

Return to an Address of the Honourable the House of Commons dated 17 November 2021 for specified minutes, notes, and correspondence relating to Government contracts awarded to Randox Laboratories Ltd.



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## HUMBLE ADDRESS: RANDOX COVID CONTRACTS

That an Humble Address be presented to Her Majesty, that she will be graciously pleased to give directions that there be laid before this House the minutes from or any notes of the meeting of April 9 2020 between Lord Bethell, Owen Paterson and Randox representatives, and all correspondence, including submissions and electronic communications, addressed or copied to, or written by or on behalf of, any or all of the following:

- (a) a Minister or former Minister of the Crown,
- (b) a Special Adviser of such a Minister or former Minister, or
- (c) a Member or former Member of this House

## **HUMBLE ADDRESS RESPONSE – PART 1**

Documents that meet the following request:

"The minutes from or any notes of the meeting of 9 April 2020 between Lord Bethell, Owen Paterson and Randox representatives."

Ref	Date	Description	Page
1	08 April 2020	Testing Task force read out	5
2	09 April 2020	Call with Randox	6
3	09 April 2020	Briefing slides provided to Ministers in advance of the meeting	7
4	09 April 2020	Private Office note confirming meeting of 9 April	10
5	09 April 2020	Bullet point briefing provided to Ministers prior to meeting	11
6	09 April 2020	Note of thanks from Ministers showing attendees of meeting	12
7	26 Nov 2020	Draft note taken at 09 April meeting	13

## HUMBLE ADDRESS RESPONSE – PART 2

Documents that meet the following request:

"All correspondence, including submissions and electronic communications, addressed or copied to, or written by or on behalf of, any or all of the following:

- (a) a Minister or former Minister of the Crown,
- (b) a Special Adviser of such a Minister or former Minister, or
- (c) a Member or former Member of this House

The documents have been separated into three groups:

#### Documents relating to the letting of the first contract

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8	26 Jan 2020	Direct communications discussing contacting Randox (WhatsApp)	15
9	27 Jan 2020	Communications between Ministers, Randox, and Chief Medical Officer in advance of contract	16
10	30 Jan 2020	Commission for advice on tests for Coronavirus and sharing of Randox contact details	18
11	18 Feb 2020	Direct communications (WhatsApp)	21
12	25 Feb 2020	Direct communications (WhatsApp)	22
13	25 Feb 2020	Direct communications (WhatsApp)	23
14	27 Feb 2020	Direct communications (WhatsApp)	24
15	Undated (on or after 27 Feb 2020)	Direct communications from Minister on Randox engagement with PHE (SMS)	25

16	1 Mar 2020	Notes from PHE on the four hour test	26
17	24 Mar 2020	Advice to Ministers on the Randox contract and authority to proceed	27
18	27 Mar 2020	Comment to Ministers on risks to Randox scaling up	30
19	1 May 2020	Note from Ministers to Randox after contract let	31

## Documents relating to the contract extension

Ref	Date	Description	Page
20	18 Sep 2020	Note from officials to Ministers on potential need to expedite Randox contract extension	32
21	19 Sep 2020	Note from officials to Ministers on performance of contract	34
22	23 Sep 2020	Note from Ministers on commercial sensitivities around Randox extension	36
23	24 Sep 2020	Submission to Cabinet Office Ministers seeking agreement to Randox contract extension. Responses providing authority with conditions.	37

## Documents relating to the Management of the Contracts

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24	01 Apr 2020	Exchange on whether Randox can make use of Northern Ireland university extraction machines	46
25	03 Apr 2020	Email showing Ministers intention to hold call including Randox	48
26	10 Apr 2020	DHSC and Cabinet Office ministerial exchange on questions relating to testing	49
27	06 May 2020	Advice to Ministers on National Testing Programme: Randox voids and capacity constraints.	50
28	12 May 2020	Email discussing 6 May submission to inform Ministers of difficulties with Randox contract,	56

and ministerial response and follow up actions

29	13 May 2020	Briefing slides to support call between Ministers and Randox	61
30	15 Jul 2020	Advice to Ministers on Randox swab sampling	67
31	16 Jul 2020	Draft note of meeting with Prime Minister on Randox safety issues	72
32	07 Aug 2020	Letter from Randox to Ministers on safety issue	74
33	17 Sep 2020	Direct communications (WhatsApp)	78
34	22 Oct 2020	Direct communications (WhatsApp)	79
35	24 Oct 2020	Direct communications (WhatsApp)	80

From: PsBethell <		>	
Sent: 08 April 2020 20:58			
To:		@dhsc.gov.uk>; psm	natthancock
<	>;		@dhsc.gov.uk>;
PsBethell <	>		
Cc:		@dhsc.gov.uk>	
Subject: RE: Testing taskforc	e reado	ut	

All,

Some additions to the readout in green below but agree a bit tricky to follow at times!

To note I'm on a shift pattern with so am acting as LB's office - have come back separately on the Friday/Monday issue and agenda.

Actions and decisions from today's testing taskforce meeting:

Peter Fitzgerald (CEO, Randox) mentioned an issue with getting RNA extraction kits and similarly asked that this issue be unblocked at Ministerial level [was there something here about options for going straight to NHS central procurement or straight to priority hospitals? But need central decision really. Sounded an important decision]

## [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

Hope useful,

From: PsBethell Sent: 08 April 2020 17:17 To: Subject:

@nhs.net> and call with Randox

Hi

,

Lord B has a couple of questions on the back of the Testing Taskforce meeting.

• We've put in a meeting with Peter Fitzgerald, CEO of Randox, later today (on the back of his comments in the call on having trouble getting hold of RNA extraction kits). It would be helpful to have you on the call if possible – just to go through what we're doing at the moment. Think you've been added to the invite for 7pm (or will be shortly).

•

Thanks!

E:

From: PsBethell Sent: 09 April 2020 08:08 To: Lord Bethell Subject: Slide for Workstream 2 stocktake at 9.30

Dear James,

Please see attached the slides for the testing workstream 2 call at 9.30am

Best,

## Private Secretary to Lord Bethell

T: M:

Lord Bethell – COVID-19 Testing Workstream 2 Update

09/04/2020

## Agenda

- 1.
- 2.
- 3.
- 4. Randox equipment issues
- 5.

## Randox

Objective of Activity	Production, delivery, analysis and results transmission of COVID-19 tests over a 12 week period	
Summary of Activity (to date)	Key work streams have been focussed on logistics, supply chain and digital:	
	<ul> <li>Logistics- supporting Randox in the delivery of test kits to testing centres (location, volumes, returns), Forecasting of future demand and supply (across multiple test centres), analysis of test results to identify lessons learnt (e.g. reasons for void tests)</li> </ul>	
	<ul> <li>Supply Chain- Supporting Randox with supply chain management including sourcing of materials, unblocking issues, forecasting demand</li> </ul>	
	<ul> <li>Digital- Working with Randox and NHSX to set up customer portal for registration of testing kits and results. Supporting setting up of contact support centre for individual queries.</li> </ul>	
Planned Activity (next seven days)	<ul> <li>Identification and requisitioning of equipment to support ramp plan</li> </ul>	
	<ul> <li>Forecasting of future demand and supply (across multiple test centres)</li> </ul>	
	<ul> <li>Development of reporting capabilities and governance</li> </ul>	

Progress on Key Deliverables		
Deliverable 1	From Monday 13 <sup>th</sup> April Randox will have test capacity of tests per day. Increasing this number is dependant on sourcing additional lab capacity (see risks/issues). If all equipment can be sourced lab capacity will increase to tests per day.	

#### Key Risks / Issues

- 1. **Equipment-** Randox current lab capacity is capped at tests per days. In order to support the increase we have been working with Randox, Office for Life Science and Number 10 on a process of requisitioning this equipment. Immediate and urgent need to identify and requisition 20 extraction systems to support ramp plan otherwise lab capacity capped at tests per day
- 2. **Materials-** Current Global supply shortage of testing swabs and reagent chemicals (essential for testing). Delays in delivery of key products will impact on delivery of ramp plan and number of tests carried out.

## Upcoming Key Decisions for Ministers / DHSC:

1. Support in requisitioning key equipment (e.g. extraction systems)

From: PsBethell Sent: 09 April 2020 10:36		
То:	@deloitte.co.uk>;	
	②officeforlifesciences.gov.ι fesciences.gov.uk>; >	@deloitte.co.uk>; ık>;
-		
Brill, thanks .		
or would you als	so like to join?	
Private Secretary to Lord Be	ethell	
T: M:		
	<pre>@officeforlifesciences.gov.u fesciences.gov.uk&gt;;</pre>	leloitte.co.uk> ık>;
Dear -		
Our colleague CEO of Randox today	would be delighted to jo	oin Lord Bethell's call w the

Best

Ref 4

From: @officeforlifesciences.gov.uk> Sent: 09 April 2020 12:50 To: PsBethell < > Cc: @deloitte.co.uk>; @officeforlifesciences.gov.uk>; @deloitte.co.uk>

Subject: Quick bullets on Randox

In advance of the call with Randox this afternoon, this is the current state of play. Will let you know what updates we get if any

- Our contract with Randox includes an agreement that we will help them source equipment if they are short or struggling to get it
- They need a range of equipment, and SoS will send a letter to universities asking for loans of the various things we need (letter currently with Private Office, we want it to go today)
- The most **urgent right now is five extraction systems.** has called today to try and get them loaned. Looks like we have two secured, and he is confident we can get the remaining three
- No10 will do a university call round to Vice Chancellors following the letter being sent

,

12

From: Lord Bethell <

Sent: 09 April 2020 16:18 To: paterson@ >; @dhsc.gov.uk>; @dhsc.gov.uk>; @Randox.com>; @dhsc.gov.uk>; @deloitte.co.uk>; @gmail.com>; @officeforlifesciences.gov.uk> Subject: RE: (HS) Phone call Lord Bethell/ Owen Paterson MP/ Dr. Peter FitzGerald (Founder and Managing Director of Randox) to discuss testing **Dear Friends** Many thanks for a terrific call. And good luck with the machines. Emails for future use are above. With thanks Bethell.

>

Lord Bethell House of Lords and Department of Health and Social Care Minister for Innovation T: @jimbethell

@nhs.net>;

From: Sent: 26 November 2020 12:23 To: Subject:

@dhsc.gov.uk>

@dhsc.gov.uk>

## Hi

Here are my notes from this time – v logistics-y:

Sunday issue sorted

Current issue – don't have enough extraction systems. Have ordered extraction systems but concerned about when they will arrive. Was hoping yourselves, gov could help us access extraction systems from universities, hospitals anywhere. Up to

tests next week and following week – few systems coming in. Nervous about having sufficient systems. Issue in a nutshell.

- could you describe in a bit more detail? Everyone struggling with RNA extraction. What platforms? Expecting delivery but didn't arrive?

Trying to develop our own extraction system but whether we can, not sure.

. Problems you're running into same as NHS and PHE labs.

on order won't come in next 4 weeks, can't get . Just off call from as they were saying don't put your hopes on

- can confirm army on way to Glasgow to pick up

and hoping to get those by Saturday with rest of heavy equipment. Latest – been promised other will be forthcoming today so we can complete that lab, get reagents ordered and consumables.

- that might get us to the

If managed to track down these machines in labs, do we have a list of these labs dong non-urgent work that we can re-requisition? — list of universities initially contacted, will be following up over next few days. In terms of powers, not a road we particularly want to be going down – appeal to national effort. Any feel for how many machines there are still out there? — no. ? Good line of sight to those, know if we have to, we can purchase some of the other equipment but Achilles heel is extraction systems. in Glasgow, another tranche of we need to get our hands on. Looking to get these from private sector as of this morning. Call to arms for machines? Very much in hands – letter drafted and in chain to get approved. Thanks,



E:

@dhsc.gov.uk

@Native Messages"> 26/1/2020, 21:23 Owen Paterson MP <" Thanks call.Peter FitzGerald's email : @randox.com If you can get 10 positive sputum samples ,they will take 2-3 weeks to develop a diagnostic test giving results for coronavirus within 2/3 hours based on raw sputum samples. Matt Hancock 26/1/2020. 21:27 Thanks Owen. I will look into it Owen Paterson MP <" @Native Messages"> 26/1/2020, 21:29 Thanks.Have told him to expect an email from you.Ring anytime if you want to discuss. Matt Hancock 2/2/2020. 16:06 Hi Owen do you have 's mobile? Owen Paterson MP <" @Native Messages"> 2/2/2020, 16:16 Any luck getting the ten sputum samples to Randox? Owen Paterson MP <" @Native Messages"> 5/2/2020, 13:37 Peter will apply for the NIHR projects but there is no mention of samples in the application.Can you get him some positive samples in parallel as they already have a respiratory multiplex assay which just needs some samples to be validated for the new virus?Discuss 1600 in vote. 5/2/2020, 13:56 Matt Hancock We only have two samples. We are seeking others from other cases abroad **Owen** @Native Messages"> 5/2/2020, 13:57 Can Peter Paterson MP <" have those so he can get started immediately? Matt Hancock > 5/2/2020, 15:47 PHE will be in touch with him directly

From: Matt Hancock Sent: Monday, January 27, 2020 10:58:46 PM To: Subject: Fwd: Tests

This is the email for CMO I mentioned today. I'd be grateful if someone looked into this

Matt

Begin forwarded message:

From: Peter FitzGerald < @randox.com> Date: 27 January 2020 at 09:59:06 GMT To: Matt Hancock < > Subject: RE: Tests

Dear Matt,

Thanks for your email.

We currently have tests for Coronovirus but not the new strain. However, we can have tests for the new strain within 2-3 weeks. To confirm the accuracy of the tests we need approximately 10 positive sputum samples (about 300µl per sample). If possible, extracted DNA from the sputum would be preferred.

We have instrument systems, one we attain results within hours and the other system within hours ( samples at one time).

The advantage of our technology is we screen and measure for other viruses at the same time, which may cause the same symptoms but not be the lethal strain. Hence no treatment needed and therefore no alarm. Furthermore, if more variations of the virus occur, we can respond promptly.

I hope this information is sufficient for you to be able to progress this matter.

Best regards,

Peter

Dr Peter FitzGerald CBE FREng DL, Managing Director

Randox Laboratories Ltd. 55 Diamond Road Crumlin Co. Antrim United Kingdom BT29 4QY T: | F: From: Matt Hancock < Sent: 26 January 2020 21:33 To: Peter FitzGerald Subject: Tests

@randox.com>

>

Hi Peter,

Thanks for getting in touch. I understand that if you can get positive sputum samples, you will be able to develop a diagnostic test within a number of weeks giving results for coronavirus within 2/3 hours based on raw sputum samples.

I would be grateful for more detail so we can look into it.

Matt

From: @dhsc.gov.uk> Sent: 30 January 2020 11:41 To: @dhsc.gov.uk>; @dhsc.gov.uk>; Whitty, Chris ; @dhsc.gov.uk>; @dhsc.gov.uk> Cc: @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk> Subject: RE: Commission: advice on tests for Coronavirus

Hi

Thanks very much for setting this out. This sounds sensible, I'm afraid I don't have an email contact for someone at Randox, but hopefully Mark Campbell, (phone number is ) should be able to point you in the right direction.

Happy to discuss.

Thanks,

From:			
Sent: 29 January 2020 14:21			
To: <u>@dhsc.gov.uk</u> >;			
@dhsc.gov.uk>; Whitty, Chris <			
@dhsc.gov.uk>;			
< <u>@dhsc.gov.uk</u> >			
Cc: @dhsc.gov.uk>;			
@dhsc.gov.uk>;	<u>@dhsc.gov.uk</u> >;		
@dhsc.gov.uk>;			
@dhsc.gov.uk>;	<u>@dhsc.gov.uk</u> >;		
<u>@dhsc.gov.uk</u> >;			
@dhsc.gov.uk>;	@dhsc.gov.uk>		
Subject: RE: Commission: advice on tests for Coronavirus			

Dear

We spoke earlier, and agreed that we will deal with the Randox proposal as part of wider efforts to review proposals on coronavirus that we have received from several groups and companies. If these prove promising, they will be channelled through targeted research funding calls currently under development. We are pursuing these as a matter of urgency.

I would be grateful if you can pass on contact details for Randox, and I will get in touch rapidly. We don't have enough information at the moment to make an initial assessment.

I will keep you updated on progress, but as agreed we will not send you formal advice today.

Best wishes

Department of Health & Social Care	Medical Officer – Professo Email: Mobile:	puty Head of the Office to the Chief or Christopher Whitty Tel: d Social Care, 7th floor, 39 Victoria
From:		
Sent: 28 January 20	20 08:57	
<b>To:</b> Whitty, Chris	>;	
-	.gov.uk>;	3
	<u>@dhsc.gov.uk</u> >	
Cc:	@dhsc.go	
<u>@dhs</u>	<u>c.gov.uk</u> >;	<u>@dhsc.gov.uk</u> >;
	@dhsc.gov.uk>;	
@dhsc.gov.uk>; @dhsc.gov.uk>		
	@dhsc.g	

Subject: Commission: advice on tests for Coronavirus

Dear CMO,

SofS mentioned this during yesterday's meeting on Coronavirus. As discussed, industry reps have been in touch on the rapid development of diagnostic tests for Coronavirus.

Randox have told SofS said that they could develop tests for the new strain of coronavirus within 2-3 weeks. To confirm the accuracy of these tests they have said that they would need approximately 10 positive sputum samples (about 300µl per sample). They have instrument systems, one where they attain results within hours and the other system within hours (samples at one time). Randox argue that the advantage of their technology is that they are able to screen and measure

for other viruses at the same time, which may cause the same symptoms but not be the lethal strain.

Could we please have some formal advice on Randox's proposal, and/or any other proposals that we're aware of? I appreciate that this was picked up during yesterday's meeting where you raised some concerns. However, SofS has since reiterated that he is keen to pursue every possible option to mitigate the risk of the Coronavirus to the UK

Would it be possible to provide some advice by **<u>3pm tomorrow</u>**? Happy to discuss.

Thanks very much,



39 Victoria St, Westminster, SW1H 0EU

" @s.whatsapp.net@WhatsApp" 18/2/2020, 21:36 Randox have still heard nothing from PHE.We are losing time .Is it possible to chase ?

Me <" @s.whatsapp.net@WhatsApp"> 19/2/2020, 06:51 I have chased - they are in the process for commercial expansion of tests. PHE tell me they spoke directly to them. M

Owen Paterson MP < @s.whatsapp.net> 19/2/2020, 07:09 Many thanks.Will keep you updated.

Owen Paterson MP <" @Native Messages" > 25/2/2020, 11:31

It is now 19 days since PHE last contacted Randox at your request .Since then EVAg have provided a positive sample

and the Randox test worked perfectly .Test kits are now being shipped to China,Mexico,Ukraine,Oman,Tunisia and

Guatemala.PHE's attitude looks incomprehensible given current developments and time pressures.Are you voting today

?Can we discuss briefly?Great announcement on pharmacies by the way !Best wishes .Owen.

Matt Hancock

> 25/2/2020, 11:36

Are you sure? I chased them again about it yesterday.

**Owen Paterson MP <"** @Native Messages"> 25/2/2020, 11:39 Yes.Sadly no contact although they are members of EVAg.Just seems no sense of urgency or understanding of the speed

of the new testsamples perhour shift with first results in hours.Matt Hancock25/2/2020, 11:42

The reason they've taken the approach they have on timing is that they can cope with tests a day in house. Which is enough for now but I'm pushing them to accelerate in case we get a big increase Matt Hancock < @s.whatsapp.net> 25/2/2020, 11:37

From Owen Paterson below. could you please ensure PHE get on this. It is now 19 days since PHE last contacted Randox at your request .Since then EVAg have provided a positive sample

and the Randox test worked perfectly .Test kits are now being shipped to China,Mexico,Ukraine,Oman,Tunisia and

Guatemala.PHE's attitude looks incomprehensible given current developments and time pressures.Are you voting today

?Can we discuss briefly?Great announcement on pharmacies by the way !Best wishes .Owen.#

" @s.whatsapp.net@WhatsApp" 27/2/2020, 11:40 of PHE has passed Randox on to .He has refused their request for extracted RNA as control materials are not being issued to any companies.Randox have previously offered to send equipment and staff to PHE labs to help speed up the process.There is absolutely no sense of urgency.In the meantime Randox kits are being

flown to China this week.Exasperating!Nb I'm a consultant to Randox.PS Good news on nurses!

Me <" @s.whatsapp.net@WhatsApp"> 27/2/2020, 11:56 Why not?

" @s.whatsapp.net@WhatsApp" 27/2/2020, 12:28 Assume material is in short supply but as it is cultured this is not clear.Also treating all companies equally.

### Matt Hancock MP

FORWARDED

of PHE has passed Randox on to . has refused their request for extracted RNA as control materials are not being issued to any companies. Randox have previously offered to send equipment and staff to PHE labs to help speed up the process. There is absolutely no sense of urgency. In the meantime Randox kits are being flown to China this week. Exasperating! Nb I'm a consultant to Randox. PS Good news on nurses!

See above from Owen Patz. I am very worried about this

Please can I have chapter and verse on our engagement with UK life sciences for covid purposes. If we are treating other companies like this we are failing

On the case

### From: Sent: 01 March 2020 23:01 To: Matt Hancock Cc: @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; psmatthancock < Subject: 4-hour test

>

Matt,

As requested, info from PHE on the four hour test. Will also print for the 815.

PHE aim to be fair to all commercial companies, and have engaged with 15 different companies. Platforms selected for early testing at Colindale (some of which are now completed) were selected based on early feedback from NHS laboratories as to what instruments they already use in their laboratories. This means that a new test for covid-19 performed on an existing platform could be rapidly deployed with the least disruption - and without the need for further equipment purchase. An assessment of the full range of platforms used in NHS labs for which covid-19 tests are under development will be completed this week, but we already know from our testing that one commercial assay is comparable to the test we currently use. We were specifically asked by several NHS labs to prioritise this platform. In a parallel effort, we undertake on-going horizon scanning for instruments that look

promising. Randox has been identified as one of these, together with an instrument made by

We are also watching the progress of These

are then prioritised for testing. Randox has been prioritised.

We also check the FIND website on regular basis. This has a comprehensive list or emerging tests, recorded without bias <u>https://www.finddx.org/covid-19/</u> Horizon scanning for platforms used by other major lab users includes regularly checking across a network of colleagues. For example, today 1st March, our public health colleagues in US CDC and in Hong Kong could not recommend a commercial platform for routine laboratories.

We note that the testing time for the Randox instrument is around the same as for our current assay being used by PHE in Colindale and in regional laboratories. The key advantages that it would have is ease of use by NHS staff, combined with being onsite and readily available to local healthcare providers rather than the current situation where samples are sent away to a small number of laboratories. This advantage will be associated with any commercial instrument, and not just Randox, and the key step is to prepare NHS laboratories for local testing which is underway

> | Principal Private Secretary | M:

Ref 16

Message				
From:	@cabinetoffice.gov.uk] @cabinetoffice.gov.uk>   @cabinetoffice.gov.u		@ appling to ffing a governed	
on behalf of <b>Sent:</b>	24/03/2020 16:24:29	e.gov.uk> [	@cabinetoffice.gov.uk]	
То:	James Bethell			
<b>CC:</b> PsBethell	(Office for Life Sciences)		<pre>@officeforlifesciences.gov.uk]; @cabinetoffice.gov.uk];</pre>	
PSDelliell	, @officeforlifesciences.gov.uk @officeforlifesciences.gov.uk]	:];	@cabinetomce.gov.ukj,	
Subject:	Re: Request for Randox Authorisation	to Proceed		
Lord Bethell, Many thanks Kind regards				
You have my	ar 2020 at 16:21, James Bethell < authorisation. Which I reiterate. we work with DW to make this happen. forward.		> wrote:	
Lord Bethel The House 0: M: @jimbethel	of Lords			
On 2 ≤	4 Mar 2020, at 16:09, @officeforlifesciences.gov	(Office for Life <u>/.uk&gt;</u> wrote:	Sciences)	

Definitely today. What time is he due out of the house? We might need to explore DW approval instead given LB has already approved this in principle (saying buy all we can) and we were just checking in for the record.

From: PsBethell
Date: Tuesday, March 24, 2020 at 3:49 PM
To: @cabinetoffice.gov.uk>, James Bethell ≤
PsBethell ,"
(Office for Life Sciences)"
≤ @officeforlifesciences.gov.uk>
Cc: @cabinetoffice.gov.uk>,
@officeforlifesciences.gov.uk>
Subject: RE: Request for Randox Authorisation to ProceedThanks

.

Lord Bethell is currently in the House of Lords debating the COVID Bill, can I check when you need a response by?

T: M: From: @cabinetoffice.gov.uk> Sent: 24 March 2020 15:47 To: James Bethell ≤ ≥: PsBethell ≥: @officeforlifesciences.gov.uk> Cc: @cabinetoffice.gov.uk>: @officeforlifesciences.gov.uk> Subject: Fwd: Request for Randox Authorisation to Proceed

(Re-sent to include additional e-mail addresses)

Dear and Lord Bethel,

## **Request:**

Randox are providing a turn-key testing solution for Covid 19. To enable them to commence the ramp-up to complete tests I ask that you please approve the following request. (Please note that we are awaiting PHE approval and the commitment to Randox **will not be made** until such times as this approval is received):

We ask that you formally approve the following:

1. The commitment to order a m	ninimum quantity of tests @	
each (£133,000,000 total)		

- 2. A payment on account of as security for their commitment
- 3. An upfront payment of to contribute towards capex

#### About Randox

Randox Laboratories is an established Northern Ireland based diagnostics company who deliver solutions for hospitals, clinical, research and molecular labs. They have 1,400 staff and turnover c with an ebitda of c

## Further Information

- 1. The commitment to order a minimum quantity of tests to be undertaken over 12 weeks at a total price of £133,000,000 (£ per test).
- 2. A payment on account of as security for their commitment to complete tests over 12 weeks. The approximate division is ( materials and wages)
- 3. An upfront payment of to contribute towards c of capex commitment which Randox are in the process of making to suppliers for additional lab hardware (Suppliers are typically requesting a upfront payment to secure the items).
- 4. A pro-rata discount will be applied to each invoice over the 12 week testing period to recover the of advance payment

Please do not hesitate to contact me if you require any further information

Thank you and regards

Complex Transactions Team 1 Horse Guards Road, London, SW1A 2HQ E <u>@cabinetoffice.gov.uk</u>

From: Matt Hancock < >
Sent: 27 March 2020 08:58
To: @dhsc.gov.uk>
Cc: Lord J B < >; psmatthancock
< ; PsBethell <
@dhsc.gov.uk>
Subject: Re: Testing numbers

## [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

3. Great.

Μ

On 27 Mar 2020, at 08:47, <

@dhsc.gov.uk> wrote:

>;

Hi,

As discussed:

Numbers from yesterday

Total tests: 104,866

## [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

3. Randox (due to start next week) is at 1400 a day until 5th April and the is due to scale up to 15, 30 and 60 – but advises there is quite a lot of risk to that scale up and we will need to work closely with them on roll out (including looking at anything we can do to bring it forward).

l hope this is helpful. Thanks

**Me <** @s.whatsapp.net@WhatsApp"> 1/5/2020, 21:02 Thank you. It really was a great team effort. And I put Randox top of the thanks because they were there right at the start chivvying me to burst this outside the PHE box and make it a national effort. They were 100% right and I'm so so grateful

to Peter and the team for all they've delivered

From: PsBethell Sent: 18 September 2020 19:12 To: @dhsc.gov.uk> Cc: @dhsc.gov.uk>; psmatthancock

Subject: RE: Randox Contract Extension

Thanks v much for this

Lord Bethell is meeting with Lord Agnew on Monday and will be keen to raise this then if we really do have to expedite. Can we update the attached slide pack he's taking him through so we can at least forewarn him that is potentially coming even though won't have been through formal DH approvals yet.

Copying PsMattHancock for awareness.

Best,

### | Senior Private Secretary |

From:@ dhsc.gov.uk>Sent: 18 September 2020 19:03To: PsBethell <</td>Cc:@ dhsc.gov.uk>Subject: Randox Contract Extension

Dear Lord Bethel,

I am writing to provide you with advance notice regarding a potential request for your assistance with expediting an approval for an extension to the Randox contract.

As we are all aware, capacity in Laboratories is a key pinch-point in our ability to keep delivering tests. Following some of the issues we have had in the past, Randox are currently our highest volume lab and they have committed to ramp up from their current tests per day.

If you recall, our contract with Randox was agreed on a volume basis with a committed number of tests. Due to the increase in demand for testing, we will have depleted our contracted capacity by the end of the month, which is significantly faster than we had anticipated.

We were working on the basis that the extension to the contract would be of a similar scale to the initial agreement (c£130m) and therefore within the approval limits of the programme. However, the team have been able to negotiate significant price reductions in return for our commitment to additional testing volume, meaning that the contract value will be c£350m, and will require both HMT and Cabinet Office approval.
While we are currently racing through approvals, we anticipate that we may need to ask for your assistance next week to expedite these please. The saving provided by the extended contract will be and we will have contractual protections should our need for tests unexpectedly reduce.

I hope that we will not need your assistance but please let me know if you require any further information.

Kind regards

| COVID-19 National Testing Programme

# Ref 21

From: Sent: 19 September 2020 21:45 To: Matt Hancock < < >; Cc: Harding, Dido Subject: RE: Randox @dhsc.gov.uk>

>

>; psmatthancock @dhsc.gov.uk>

Hi Matt,

Updates below:

#### RANDOX

- Randox is meeting all requirements under the contract;

- Plans are in place to expand Randox capacity as part of the increase of capacity to 500k;

- Randown have tested samples in total.

- In the last 7 days Randox has tested samples, on average above daily capacity of

- Average turnaround times in this period have been in hours; in

hours; in hours. Void samples on arrival (at accessioning) have been (mainly leaking tubes, followed by aged).

#### CONSUMABLES/SUPPLIES

- A standard specification has been developed for future orders of consumables. Just two sizes of tubes (for saliva and swabs) are procured - we are exploring consolidating this further;

We have recently started a mini-competition where we are requesting new suppliers to support consumables production to a standardised specification;
Whilst we are pursuing standardisation we are also ensuring there is flexibility of supply for new technologies - e.g. larger tubes for sample pooling.

Best,

Test and Trace Programme

-----Original Message-----From: Matt Hancock < Sent: 19 September 2020 11:55 To: psmatthancock < <u>@dhsc.gov.uk</u>>; Subject: Randox

>

@dhsc.gov.uk>

@dhsc.gov.uk>;

# Hi

Can I have a one-pager on where we are Randox? Last time I spoke to said they were getting into very good shape.

Matt

**Ref 22** 

From: PsBethell Sent: 23 September 2020 00:29 To:

@dhsc.gov.uk>;

@dhsc.gov.uk>: @phe.gov.uk:

@dhsc.gov.uk>; 'PS Lord Agnew Mailbox'

Cc:

@cabinetoffice.gov.uk>;

@cabinetoffice.gov.uk; gareth.rhyswilliams

Subject: Readout: Phone call Lord Bethell/ Lord Agnew to discuss Test and Trace business case approvals

# [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

5. On upcoming commercial deals, PS(I) noted the commercial sensitivities around Randox so asked to make sure that we were fully scrutinising their proposal to make sure carefully screened and able to deliver contact they've proposed;

# [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

Best,

| Senior Private Secretary |



# MINISTERIAL SUBMISSION: HMGC5723 - COVID-19 - Randox Lighthouse Lab extension, Full Business Case (FBC) 3 messages

<b>Cabinet Office Controls Mailbox</b> < To: PS Lord Agnew Mailbox <	>,	> @cabineto	24 September 2020 at 13:02 office.gov.uk>, PSAlexChisholm	
Mailbox <	>,	@cabinetoffice.gov.uk>		
Cc: Gareth Rhys Williams <	>,	@cabinet	office.gov.uk>,	
@cabinetoffice.gov.uk>,	@cabinetoffice.ge	@cabinetoffice.gov.uk>, Commercial Assurance Mailbox		
< .	@cabinetoffice.gov.uk>, "Cabinet Office Controls -			
	>,	@cabinetoffi	ce.gov.uk>,	
<pre>@cabinetoffice.gov.uk&gt;,</pre>	@cabine	etoffice.gov.uk>,	-	
@cabinetoffice.gov.uk>,	@cabinetoffice.gov.uk>, @hmtreasury.gov.uk,		@hmtreasury.gov.uk,	
@hmtreasury.gov.uk,	@hmtreasury.gov.uk,	@hmtreasury.gov.uk,	@hmtreasury.gov.uk	

#### Lead PS:

Timing: URGENT. Grateful for a reply by 25 September.

# HMGC5723 - COVID-19 - Randox Lighthouse Lab extension, Full Business Case (FBC)

**Summary:** The Department of Health and Social Care (DHSC) is seeking approval to extend a contract under Reg 32(2)(c) with Randox for provision of tests over a period of 6 months from 1st October 2020. The whole life cost of the contract extension is expected to be £346.5m.

We recommend that you **approve** this request subject to the conditions within.

This is being dealt with through the expedited COVID-19 process, using a short form submission and requesting a shorter turnaround. This submission is being submitted simultaneously to the Chief Operating Officer of the Civil Service due to

urgency.

We look forward to hearing from you,

# **CO Spending Controls**

Cabinet Office

Civil Service Group Cabinet Office |1 Horse Guards Road| London SW1A 2HQ E:

# Follow us on Twitter @cabinetoffice

	@cabinetoffic	ce.gov.uk>				25 September 2020 at 09:28
To: Cabine	t Office Controls Mailbox <			>		
Cc: PS Lor	d Agnew Mailbox <		>,		@cabinetoffice	e.gov.uk>, PSAlexChisholm
Mailbox <		>, Gareth R	hys Williams			
<		>,	@ca	abinetoffice.gov.uk>,		
	@cabinetoffice.gov.uk>,		@cabinetoffic	e.gov.uk>, Commerc	cial Assurance N	<i>l</i> ailbox
<			@cabinetoffice.gov.u	uk>,		
	@cabinetoffice.gov.uk>,		@cabine	etoffice.gov.uk>,		
	@cabinetoffice.gov.uk>,		@cabinet	office.gov.uk>,		
	@cabinetoffice.gov.uk>,			@hmtrea	sury.gov.uk>,	
	@hmtreasury.gov.uk>, @hmtreasury.gov.uk			@hmtreasury.gov.u	uk>,	@hmtreasury.gov.uk,

Alex Chisholm says: "I am disappointed that despite entering into the original contract on 30 March DHSC have not moved to organise and conclude a competitive contract process and are now in a position where extension by direct award is the only viable option. Can we please insist on a written commitment from DHSC to initiate a competitive process in time for new contracts to be let from March 2021. At least the price has been negotiated down and is now comparable to benchmarks, and quality has been good." I think

that should be taken as approval with conditions.

Many thanks,

---

,

Alex Chisholm

Office of the Civil Service Chief Operating Officer & Cabinet Office Permanent Secretary

PS Lord Agnew Mailbox	<	>	25 September 2020 at 11:02
То:	@cabinetoffice.gov.uk>		•
Cc: Cabinet Office Control	s Mailbox <	>,	
@cabinetof	fice.gov.uk>, PSAlexChisholm I	Mailbox <	>, Gareth Rhys Williams
<	>,	@cabinetoffice.g	jov.uk>,
@cabinetoffice	.gov.uk>,	@cabinetoffice.gov.uk>, C	commercial Assurance Mailbox
<	>,	@cabinetoff	ice.gov.uk>,
@cabinetoff	ce.gov.uk>,	@cabinetoffice.gov.u	lk>,
@cabinetc	ffice.gov.uk>,	@cabinetoffice.gov.uk	(>,
@cabinetoff	ice.gov.uk>,	(0)	hmtreasury.gov.uk>,

Dear

Lord Agnew's comments: "Ok but can you confirm that any conditions we put in last time have been met? (reading further down it suggests there are none. Can you please clarify).

- Can you please send the metrics of the last KPIs and outcomes of the conditions applied.
- Please ensure as a standard condition we now always require name of SRO/ %FTE Deployed and 2 sentence bio. [ I believe we are expecting another urgent covid-19 case today, please can we include this. Lord Agnew really cares about having this from now on]
- I'm very worried about pricing. Given the huge volumes we are paying dramatically over the odds.
- Can you please add as an additional condition that a proper international benchmarking of pricing for comparable tests takes place over the next month so that they are properly informed for their pricing negotiations.
- Please ensure that 2<sup>nd</sup> Perm Sec of DH sees my comments." As per

Alex's comment above - approval with conditions.

Many thanks



Office of Lord Agnew, Minister of State Cabinet Office & HM Treasury

Head of Office: Senior Private Secretary: Private Secretary: Secretary: Private Secretary: Private Secretary:

Senior Private

Assistant Diary Manager:

From:	Tel:
Central Commercial Teams	Date: 24 September 2020

HMGC5723 - COVID-19 - Randox Lighthouse Lab extension, Full Business Case (FBC)

# MINISTER FOR TRANSFORMATION AND EFFICIENCY

#### Issue

 The Department of Health and Social Care (DHSC) is seeking approval to extend a contract under Reg 32(2)(c) with Randox for provision of of 6 months from 1st October 2020. The whole life cost of the contract extension is expected to be £346.5m.

# Recommendation

- 2) That you approve this request subject to the following conditions:
  - a) DHSC provides confirmation of the top 6 KPIs in the contract;
  - b) DHSC reports on performance against the KPIs for this contract monthly;
  - c) DHSC adopt recommended actions from legal advice to reduce the risk of legal challenge;
  - d) DHSC return with an OBC setting out a procurement strategy that supports competition for future laboratory testing requirements by 31 October.
  - e) DHSC reports to Cabinet Office on their plans for minimum volume commitments for the final 12 weeks of the contract and outcomes from negotiations to secure per test by 15 November.

# Timing & Handling

3) Urgent, Sensitive, **COVID-19 case.** Approval is requested ahead of Friday 25 September 2020, when the current contract expires.

# Background

- As part of the UK Government's measures for addressing the Covid-19 pandemic, the Department of Health and Social Care (DHSC) has engaged Randox Laboratories Limited to provide COVID-19 test kits and Testing Services.
- 5) DHSC and Randox entered into a contract on 30 March 2020. The Agreement provides for both the delivery of COVID-19 sampling test kits and the carrying out of testing on returned samples.
- 6) The Agreement was awarded by DHSC to Randox by way of a direct award (namely without any advertisement of the opportunity). DHSC relied upon the grounds of extreme urgency under public procurement law in awarding the contract.

7)

which is set to be depleted by the end of September. In the last six weeks, Randox has processed

# Requirement

- 8) DHSC must secure Randox's testing capacity to support the objectives of the Test and Trace programme and wider Government objectives; especially as the UK expects demand for testing to increase during winter.
- 9) This agreement will follow the specification outlined below:
  - Test reports would be reported on Laboratory Information System (LIMS) 1 and individual test subjects;
  - Randox manufacture the test kits and ship them to the warehouse, with then arranging for direct delivery of test kits to relevant individuals;
  - · Individuals register online via Randox's registration portal;
  - Randox runs testing and reports results directly back to individual test subject (via email address entered on Randox's registration portal).
- The total costs of the test kits do not include the price of delivery. These costs are covered under separate existing logistic contracts which will be addressed under separate approval requests.
- 11) The proposed contract extension will include a requirement to ramp up capacity from tests per day to per day by the end of December.
- 12) As part of extending with Randox, the cost of a test will reduce under this extension from to . In order to secure this price reduction, DHSC will commit to a minimum of tests in the first 12 weeks (approximately 50% of capacity). This is well within the forecast test volumes required for the next 12 weeks.





#### **Options analysis**

- 13) As a critical contributor to existing testing volumes, an extension is deemed the only viable course of action in light of increasing demands for testing through the winter period.
- 14) DHSC is intending to commence a new advertised procurement competition via the PHE framework imminently in order to appoint additional providers to continue to deliver COVID-19 testing. It is estimated these contracts will be able to be awarded by the end of March 2021.

# Pricing

- 15) The cost of a test is currently under this contract. As part of this extension the cost per test has been negotiated down to . Cabinet Office has seen benchmarking data to indicate equivalents costs per test of between and from other providers.
- 16) DHSC are engaged in continued negotiations with Randox to reduce the price per test further to from 1st January, once expansion to per day is complete. A condition of approval is recommended to see the final outcome of this negotiation.

#### **Contract and Contract Management**

- 17) The service that Randox provides will not change through this extension. DHSC will improve the ability to manage Randox by:
  - Introducing KPIs into the contract
  - Specifying accessioning capacity
  - Setting formal Capacity increase milestones
- 18) The contract includes a mechanism for reducing minimum volume commitments to after weeks, subject to weeks notice. As such, DHSC will be required to confirm test volume requirements for the second half of the contract. This mitigates against an unlikely scenario where supply of tests outstrips demand from January 2021.
- 19) The DHSC team has indicated close management of this contract.

20)

21)

**Risks and Issues** 

22)

#### 23) Delivery strategy

- a) DHSC will have purchased tests that are not required if demand falls, potentially wasting public funds.
- b) This is considered low likelihood and is mitigated from the end of December with the option to reduce the minimum commitment.

- 24) Not achieving value for money
  - a) Direct award approach reduces commercial leverage to negotiate, resulting in a failure to adhere to Government regulations (e.g. managing public money), and poor value for money for the public.
  - b) DHSC are ensuring that Randox's costs are comparable with others in the market to ensure value for money, and will look to conduct a compliant framework competition as soon as possible.
  - 25) Reputational damage
  - c) Randox were the subject of recent negative press in a Sunday Times article. The DHSC team insists that the criticism of poor performance is not justified
  - d) DHSC are preparing a media handling plan to manage any media focus on this contract extension.

#### **Approvals**

- 26) The recommendation has been approved by the Test & Trace Investment Board and DHSC's Second Permanent Secretary and Director General, Finance and Chief Operating Officer, David Williams.
- 27) HMT are providing a request for approval to CST in parallel.

#### Advice

- 28) The Randox laboratories form a core part of the UK testing capacity and this must be continued as we enter into the winter period and respond to the need for increased testing. DHSC have secured a significant price reduction, reflecting an improved understanding of the requirement, associated costs and competitive landscape. As such, we support this extension and the need to accept some risk of challenge to the award.
- 29) We recommend placing firm emphasis on T&T developing a commercial strategy to meet testing needs into 2021 and move away from continued reactive contracting. We recommend you write to the programme setting out your expectations on a shift towards a more strategic commercial approach and greater focus on performance management of the contracts we have in place.

Cc: <u>Ministerial Office:</u>pslordagnew @cabinetoffice.gov.uk

Perm Sec's Office: psalexchisholm@ @cabinetoffice.gov.uk

<u>The Cabinet Office Commercial Team:</u> gareth.rhyswilliams @cabinetoffice.gov.uk @cabinetoffice.gov.uk @cabinetoffice.gov.uk commercialassurance@ @cabinetoffice.gov.uk

<u>HMT:</u>	@hmtreasury.gov	v.uk
	@hmtreasury.gov.uk	
	@hmtreasury.gov.uk	44

@hmtreasury.gov.uk @hmtreasury.gov.uk Service Quality & Controls: cabinetofficecontrols

@cabinetoffice.gov.uk
@cabinetoffice.gov.uk
@cabinetoffice.gov.uk

@cabinetoffice.gov.uk @cabinetoffice.gov.uk

#### Ref 24

From: (Office for Life Sciences) @officeforlifesciences.gov.uk> Sent: 01 April 2020 09:32 To: psmatthancock < >; @dhsc.gov.uk>; @nhsx.nhs.uk>; @phe.gov.uk>; @officeforlifesciences.gov.uk> >; PsBethell Cc: < @nhsx.nhs.uk' < >: @nhsx.nhs.uk> < Subject: Re: Urgent - advice on RANDOX

Hi

No they haven't been given a remit to remove anything. I am amazed this has been escalated in this way as I called my counterpart in NI a few days ago and explained we were looking for equipment for Randox and wanted to ask the universities to help but not at the expense of their own ramp up efforts.

Could you go back and ask them to call me if they are concerned but the bottom line is no one has given anyone permission to remove anything against the wishes of NI and the universities involved? The reason for the request was to be able to ramp up production in Randox labs in NI, some of the capacity of which would be offered to NI but if they can't or don't want to help we will try to find the equipment elsewhere.

I will get all the relevant parties on the phone today and see if we can find another solution

From: psmatthancock < Date: Wednesday, April		>	
To:	@nhsx.nhs.uk>, "	(DHSC)"	
@dhsc.gov	.uk>,		<pre> phe.gov.uk &gt;, </pre>
-	@officeforlifescier	<u>nces.gov.uk</u> >, "	(Office
for Life Sciences)"	@officeforli	fesciences.gov.uk>	
Cc:		PsBethell	
	," @	nhsx.nhs.uk'"	
<u>@nhsx</u>	. <u>nhs.uk</u> >		

**Subject:** Urgent - advice on RANDOX

Hi all,

The SofS has been sent an email from his counterpart in Northern Ireland asking if RANDOX as part of the UK wide testing agreement have been given a remit to remove lab equipment from both Queen's and Ulster Universities and the AFBI Lab.

They said that these labs are part of plans for their own internal testing ramp up and their removal would have a serious effect on that.

Can you let me know, if possible by this morning, if this is the case? Thanks,



Department of Health & Social Care Private Secretary Secretary of State for Health and Social Care Phone: Mobile: 9<sup>th</sup> Floor, 39 Victoria Street, SW1H 0EU @dhsc.gov.uk

# Ref 25

From: PsBethell on behalf of PsBethell
Sent on: Friday, April 3, 2020 7:17:44 PM
To: (NHS ENGLAND & NHS IMPROVEMENT X24) @nhs.net>;
@officeforlifesciences.gov.uk>;
@dhsc.gov.uk>;
@dhsc.gov.uk>
Subject: Lord Bethall Colle with Stakeholdere

Subject: Lord Bethell Calls with Stakeholders

Hi All,

Lord Bethell is having brief 15 minute calls with the following people over the weekend.

I would be grateful if you let me know if there are any particular issues that would be helpful for him to raise on these phone calls. I appreciate everyone is extremely busy, but if you do have a view please let me know by **9am tomorrow** 

- Lord Agnew
- •
- from Nanopore
- Abingdon
- Adjuvo
- from the Crick.
- ABHI,
- ABPI,
- APBI/Novartis
- BIA,
- BIVDA,
- Peter Fitzgerald Randox MD
- Primer Design-Novacyt

Kind Regards,

Private SecretaryDepartmentof Health &Social CareE:@dhsc.gov.ukT:

#### Ref 26

 From:
 Matt Hancock <</th>
 >

 Sent on:
 Friday, April 10, 2020 10:00:24 PM
 >

 To:
 Michael Gove MP
 >

 CC:
 Lord Bethell <</td>
 >; Theodore Agnew <</td>

 Subject:
 Re:
 >

Thanks for the questions. Answers below - let me know where you think we should be going further.

#### [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

I note references to test kits from Randox (apparently being tested themselves this week) – being used by PHE. I presume they are closed platform kits, for use in existing PHE labs. Is that right? How many are we assured of getting?

THE RANDOX OPERATION IS WELL-INTENTIONED, WE LIKE THEM, THEY ARE LONG-TERM PARTNERS, BUT IN THE SHORT TERM NUMBERS ARE LIMITED. WE ARE MOBILISING THE ARMY TO GET HIM THE KIT HE NEEDS. THEY HAVE COMMITTED TO PER DAY, BUT WE HAVE PENCILLED IN ONLY , AND MAYBE WE WILL BE SURPRISED IF THEY OVERPERFORM

As far as open platforms go, I understand that we are looking to bring in new suppliers who can make use of open access platforms. Do we think they can supply in a timely way?

#### [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

Who can we be certain will supply more closed platform tests in April? Randox? Who else? How many more? By when?

IF YOU HAVE FURTHER LEADS OVER AND ABOVE WHATS SET OUT ABOVE LET US KNOW.

#### [TEXT REDACTED AS NOT RELEVANT TO TERMS OF THE HUMBLE ADDRESS]

If it's at all helpful, even in a small way, I'm always happy to discuss and support in any way I can

all v best

Michael

12.22

# **CLEARANCE CHECKLIST**

Inclusion of this checklist is mandatory. Please complete the whole list and private office will remove before putting submission in the box. <u>A submission without it will be sent back</u>.

<u>Note</u>: Contact names provided must have seen and approved the submission.

# Finance:

Does this involve any spending or affect existing budgets?

□ If yes, named official:
 Click here to enter text.
 ☑ No

#### Legal:

Does this include legal risk, a court case or decisions that can be challenged in court?

 $x\Box$  If yes, named official:

No

# **Communications:**

Could this generate media coverage, or a response from the health sector? ☑ If yes, named official:

□ No

# Analysis and data fact-checking:

Does this include complex data, statistics or analysis?

☑ If yes, named official:

□ No

#### **Devolved Administrations:**

Will this affect Scotland, Wales or Northern Ireland?

□ If yes, named official: ☑ No

#### Fraud:

Have you considered fraud risks?
□ If yes, named official: Click here to enter text.
☑ No

#### Commercial

Does this include commercial or contractual implications? ☑ If yes, named official:

□ No

#### **Strategy Unit:**

Does this relate to cross-cutting or longer-term implications for wider DH strategy?

□ If yes, named official: Click here to enter text. ☑ No

#### **Implementation Unit:**

Does this relate to one of the Secretary of State priorities?

□ If yes, named official:
 Click here to enter text.
 ☑ No

#### Legislation:

Does this include options that may require secondary legislation?

□ If yes, do you have a prioritisation reference number? (contact Parly or SOPL if unsure): Click here to enter text.
 ☑ No

# **Duties, Tests and Appraisals:**

The following tests apply and have been considered.

□ Secretary of State Statutory Duties, including on health inequalities

□ Public Sector Equality Duty

□ Family test

□ Other(s) (please specify)

Click here to enter text.

To: SoS, PS(I), MS(C)

From: Clearance: Date: 06 May 2020 Copy: PS(I),MS(C)

> Private Office Submissions Copy List

# NATIONAL TESTING PROGRAMME: RANDOX VOIDS AND CAPACITY CONSTRAINTS

Issue	operational issue affecting Randox samples in process at their laboratory from 3rd May, leading to restrictions on planned laboratory capacity.
Timing	<ul> <li>Urgent (two working days)</li> <li>There is a clear reputational risk from: <ul> <li>Pillar 2's capacity to deliver testing being lower during the week after achieving the target;</li> <li>Delays to results issued from Randox samples, and void samples affecting many people tested.</li> </ul> </li> </ul>
Recommendati on	<ul> <li>That the Department's public lines when questioned about many void test results explain that these are short-term operational challenges.</li> </ul>

#### Discussion

1. **Background:** The contract with Randox to provide support to the National Testing Programme (NTP) was envisaged to deliver an end to end solution, in which the company provides testing kits per day and the associated lab capacity to analyse all returned samples. Randox are on track to produce test kits per day by mid-May.

their lab capacity was not forecast to rise above tests per day due to a shortage of lab equipment. This lab capacity constraint limits the NTP's use of Randox's test kits. We are separately submitting a recommendation to you that we negotiate a contract change with Randox to permit their test kits to be used in the Lighthouse labs. This would be achieved by severing the commercial link between test kit availability and lab capacity.

2. On 4th May (Monday) Randox contacted the Pillar 2 programme to inform us that safety cabinets being used to store COVID-19 test swabs at their laboratory had malfunctioned. From that day the Randox laboratory processing capacity has been set at only samples per day. Randox are urgently working to address the issue with the cabinets. We expect that the

cabinets will be repaired and capacity fully restored once an audit, requested by the programme, has validated Randox's laboratory.

- The impact of the reduced Randox processing capacity has been a backlog of samples (as at 7am on 5<sup>th</sup> May), dating from 30th April laboratory arrivals to laboratory arrivals on 4th May.
  - Approximately samples were shipped to the Milton Keynes lighthouse labs urgently and processed before they were voided (after 72 hrs). As of today the lighthouse lab network capacity sits at tests per day;
  - Approximately **further samples were intercepted** before arriving at the Randox lab and re-routed to the Milton Keynes lighthouse lab for processing;
  - For both the intercepted and shipped samples, Randox will communicate all results to those tested, including voids, when they receive them from the lighthouse labs;
  - Randox samples were frozen (as of 4<sup>th</sup> May) to prevent them being voided, in accordance with WHO guidelines on preserving samples. Randox expects to have completed tests on these samples by tomorrow morning.
- 4. Approximately samples that arrived at the Randox lab on 30th April and 1st May were voided as a result of the backlog; the freezing and shipping mitigations were available too late for these samples. Those affected have already been contacted to inform them of their void results, asking that they book a re-test.
- 5. The approximately voided Randox samples are sourced from multiple Pillar 2 testing channels, including regional testing sites in Northern Ireland, home-test deliveries, mobile testing units and satellite test deliveries across the country. There is a possibility that a number of care homes and NHS Trusts will be told that a large number (if not all) of their testing samples are voids.
- 6. **Mitigations:** An audit is being carried by (NHSE Chief Scientific Officer) into the Randox laboratory, in order to provide assurance that Randox can continue to operate at their previous per day capacity. NHSD are also requesting that Randox bring testing subjects onto their portal, both to support registration and the issuing of results.

#### Communications

8.

Possible impacts include:

- Individuals and organisations (e.g. NHS facilities and care homes) being left without test results, potentially leading to those individuals or care homes going to the media;
- The effect on those individuals could be that they may no longer be able to be tested (if they no longer have symptoms), and that therefore their ability to end their self-isolation is affected. This could lead to a decline in trust from the public about the reliability of the service;
- Broadly this issue should be contained, but could lead to accusations that the infrastructure isn't fit for purpose or can't cope with the demand that we have put on it, drawing into question our readiness to scale-up testing further.

9.

10. A set of public lines has been agreed with Special Advisers (Annex A). In addition, we recommend that this short-term operational issue is contextualised within the overall void rate for Randox tests being

#### Conclusion

11. We will keep ministers informed of progress in building resilience in the laboratory network, and of progress in resolving the specific operational issues in Randox labs. We propose proactive communication to those affected, and that this incident is contextualised in reactive public communications within what has overall been a highly-successful testing programme with a low overall void rate.

#### , COVID-19 PILLAR 2 TESTING PROGRAMME,

# Annex A: DHSC Q&A Lines on reduced testing capacity

#### Why have tests halved compared to Friday?

Today's figures reflect some technical issues in the laboratory system which have impacted the total number of samples that could be processed over the last 24hrs. We have worked to resolve these problems and capacity is rapidly being restored.

#### Is this a big problem?

The issues arose in our lab network – it is not surprising when a system is brand new, as this one is, that there will be some teething problems in first weeks of operation. It is important not to draw too many conclusions from a few days' worth of data.

#### What's gone wrong exactly?

One of our laboratory providers, Randox, experienced a temporary problem with their storage facilities for testing samples. This has led to temporary restrictions that have substantially reduced the quantity of tests Randox can process each day.

#### How many tests does this affect?

This has affected a number of samples but most of those are currently being processed.

#### Will any tests need to be retaken? If so, why?

"We are currently aware of a small proportion of this total that require re-testing. We will inform all of those affected within the next 24 hours to let them know whether or not they will need to retake their test."

#### Will those tests be counted again ie twice in your figures?

No.

#### Have these people been notified, or do they need to be?

We will be notifying all those affected within the next 24 hours.

#### What have you done to ensure this doesn't happen again?

A full audit is being carried out on Randox's testing facilities to ensure testing can continue at its previous higher volume. We have also taken rapid action to increase capacity in our Lighthouse labs in order to provide resilience in the system.

#### Which labs did this affect?

A single Randox laboratory in Northern Ireland

#### Ref 28 From: Sent: 13 May 2020 10:31 (Office for Life Sciences) To: @officeforlifesciences.gov.uk>; PsBethell < @dhsc.gov.uk>; < >; @dhsc.gov.uk> @dhsc.gov.uk>; Cc: @cabinetoffice.gov.uk>: @crowncommercial.gov.uk> Subject: RE: Submission: Randox Testing Capacity Constraints Thanks I have now managed to track down Peter Fitzgerald office contact details. Best,

 From:
 (Office for Life Sciences)

 <</td>
 @ officeforlifesciences.gov.uk>

 Sent: 13 May 2020 10:25
 @ dhsc.gov.uk>; PsBethell

 To:
 @ dhsc.gov.uk>; PsBethell

 >;
 @ dhsc.gov.uk>;

 @ dhsc.gov.uk>;
 @ dhsc.gov.uk>;

 Cc:
 @ cabinetoffice.gov.uk>;

 @ crowncommercial.gov.uk>
 Subject: Re: Submission: Randox Testing Capacity Constraints

– could you let know who the DHSC lead lawyer on this is? We should have them on the call at 3.15 today pls

- can you track down an email address for as I don't have?

From:	@dh	sc.gov.uk>
Date: Tuesday	, May 12, 2020 at 5:1 <mark>3 P</mark> M	
То:	(Office for Life Scier	ices)"
<	@officeforlifesciences.go	v.uk>, PsBethell
<	>,	@dhsc.g <u>ov.uk</u> >, "
	@dhsc.gov.uk>,	@dh <u>sc.gov.uk</u> >
Cc:	@cabinetoffic	<u>ə.gov.uk</u> >,
	@crowncommercial.gov	<u>.uk</u> >
Subject: RE: Submission: Randox Testing Capacity Constraints		

Thanks we will look to schedule the pre brief tomorrow at 15:15, does that work well for you all?

Do you have an email address for Peter Fitzgerald and the lawyers we would need to invite to the actual meeting?

Best,



From: (Office for Life Sciences) < @officeforlifesciences.gov.uk> Sent: 12 May 2020 16:37 To: PsBethell >; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @dhsc.gov.uk>; @cabinetoffice.gov.uk>; @crowncommercial.gov.uk>

**Subject:** Re: Submission: Randox Testing Capacity Constraints

Hi

Between them, and can give the briefing, and I will join too if we can. We will also need lawyers.

I think before Lord Bethell has the conversation we need to be crystal clear what we are asking them to do. I think it is as follows:

- 1. Work with us constructively to get lab capacity to a day
- 2. Break the commercial link between kit supply and the end to end process, so we can use them as a test kit supplier
- 3. Break the closed loop Randox offer and bring them into our network as a lab, so that they aren't using their own digital system and results system

so I would suggest that

we have a briefing meeting with Lord Bethell tomorrow but only set up the conversation with them the day after so that we have time to respond to anything LB needs before the actual conversation. The actual conversation should be kept very small but it will need plus a lawyer present with a detailed note being taken From: PsBethell < >
Date: Tuesday, May 12, 2020 at 2:34 PM
To: @dhsc.gov.uk>, (Office for Life
Sciences)" < @officeforlifesciences.gov.uk>,
@dhsc.gov.uk>,
Cc: @dhsc.gov.uk>

Subject: RE: Submission: Randox Testing Capacity Constraints

Hi all,

Grateful for an update on this by COP today please. Keen to get in the diary tomorrow.

Best,

| Senior Private Secretary |

From: PsBethell Sent: 11 May 2020 11:02 To: @dhsc.gov.uk>; @dhsc.gov.uk>;

@dhsc.gov.uk>

Subject: FW: Submission: Randox Testing Capacity Constraints

Hi all,

Lord Bethell is keen to take this forward with Randox, but would like 15 min briefing from the team beforehand on the interactions with Randox to date and what our financial arrangement with the company is.

Who is best to attend this / can provide some briefing? Please feel free to widen the copylist.

Also grateful for names on who we should be inviting from Randox side for this meeting? Lord Bethell has indicated that he would like a 1:1 with Owen Patterson beforehand as well (who I understand is a consultant employed by Randox), grateful for this contact details if you have them?

Best,

| Senior Private Secretary |

From: psmatthancock Sent: 07 May 2020 16:00 To: < pshelenwhately <

> @<u>dhsc.gov.uk</u>>; psmatthancock >; PsBethell < >; >; Special Advisers



Hi

The SofS has reviewed the submission – he has agreed that Randox should:

•

•

He has also asked to see what contact you have had with Randox about this issue (can you send anything on this through ASAP) and has asked that **Lord Bethell** takes forward a conversation with Randox about their long-term involvement in the testing programme and seeking assurances about resilience.

Thanks,

From: @dhsc.gov.uk> Sent: 06 May 2020 23:01 To: psmatthancock < >; PsBethell < >; pshelenwhately < >; Special Advisers < ; @dhsc.gov.uk>; @dhsc.gov.uk>;

Cc:	<u>@dhsc.gov.uk</u> >;	
	<pre>@officeforlifesciences.gov.uk&gt;;</pre>	
	@dhsc.g <u>ov.uk</u> >;	@dhsc.gov.uk>;
	@dhsc.gov.uk>;	
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	<u>@dhs</u> c.gov.uk>;	
	@dhsc.gov.uk>;	<pre>@cabinetoffice.gov.uk&gt;;</pre>
		<u>on.gov.uk</u> >;
	<u>@dhsc</u> .gov.uk>;	
	@dhsc.g <u>ov.uk</u> >;	
	@officeforlifesciences.gov.uk>;	
	@officeforlifesciences.gov.uk>;	
	@dhsc.gov.u <u>k</u> >;	<u>@dhsc.gov.uk</u> >;
	@ <u>phe.gov.uk</u> >;	<u>@dhsc.gov.uk</u> >;
	<u>@dh</u> sc.gov.uk>;	
	@dhsc.go <u>v.uk</u> >;	@dhsc.gov.uk>;
	@dhsc.gov.uk>;	
o	@dhsc.gov.uk>;	@dhsc.gov.uk>
Subje	ect: Submission: Randox Testing Capacity Cor	nstraints

Dear all,

Please see attached a submission on operational constraints in the Randox laboratory, which have led to a temporary contraction in Pillar 2 testing capacity this week.

Many thanks,

Covid-19 Key Worker Testing Programme Department of Health and Social Care

Ref 29

From: Sent: 13 May 2020 15:24 To: Lord Bethell < > Subject: FW: Slides for 3:15 Randox call

Here they arE!

# Private Secretary to Lord Bethell

From: @cabinetoffice.gov.uk> Sent: 13 May 2020 15:16 To: DHLordsDiary < >; @dhsc.gov.uk>; James Bethell < >; @crowncommercial.gov.uk>; @officeforlifesciences.gov.uk>; Lord Bethell < >; @dhsc.gov.uk> Subject: Slides for 3:15 Randox call

Hi, The slides for our call Regards

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Government Commercial Function	Pillar 2 Commercial Lead - Covid19 Testing Team
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# **Randox commercial briefing**

**Synopsis and recommendations** 

13 May 2020

#### Overview

Randox are the only supplier in WS2 to provide both test kits and lab tests. Their contract was predicated on the basis they would provide an end to end solution to process lab tests for of their own kits per day. This was under the assumption HMG would provide assistance to obtain equipment to fill their capability gap. Currently only Randox labs can process Randox test kits in a closed loop, however there is a widening delta emerging between test kits issued and lab capacity.

To date Randox has:

- Provided c. test kits
- Forecast to provide c. further test kits at an approximate rate of test kits per day
- Lab capacity to test tests per day

Randox had stated their lab capacity to be tests per day on 30 April 2020 however on 5 May 2020 they reported operational issues that reduced their capacity to tests per day, creating a backlog of tests and a spike in void rates. They have subsequently revised their lab capacity to per day, and remain confident they can ramp up to tests per day although are yet to commit to a firm date to achieve that target.

Prior to Randox's operational issues materialising we reviewed options to address the test kits supply v lab capacity imbalance making three recommendations. All recommended options were accepted. Progress has been made however a contract change would be required to make further progress and achieve the best outcome for the programme.

To mitigate Randox's immediate operational issues we have now validated:

- Randox test kits can be processed in lighthouse labs although throughput is lower, effectively reducing lab capacity by 33%.
- A manual process to return results to patients has been implemented
- Integrating Randox into the NTP digital solution would mitigate the impact on throughput and lab capacity

Our strong view is the contract is for payment of per test processed and result communicated. This difference equates to a difference of around , their ability to distribute swabs far out strips their ability to process them.

To resolve this issue we are beginning negotiations on a new finance model which delineates between test kit distribution and test processed in the lab.

We also hope negotiations achieve:

- Their agreement to use their testing kits in other labs
- Cooperation to align and integrate into the NTP digital solution

•

#### To support our commercial negotiations we request the following:

- 1. Re-iterate our desire to work with Randox to support the NTP, supportedby:
  - Enable separate purchase of the swab test kits and the labservice
  - Cooperation to align and integrate into the NTP digital solution
  - Improved price for lab service processing tests
- 2. Confirm HMG will play no further role in requisitioning equipment for Randoxlabs
- 3. Concise and focused management information

# To: SoS, PS(I), Baroness Harding Second Permanent Secretary

From:

Clearance Date: 15 July 2020 Copy:

# Randox

Issue	As part of assurance processes to integrate Randox into the wider testing programme, random sampling of their swabs for sterility was carried out. Randox have so far been unable to produce sufficient documentation to demonstrate the certification of their kits.
	Currently there are approximately unregistered Randox test kits within the satellite network that remain unregistered.
Timing	Urgent – communication to 5,000 care homes needs to be issued this evening in order to minimise the risk of usage
Recommendation	<ul> <li>That you indicate whether or not you wish to make a pre-emptive WMS about this issue, noting the number of users impacted.</li> </ul>

#### Background

- Randox laboratories has purchased a number of swabbing kits for use within the National Testing Programme. of these kits were purchased from a Chinese supplier named These were kitted by Randox and to date have been shipped to the National Testing Programme.
- 2. Until recently Randox were contractually responsible for the quality of the test kits, including supply chain assurance. In March Randox was evaluated and approved for use as a 'closed-loop' (standalone kits and laboratory processing) end-to-end diagnostic provider in Pillar 2 by PHE. As such, the

Pillar 2 due diligence and validation process applied to Kingfisher kits was not performed for Randox-provided kits at this time.

3. A process was initiated in June to integrate Randox into the wider testing programme. An issue arose at this stage when Randox notified the NTP of their intention to release a new kit that had a breakpoint. NTP, at this stage, asked for it to be confirmed that this new breakpoint was covered by a CE marking, on the advice of MHRA.

#### Randox Swab Sample Assessment:

- 4. On Friday 10th July, there was an escalation to the NTP clinical and public health advisers ( ) that, while these kits were CE marked, they lacked the appropriate documentation of this or appropriate assurance of the sterility of the swabs. With the information provided by to date, this won't be immediately possible. Randox were advised to consider applying for a derogation from MHRA for their home sampling kits. Upon discussions with MHRA and other clinical advisors, it was decided that a random sample of swabs should be tested to see if they were sterile. If sterility could be shown this would have helped with the evidence for the derogation.
- 5. The results that were returned to us suggested only were negative (though swabs were tested in batches of 3). PHE have advised that these results are unlikely to be due to the manner in which this random testing was carried out. In essence these swabs should not be used
- 6. Further risks include:
- •

- 7.
- The documentation they have previously provided demonstrates sterility of other products,
- They have asked (the manufacturer) to work with its 'Notified Body' (i.e. statutory regulatory intermediary) to update their EC certificate to cover the swabs
- They are not in control of the timeline for this being completed. stressed the utmost urgency of this being done swiftly and they have
committed to speaking to to expedite the process (N.B. they commented that have been very cooperative to date and that they have confidence in them)

8. Immediate Recommendations:

#### •

## Next Steps:

9.

This should be undertaken in a

format recommended by PHE;

- 10. That the NTP will urgently review all other kits in circulation from other suppliers to make sure we have the appropriate assurance for those.
- 11. We will rapidly establish a process whereby care homes impact can secure safe replacement kits for testing of their residents and staff.

## **Communications:**

Handling Sequence::

- Email to care homes asking to cease use of Randox kits, and supporting call script (Weds 15 July PM)
- Potential WMS issued Thurs 16 July TBC
- Media and Q&A lines in place

Note: T&T press release and weekly stats issued Thurs 16 July 11 am - data will show drop in satellite turnaround time and annex on care home testing stats, showing that by 8 July, more than a million tests had been carried out as part of regular and routine testing in care homes.

#### Toplines:

Draft WMS - Reassuring, sterile and factual in tone

'We have very high safety standards and found this doesn't meet our standard.

As a precautionary measure we have recalled all Randox kits currently in circulation to enable further safety testing of the kits.

It has come to our attention that some Randox test kits may not meet our high safety standards. Therefore as a precautionary measure while we investigate further we have ceased the use of Randox kits for covid-19 testing.

All care homes will be provided with replacement kits from another supplier. All care homes should receive replacement kits within 3 weeks.

No results are affected

Message is cease

Identified a number of kits in circulation without appropriate certification As a precautionary measure'

#### Annex: Comms materials

## Q&A:

- Until June, Randox was legally responsible for the certification of their test kits;
- This issue arose as we recently sought to integrate Randox into wider testing programme and undertook assurance activity in accordance with this.

## Q. How have they failed safety standards?

We have high safety standards for all covid-19 test kits which involve...xyz. All Randox test kits have a safety certificate, however, following a recent assurance of safety checks the supply chain we found that one Randox supplier lacked supporting documentation for [sterility of the swabs]. Therefore, as a precautionary measure we have ceased the use of all Randox test kits while we investigate further.

# Q. Should care homes be concerned for the welfare of anyone who has been tested using these kits?

No. We are ceasing use of Randox kits as a precautionary measure while we investigate the issue further. All Randox kits provided had a safety certificate.

#### Q. Does this bring into question any historic test results they have received?

No. Any results from covid 19 testing are not affected and test users should continue to follow instructions to isolate and contact trace if tested positive.

#### Q. When did DHSC/T&T learn of the issue?

This issue came to the department's attention on 14<sup>th</sup> July, following discussions with PHE etc, we notified care homes to cease using Randox kits on 15 July.

## Draft Note to Care Homes (to issue 8pm 15<sup>th</sup> July):

Hello,

You are receiving this email because you have been sent Randox coronavirus test kits from the Department for Health and Social Care's National Testing Programme, to conduct regular whole home testing in your care home.

It is has come to our attention that some Randox test kits may not meet our high safety standards for coronavirus testing. As a precautionary measure we are ceasing all use of Randox test kits and are recalling all unused kits.

We ask that you **immediately stop all coronavirus testing** in your care home using Randox kits.

Note that this only applies for Randox tests, if you have any non randox (also known as Kingfisher) kits from the National Testing Programme, then you are able use these to continue testing.

Please store all of your unused Randox kits in a safe place to ensure that they are not used or mixed with other test kits. One of our team will be in contact with you next week to confirm what you should do with these next.

You can apply for replacement test kits using our website at <u>https://request-testing.test-for-coronavirus.service.gov.uk/</u> we will send these kits to you as quickly as we can, but please expect this to take up to 2 weeks.

If you have already used some of the kits that we sent you then do not worry, used kits can still be collected for processing as per normal arrangements, however, you must not conduct any further testing using these kits.

#### How can I find out more information?

If you have any further questions please join our care home testing webinars tomorrow, where we will cover this issue in detail. You can sign up at: <a href="https://event.on24.com/wcc/r/2375949/724EF6345473A192F6B9C19334699A29/10">https://event.on24.com/wcc/r/2375949/724EF6345473A192F6B9C19334699A29/10</a> 77953

**Covid-19 National Testing Programme** 

Ref 31

From: Sent: 16 July 2020 12:02 To: Subject:

@dhsc.gov.uk>

PM worried about swabs and the number of swabs that turned out not to be sterile when tested. Randomly sampled . All swabs may have problems with bacteria. What evidence do we have that the evidence is confined to randox or could there be infectious swabs.

Is it a batch issue at manufacture or wider issue in production. All swabs from this manufacturer, not all swabs.

- sought microbiology advice, they're all skin bugs that would get from touching stuff. Swabs need to be sterile bc you want them to grow bacteria. Are you inoculating ppl with something new which could cause illness. No bacteria likely to cause significant disease. Unlikely to have made anyone ill.

PM important for confidence in regime to say it's a medical opinion. to restore confidence we should figure out what's going on and test all swabs an all manufacturers to seek assuments.

PM issue with these swabs as far as wel know.

SofS randox delivery is separate from the large part of the testing. Randox have separate end to end contract.

identified bc looking to use randox in our own system. We're responsible for ours but randox in contract have they are responsible.

Do we know swabs aren't anywhere else. yes, not in the UK.

SofS, should test across board

Pm are we happy with the process e.g. immediately checked. Will ppl say why did so many get into system.

- does it invalidate test response?

PM do we have records of ppl? we can identify majority but potentially not all e.g. depending on whether care homes record.

Also risk of anxiety higher than effect of swabs

Are we confident on the lot. need to test and find no significant issues. PM randox big strike rate, fortify backward line of defence. Worried all swabs have issue. Not things that can kill, nothing to see. What if issue with all

V unlikely to have affected swabs we buy as we don't do it retrospectively. High degree of confidence that it's not in lighthouse. Thinks we should say highly unlikely to have caused harm, pause is for precautionary reason whilst carrying out test and no evidence that affected other swabs.

Randox website is testing organisation and pride themselves on testing, do they do anything else with NHS

SofS going in we didn't have a big diagnostic capability and randox were one of the biggest. Also

do a lot in NI health service and do a lot in NHS across UK. Expanded massively as part of testing and is a huge part of portfolio.

they are apologetic and stressed need for being collaborative.

Likely to be pulling together their defence as they

also test sterility.

PM no conclusive answer about all swabs being in the randox swabs.

SofS what want to do in terms of going public. Doing statement on Leicester and include some sentences. PM be transparent but need to not cause worry. Front it up, appropriate in this context mr speaker to say have identified swabs and will be testing, otherwise have utmost confidence. PM important decision is on medical grounds it's not necessary to contact either or trace SofS have paused use of pending testing. SofS don't need to contact individuals.

Two sentences

Department of Health & Social Care Private Secretary to Secretary of State for Health and Social Care 9<sup>th</sup> Floor, 39 Victoria Street, SW1H 0EU Ref 32

From: PsBethell Sent: 07 August 2020 16:10 To: @randox.com>; PsBethell Cc: Special Advisers @dhsc.gov.uk> Subject: RE: Letter from Dr Peter FitzGerald

Thanks , it will be a Microsoft Teams call as Lord Bethell not in the office and so a Private Secretary can join. will be joining the call from our side as well.

Best,

| Senior Private Secretary |

From: @randox.com> Sent: 07 August 2020 15:53 To: PsBethell Cc: Special Advisers @dhsc.gov.uk> Subject: RE: Letter from Dr Peter FitzGerald

Dear

Many thanks for your email and apologies for the slow response.

Dr FitzGerald is available to take a call from Lord Bethell at 4pm today. What is the best number to reach him on?

Best regards,

## PA to Dr Peter FitzGerald CBE FREng DL, Managing Director

Randox Laboratories Ltd. 55 Diamond Road Crumlin Co. Antrim United Kingdom BT29 4QY



From: PsBethell Sent: 07 August 2020 13:58 To: @randox.com> Cc: Special Advisers @dhsc.gov.uk> Subject: FW: Letter from Dr Peter FitzGerald

Hi

,

DH SoS is now on A/L, but Lord Bethell would be happy to take a short call to discuss the attached this afternoon if helpful. He has availability at 4pm?

;

Best,

| Senior Private Secretary |

From: @randox.com> Sent: 07 August 2020 11:54 To: @dhsc.gov.uk> Subject: Letter from Dr Peter FitzGerald

Dear

Hope you are well.

,

Dr FitzGerald asked that I forward you the letter sent to Matt Hancock yesterday evening. Please see attached.

Please do not hesitate to contact me should you require anything further.

Best regards,

#### PA to Dr Peter FitzGerald CBE FREng DL, Managing Director

Randox Laboratories Ltd. 55 Diamond Road Crumlin Co. Antrim United Kingdom BT29 4QY



Managing Director Randox Laboratories Limited 55 Diamond Road Crumlin Co Antrim BT29 4QY

Tel: E:

@randox.com

(R)

Rt Hon Matt Hancock MP House of Commons London SW1A0AA

6<sup>th</sup> August 2020

Dear Secretary of State,

I am writing to you to express concern over the potential consequences of the swab issue in which we are engaged with DHSC on the Government's Pillar 2 Testing Programme.

As I am sure you are aware it is, in practice, impossible to ensure absence of contamination on any swabs. If the Government's position is that it is a health risk to use any swab that is not absolutely sterile, it has major implications for not only the healthcare industry but all other industries which use these swabs.

The DHSC is anxious that we recall our kits from the care homes which we have always stated we are willing to do. However, we feel that if it is felt necessary for Randox kits to be withdrawn on the basis of sterility, then surely this must also apply to all other swabs in use in the COVID Testing Programme. Indeed, we have not been successful in obtaining the name of a suitable replacement for our swabs from the DHSC despite there being upwards of 60 different swabs in use in the Programme.

The consequence of this action, if the Department is to act consistently, and recognise that no supplier can supply 100% sterile swabs, would be to end the Testing Programme. Which in our opinion, would cause a public outcry.

However, as the issue is one of lack of CE certification for the swabs, Randox would be willing to voluntarily initiate a recall on this basis. We would appreciate your Department's support in a constructive and positive press release for Randox and therefore the Programme. Yours sincerely,

Ment

Dr Peter FitzGerald

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antr im, BT29 4QY, United

I marketing@randox.com I randox.com

...

## @s.whatsapp.net@WhatsApp" 17/9/2020, 14:12

On a positive note I visited Randox today (for whom I am a paid consultant) for the first time since February.What they have achieved is astonishing. invested,800 new skilled staff,still recruiting at 40/week Covid tests carried out,current Covid testing capacity /day,actually achieving /day,aiming for /day by end October,4 new labs built and one more on the way.The staff have a huge pride in their achievement but output could be further improved by 1.Ensuring consistent delivery of steady volumes of samples. 2.Establishing a standard tube to enable wider use of robots. Finally there is widespread exasperation that Randox's achievements have

not been promoted.

.Peter FitzGerald is

interested in making a significant further investment in new testing facilities based in GB.It would be really good if you

could revisit even briefly and privately to discuss the longer term future with him.

Me <"

@s.whatsapp.net@WhatsApp"> 17/9/2020, 20:52

Hi Owen,

On Randox, I'm really thrilled they are performing so well. My team really happy with their expansion. Totally agree about need for tube standardisation.

Free to talk tmrw?

"

## @s.whatsapp.net@WhatsApp" 22/10/2020, 07:26

Best of luck later . in The Guardian yesterday yet again ran the story that you only gave Randox the testing

contract because I am a paid consultant.

.If it comes up can you kill

this once and for all as I know absolutely nothing about the contract ?Many thanks .

## **Me <"** @s.whatsapp.net@WhatsApp"> 22/10/2020, 09:46

Of course

...

.whatsapp.net@WhatsApp" 24/10/2020, 14:21

Just back from Randox (for whom I am a paid consultant ). They have just completed tests. Current capacity is /day

(despite still getting 6 or 7 different sized tubes) and they had planned to move up to /day this weekend.However

,deliveries although improved have been erratic.Worse ,to prioritise turnaround time they will only receive Sunday,

Monday and Tuesday.So over half their capacity will be idle.A month ago I saw a prototype robot handling

tubes.Yesterday I saw six in full production.They are now making real progress on automation of other processes.Peter

has committed investment by the end of December and has recruited new staff.He is predicting /day by

January and /day by February with a new high throughput line.He is confident that a new purpose built plant ,possibly

in GB ,could handle tests per day but he is looking for reassurance through a long term strategic partnership with

DHSC.This could provide capacity for future national pandemics and in non epidemic times population prescreening tying

in with Early Disease Detection Research Project. They have built up excellent relations with DHSC officials

who they find professional and responsive but clearly any major strategic decisions would have to be taken at your

level.Peter would like to talk to you soon.The fifth new laboratory built this year will be finished in early December.It would

be great if you could visit briefly to see what they have achieved this year. I have more to tell which is too long for a text. I'm

free all weekend.Please ring whenever suits.

E02714158

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