UK NEQAS
International Quality Expertise

Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
Distribution : **4885**	Page 1 of 14
Dispatch Date : 25-Jun-2020	

Intended Result		Your Report	Your Score
Specimen 6330	SARS-CoV-2 not detected	SARS-CoV-2 not detected	Not scored
Specimen 6331	SARS-CoV-2 not detected	SARS-CoV-2 not detected	Not scored
Specimen 6332	SARS-CoV-2 detected	SARS-CoV-2 detected	Not scored

Distribution 4885 is the second pilot studies for the UK NEQAS Molecular Detection of SARS-CoV-2 scheme.
As from the 3rd August 2020, this scheme will go live (non accredited). A separate registration process for the live EQA scheme is required. If you are interested to participate and have not done so, please contact us by email : 5.1.2e @ukneqasmicro.org.uk for further information.

Specimen comments:
For this pilot specimens 6330, 6331 and 6332 were distributed.

Specimen 6330
Represented a simulated nasopharyngeal swab from a 17-year-old female complaining of fever and sore throat for the last 10 days.
The specimen was **negative** for SARS-CoV-2. 99.2% of participants reported the intended result. One participant reported an invalid result.

Specimen 6331
Represented a simulated nasopharyngeal swab from a 50-year-old female with history of asthma presenting with shortness of breath and fever for the last 4 days.
The specimen was **negative** for SARS-CoV-2. 97.6% of results returned for this specimen were as intended. 1 participant reported the specimen as positive. 2 returned responses indicated that an invalid result was returned by the testing platform.

Specimen 6332
Represented a simulated nasopharyngeal swab from an asymptomatic 28-year-old male paramedic who had attended to a patient with respiratory distress 7 days ago.
The specimen was **positive** for SARS-CoV-2. 99.2% of participants reported the intended result for this specimen. One response indicated that an invalid result was returned by the testing platform.

The histograms on page 2 and subsequent pages display results obtained using different nucleic acid detection methods and list extraction and amplification platforms used by participants. The method used in your laboratory is indicated by an arrow. As this distribution is a pilot, the specimens are not scored.

Comments regarding the distributed SARS-CoV-2 genetic material:
The distributed material positive for SARS-CoV-2 RNA contained recombinant SARS-CoV-2 genetic material and is non infectious. Participants using internal PCR controls with cellular targets could expect those controls to fail.
The material was intended to be shipped frozen. Several participants reported receiving thawed specimens; however, based on returned results thawing did not have an adverse impact on the stability of the specimens.

Please see pages 11 to 14 for further comments

Enquiries: Written enquiries about this distribution should be addressed to 5.1.2e at 5.1.2e **@ukneqasmicro.org.uk** .

Report authorised by: 5.1.2e for UK NEQAS Microbiology

Operated by Public Health England
National Infection Service
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PO Box 63003
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Published at 13:08 on Thursday 23 July 2020

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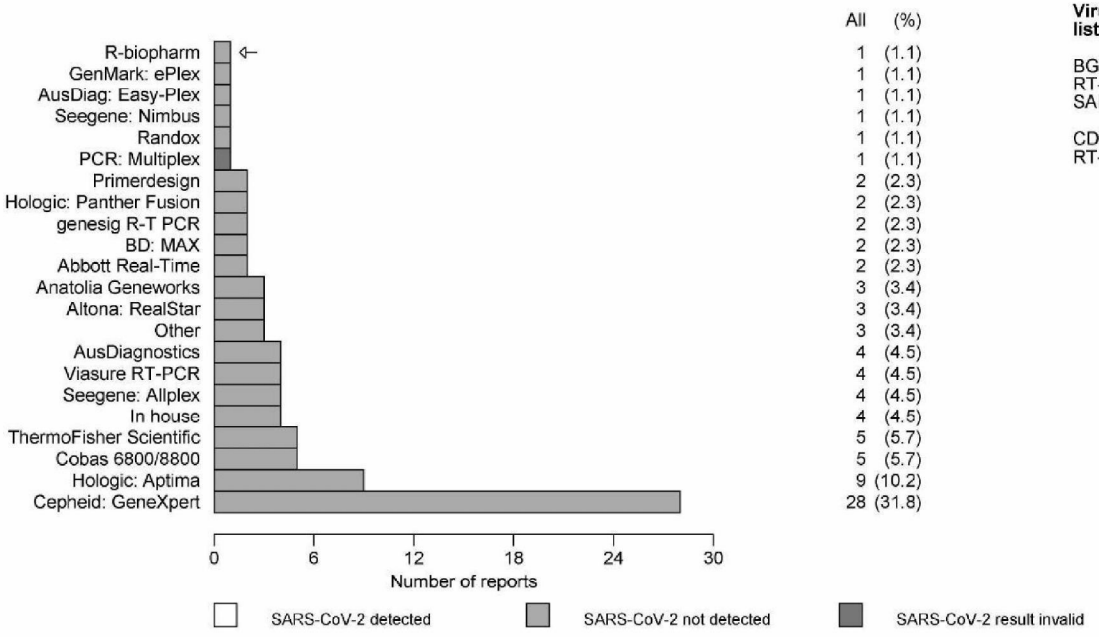
Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimens 6330 and 6331 were negative containing only the specimen matrix. Specimen 6332 was positive for SARS-CoV-2 RNA.

Specimen : 6330

Clinical details: Nasopharyngeal swab from a 17-year-old female complaining of fever and sore throat for the last 10 days

Intended result: SARS-CoV-2 Not Detected

SARS-CoV-2 nucleic acid detection results by assay



Virus detection methods listed under 'Other':

BGI's Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2

CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

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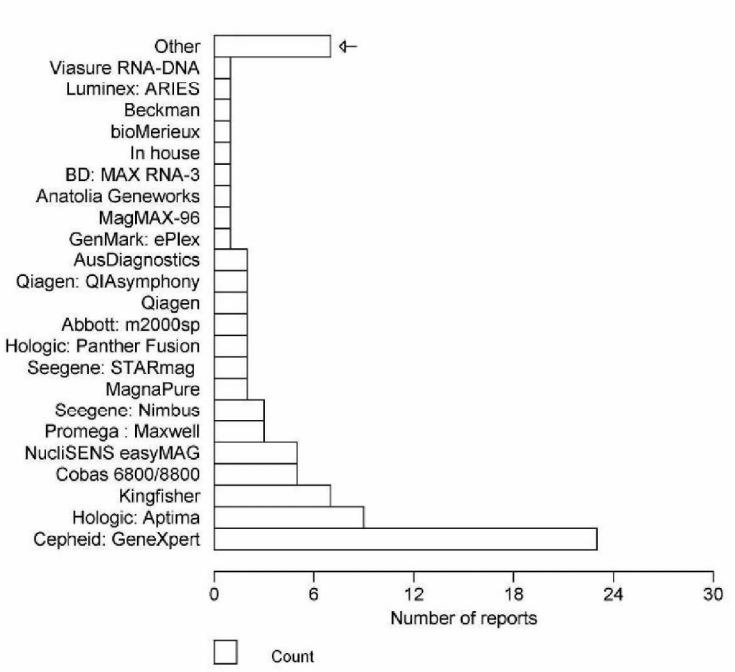
Specimen : 6330

Clinical details: Nasopharyngeal swab from a 17-year-old female complaining of fever and sore throat for the last 10 days

Intended result: SARS-CoV-2 Not Detected

Methods/platforms used for nucleic acid extraction



Virus extraction methods listed under 'Other':

PerkinElmer chemagic Prepito

molg3n PurePrep Pathogens Kit

Zymo Research *Quick* -DNA/RNA Viral Kit

Liferiver Automatic Nucleic Acid Extraction system

Canvax HigherPurity Viral RNA Extraction Kit

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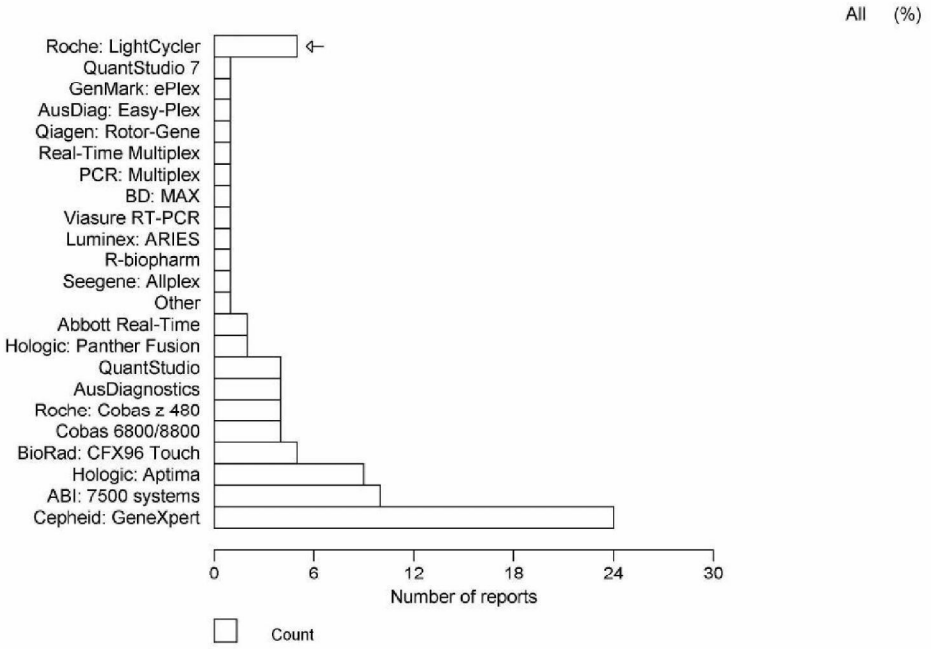
Specimen : 6330

Clinical details: Nasopharyngeal swab from a 17-year-old female complaining of fever and sore throat for the last 10 days

Intended result: SARS-CoV-2 Not Detected

Methods/platforms used for nucleic acid amplification



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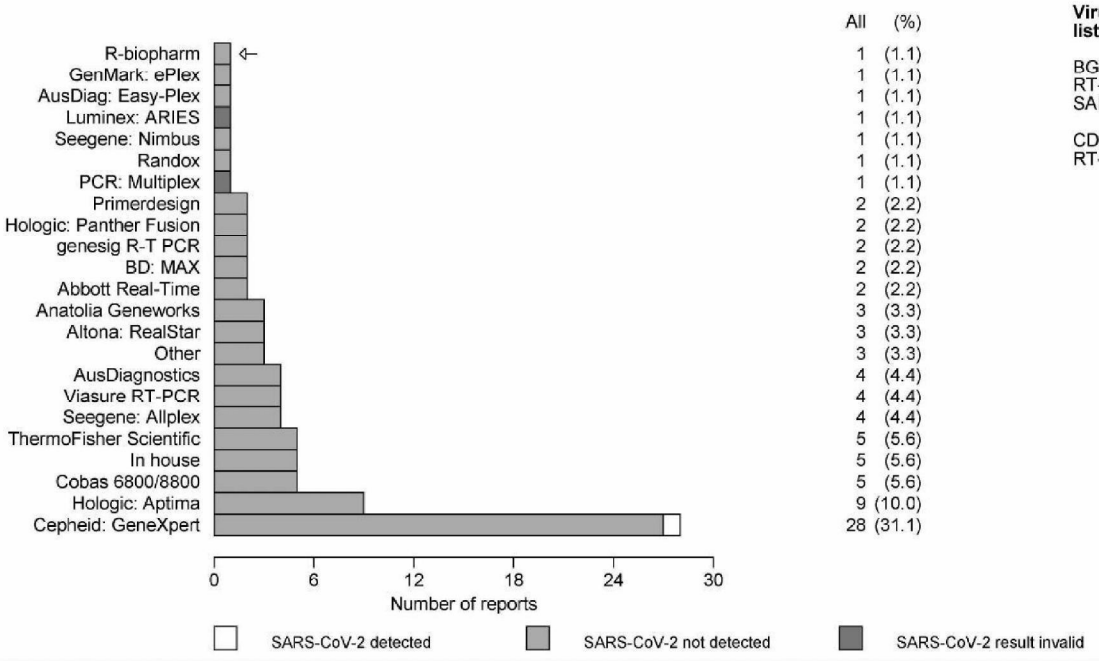
Specimen : 6331

Clinical details: Nasopharyngeal swab from a 50-year-old female with history of asthma presenting with shortness of breath and fever for the last 4 days

Intended result: SARS-CoV-2 Not Detected

SARS-CoV-2 nucleic acid detection results by assay



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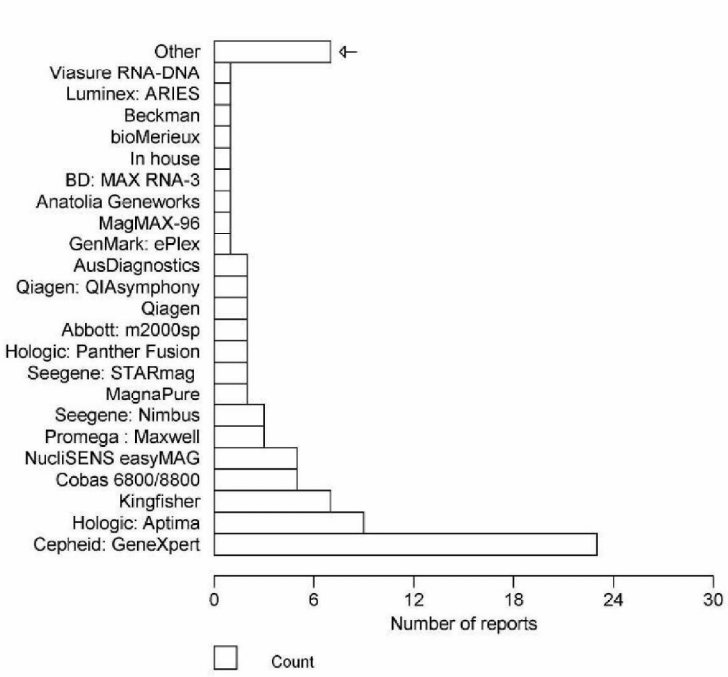
Specimen : 6331

Clinical details: Nasopharyngeal swab from a 50-year-old female with history of asthma presenting with shortness of breath and fever for the last 4 days

Intended result: SARS-CoV-2 Not Detected

Methods/platforms used for nucleic acid extraction



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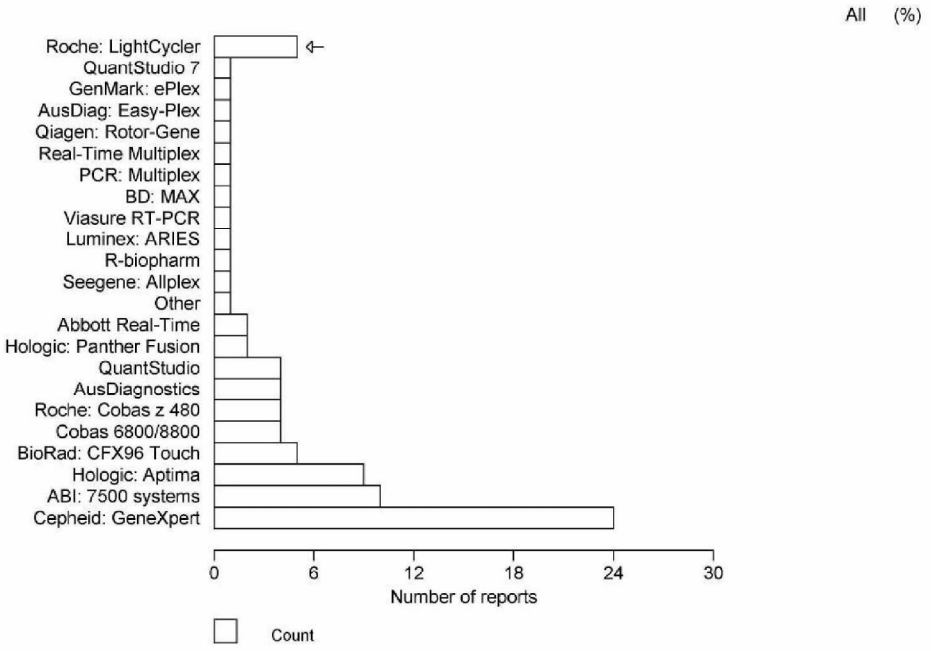
Specimen : 6331

Clinical details: Nasopharyngeal swab from a 50-year-old female with history of asthma presenting with shortness of breath and fever for the last 4 days

Intended result: SARS-CoV-2 Not Detected

Methods/platforms used for nucleic acid amplification



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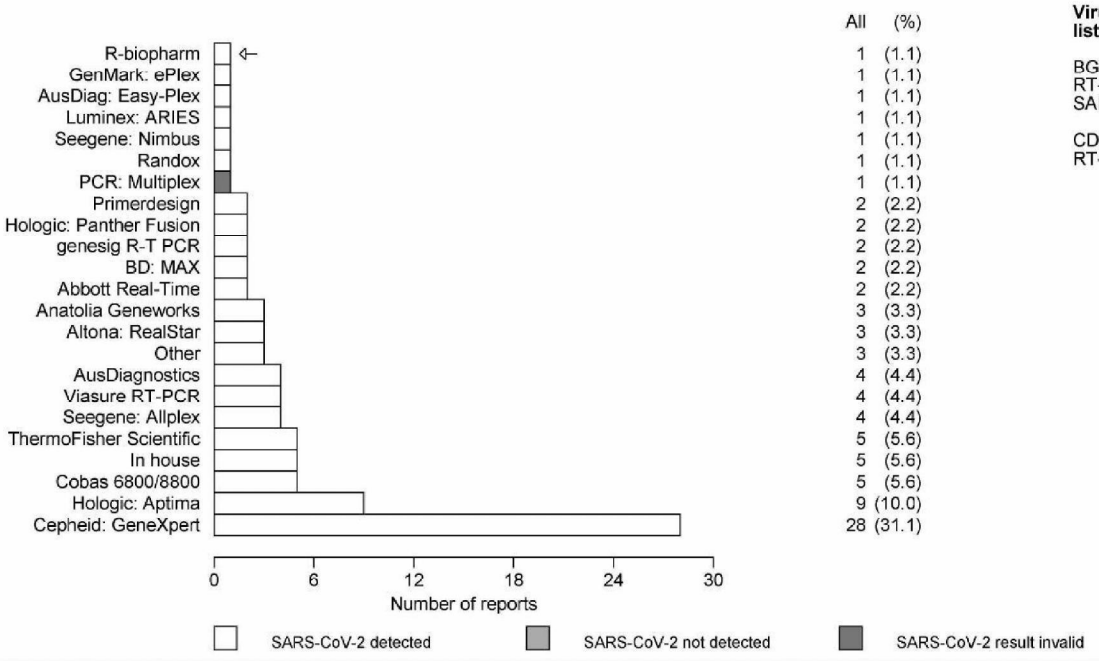
Specimen : 6332

Clinical details: Nasopharyngeal swab from an asymptomatic 28-year-old male paramedic who had attended to a patient with respiratory distress 7 days ago

Intended result: SARS-CoV-2 Detected

SARS-CoV-2 nucleic acid detection results by assay



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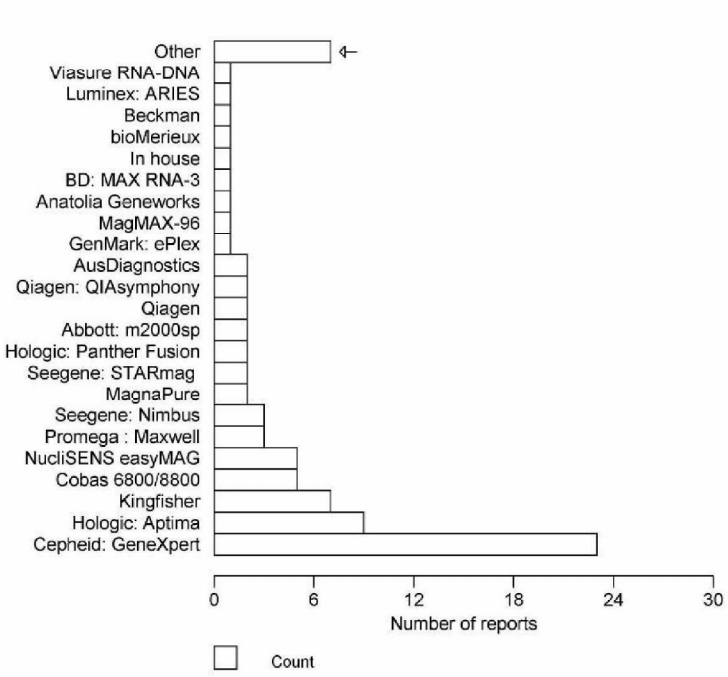
Specimen : 6332

Clinical details: Nasopharyngeal swab from an asymptomatic 28-year-old male paramedic who had attended to a patient with respiratory distress 7 days ago

Intended result: SARS-CoV-2 Detected

Methods/platforms used for nucleic acid extraction



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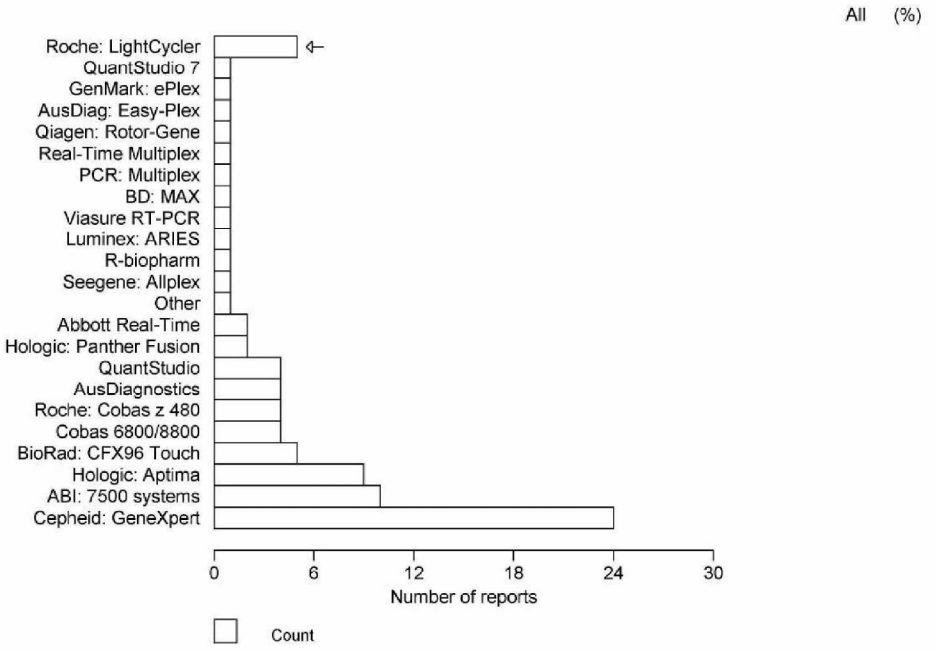
Specimen : 6332

Clinical details: Nasopharyngeal swab from an asymptomatic 28-year-old male paramedic who had attended to a patient with respiratory distress 7 days ago

Intended result: SARS-CoV-2 Detected

Methods/platforms used for nucleic acid amplification



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Comments on Distribution 4885

Latest figures from the World Health Organisation (WHO) at the time of release of this report (22nd July 2020) suggest that the number of cases of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) causing COVID- 19 is on the rise.

To- date, there are 14 731 563 confirmed cases of COVID 19 reported in 216 countries worldwide. The number of confirmed death caused by COVID 19 now amounts to over 611 000. (https://www.who.int/emergencies/diseases/novel-coronavirus-2019).

Evidence suggest that COVID 19 is transmitted from person to person through contact with respiratory droplets generated by breathing, sneezing, coughing, but also through the transfer of virus from contaminated fomites to the mouth, nose or eyes. But so far transmission through fomites has not been documented.

Recent updates from European Centre for Disease Prevention and Control (ECDC) (https://www.ecdc.europa.eu/en/covid-19/latest-evidence/transmission) suggest that in infected individuals, SARS-CoV-2 RNA has been identified at least 2 days prior to the onset of symptoms and can persist for up to 8 days in mild infections extending to a longer period for more severe cases, peaking 2 weeks post infection. Viral RNA was detected in nasopharyngeal swabs from infected adults up to 63 days and in faeces of paediatric patients 30 days after infection.

In this second pilot distribution of the UK NEQAS Molecular Detection of SARS-CoV-2 EQA, 127 sets of specimens were sent to various laboratories. Of these, 110 returned results before closing date, representing a participation rate of 86.6%.

This distribution consisted of 3 specimens; 6330, 6331 were negative and 6332 was positive for SARS-CoV-2 RNA.

The overall performance in this distribution was excellent with 98.6 % of participants returning the intended results.

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Of the 110 participants returning results for this distribution, 63 provided a Ct value for specimen 6332. These values are illustrated in table 1 below.

Table 1: Ct values reported by participants

Lab	Ct value	Lab	Ct value
1	15.84	33	31.3
2	18.03	34	31.4
3	18.34	35	31.4
4	18.62	36	31.4
5	19.8	37	31.4
6	22.21	38	31.42
7	23.32	39	31.65
8	24.01	40	31.67
9	25	41	31.98
10	25.28	42	32
11	25.9	43	32.2
12	26	44	32.3
13	28.11	45	32.3
14	28.37	46	32.4
15	28.62	47	32.4
16	28.69	48	32.4
17	28.75	49	32.6
18	28.78	50	32.7
19	29	51	32.83
20	29.06	52	33
21	29.43	53	33
22	29.447	54	33.19
23	29.49	55	33.2
24	30.22	56	33.59
25	30.44	57	33.85
26	30.64	58	35.6
27	30.9	59	36
28	30.9	60	36.8
29	31	61	37.3
30	31	62	38
31	31	63	39.9
32	31.2		

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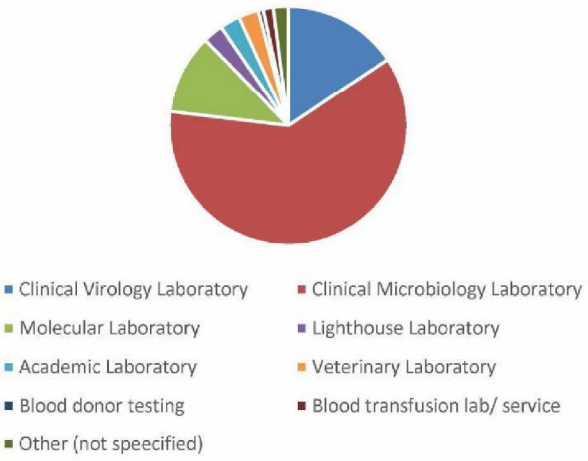
The Ct values ranged from a minimum of 15.84 to a maximum of 39.9. The mean Ct value reported was 29.9 with a standard deviation of 4.67 and a median of 31.1. The Ct values collected so far indicate that the sensitivity of the assays employed by the laboratories varied. The sensitivity of the assays are influenced by various factors including amount of starting material, elution and amplification volumes and also the gene targets used (**DOI:** 10.1128/JCM.00310-20).

A questionnaire was sent as part of the registration process for this distribution. Part of the data collated is presented in this report and further data will be presented in subsequent reports.

Of those laboratories registered for the second distribution of the Molecular detection of SARS-CoV-2 EQA, 61.2% were clinical microbiology laboratories, 15.7% clinical virology laboratories, 10.9% were molecular laboratories. Academic, veterinary and lighthouse laboratories accounted for 2.7% each, whilst blood donor testing and blood transfusion laboratories accounted for an aggregate of 2.0% and the remaining 2.1% were manufacturers and suppliers of diagnostic kits as illustrated in figure 1 below.

Figure 1: Type of laboratories participating in EQA



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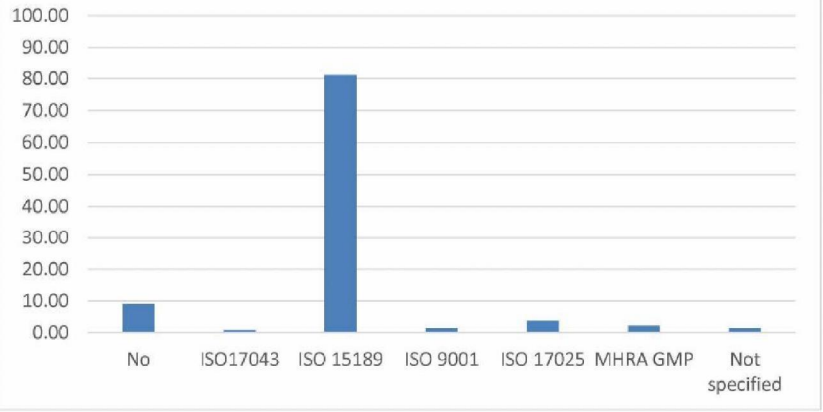
All participating laboratories (100%) have standard operating procedures (SOPs) in place for molecular detection of SARS-CoV-2, 93.3% use commercial kits whilst 6.7% of laboratories use in house kits.

One hundred and thirty three responses were received on accreditation status: 81.2% were accredited to ISO 15189 standards, 9.02% of laboratories were not accredited, 1.5% did not specify the standards of their accreditation. Other standards included ISO 17043 (0.75%), ISO 9001 (1.5%), ISO 17025 (3.76%) and 2.26% of participants adhered to MHRA GMP standards.

The data is presented in figure 2 below.

Figure 2 Accreditation/ certification status of participating laboratories



As from the 3rd of August, the UK NEQAS Molecular detection of SARS-CoV-2 EQA will go live and will be distributed on a monthly basis.

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