indication of any significant onward clinical transfer of organisms to individuals observed in either the laboratory testing outcomes or in the surveillance data from care homes. The risk to safety was low.

Impact on testing in care homes

As noted above, on 15 July 2020, advice was put to care homes to stop using Randox kits and alternative provision was put in place. There was a short period of time during which alternative sample test kits were made available to care homes.

There is no evidence of an overall reduction in the number of tests taken (or rate of positivity) in the week after 15 July 2020, compared to the week prior. Published data showed that over the full course of the month there was a significant increase in the total number of tests taken by care home staff.

Link to published data

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1050644/Tests_conducted_2022_01_27_1 ods

Ramp down of Randox contracts

The Committee asked for more information about how performance was managed during the ramp down of Randox contracts. The remaining Covid testing contract with Randox Laboratories, awarded under the National Microbiology Framework, expired on 31st March 2022. We have agreed a run-off period to end on 20th June. During this time, Randox will continue to test samples received from UKHSA up to the contracted capacity and use “all reasonable endeavours” to undertake tests in excess of that volume. UKHSA has committed to ordering a minimum number of tests during the run-off period and to pay the agreed contract price.

A number of performance indicators have been agreed between UKHSA and Randox for additional services. These indicators include the turnaround times to be achieved by Randox. UKHSA will pay Randox a weekly amount for each week Randox carries out reflex assay testing and provides the positive samples for sequencing. This amount includes labour, equipment, overhead and consumables.

UKHSA’s last contract with Qnostics, a subsidiary of Randox, to supply positive controls for laboratory tests also came to an end on 31st March 2022 and stock purchased under this contract is supporting ongoing operations.

Record Keeping

As mentioned during the hearing, despite being unable to locate notes of some key meetings, we are nonetheless able to understand the content of the meeting from the supporting documents that we do hold (such as email chains indicating a meeting was organised, agendas or other meeting papers). These documents, when read together, give an indication of what the meeting was about and what was discussed.

Due to the time that has lapsed since these meetings were held and the significant staff turnover of the Department throughout the pandemic, we do not think it would help with the creation of an accurate record to ask officials, Randox or Owen Paterson for a verbal retrospective account of these meetings. The Department does not, therefore, intend to make such enquiries.

I would however like to notify the committee that the Department has now identified that it does hold a note of a meeting on 07 August 2020. This note was identified subsequent to both the recent Humble Address and NAO investigation into the Department’s contracts with Randox. It is also being released in response to a Parliamentary Question and I attach it for information at Annex A.

We recognise that at times, due to the incredible pace of work tackling the biggest public health emergency in living memory, the recording of minutes from some

meetings did not happen or did not meet the high standards of the Department. We will do our utmost to ensure this does not happen again. We have already enhanced our quality assurance process and reviewed and refreshed other processes and procedures.

Finally, in order to provide clarity on questions relating to the search of Baroness Harding's inbox, I would like to reiterate that Baroness Harding fully cooperated with the Department throughout. Baroness Harding gave permission for her inbox to be searched and she was not involved in any way in the Department's work to respond to the report.

We hope the Committee finds the information set out in this letter helpful.

Yours sincerely,



Shona Dunn
Second Permanent Secretary
Department of Health and Social Care



Dame Dr Jenny Harries OBE
Chief Executive
UK Health Security Agency

Annex A

From: PsBethell < >
Sent: 07 August 2020 20:14
To: @akesoco.com>; @genomicsengland.co.uk>; @dhsc.gov.uk>;
@officeforlifesciences.gov.uk>;
@dhsc.gov.uk>; @dhsc.gov.uk>
Cc: @dhsc.gov.uk>
Subject: READOUT: Peter Fitzgerald discussion

Hi all,

Please see below for a brief readout of the call with Radox earlier – ,
many thanks for joining, your knowledge of the history was v appreciated.

Attendees: Peter Fitzgerald, Mark Campbell, , Lord Bethell, .

- Peter Fitzgerald accepts that Radox don't have the right certification, but along with reputational damage to Radox, wanted to highlight the potential wider consequences on the wider testing programme;
- PF asked whether we're evaluating the sterility of other swabs across the testing programme. explained that MHRA don't require us to test the sterility of swabs if they have a CE mark, however we are undertaking a wider systematic set of tests across the piste to confirm that it complies with the high standard of safety that we set our tests;
- Lord Bethell set out that the reason that we're initiating a recall is due to the lack of CE certification and that we are not yet able to comment on the issue around sterility of the swabs given that evaluation is not yet complete;
- PF asked what the results of the testing of the Radox swabs were. confirmed that they weren't able to readout after 7 days, but there was probable cause to keep assessing the sterility of the swabs. Lord Bethell was clear that we are not pre-empting the sterility tests on this phone call, however final results are expected next week;
- Mark Campbell asked how we will communicate the results of any report about the sterility of the swabs. Lord Bethell was unclear on the comms plan, but confirmed that final results will be communicated in the spirit of partnership and we're keen to continue the very good relationship that we have with Radox. **Action – , grateful if you could contact Radox to set out our plans for publication (or not) when we receive the final sterility report and how we're going to ensure that Radox are kept in the loop;**
- The issue of comms was raised again, Lord Bethell confirmed that any comms coming out from the Department around the recall will be focussed on the regulatory issue.

Best,

| Senior Private Secretary | T: | M:

-----Original Appointment-----

From: On Behalf Of DHLordsDiary

Sent: 07 August 2020 16:09

To: DHLordsDiary; ; ;Lord
Bethell; , (Office for Life Sciences); ;James
Bethell

Cc:

Subject: Pre-meet ahead of Peter Fitzgerald discussion

When: 07 August 2020 16:20-16:30 (UTC+00:00) Dublin, Edinburgh, Lisbon, London.

Where: Microsoft Teams Meeting

Join Microsoft Teams Meeting

+44 20 3443 8728 United Kingdom, London (Toll)

Conference ID: 598 598 642#

Local numbers | Reset PIN | Learn more about Teams | Meeting options
