

	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 1 of 14
	Dispatch Date : 21-May-2020	

Intended Result	Your Report	Your Score
Specimen 6327 SARS-CoV-2 Detected	SARS-COV-2 Detected	Not scored
Specimen 6328 SARS-CoV-2 Not Detected	SARS-COV-2 Not detected	Not scored
Specimen 6329 SARS-CoV-2 Detected	SARS-COV-2 Detected	Not scored

Distribution 4884 is a pilot distribution for the EQA scheme Molecular Detection of SARS-CoV-2 due to be launched by UK NEQAS Microbiology.

**Specimen comments:**

For this pilot specimens 6327, 6328 and 6329 were distributed.

**Specimen 6327**

Represented a simulated nasopharyngeal swab from a diabetic 40-year-old female complaining of fever and sore throat for the last 5 days. The specimen was **positive** for SARS-CoV-2. All participants reported the intended result for this specimen.

**Specimen 6328**

Represented a simulated nasopharyngeal swab from a 82-year-old male in a residential home with cough, headache and exhaustion for the last 7 days. The specimen was **negative** for SARS-CoV-2. 95.7% of results returned for this specimen were the intended result. 5 returned responses indicated that an invalid result was returned by the testing platform.

**Specimen 6329**

Represented a simulated nasopharyngeal swab from a 20-year-old university fresher with shortness of breath, diarrhoea and fever for the last 4 days. The specimen was **positive** for SARS-CoV-2. 99.1% of participants reported the intended result for this specimen. One unspecified platform failed to detect SARS-CoV-2 RNA.

The histograms on page 2 and subsequent pages display results obtained using different viral detection methods and list extraction and amplification platforms used by participants. The method(s) used in your laboratory are indicated by an arrow(s). 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. 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 .

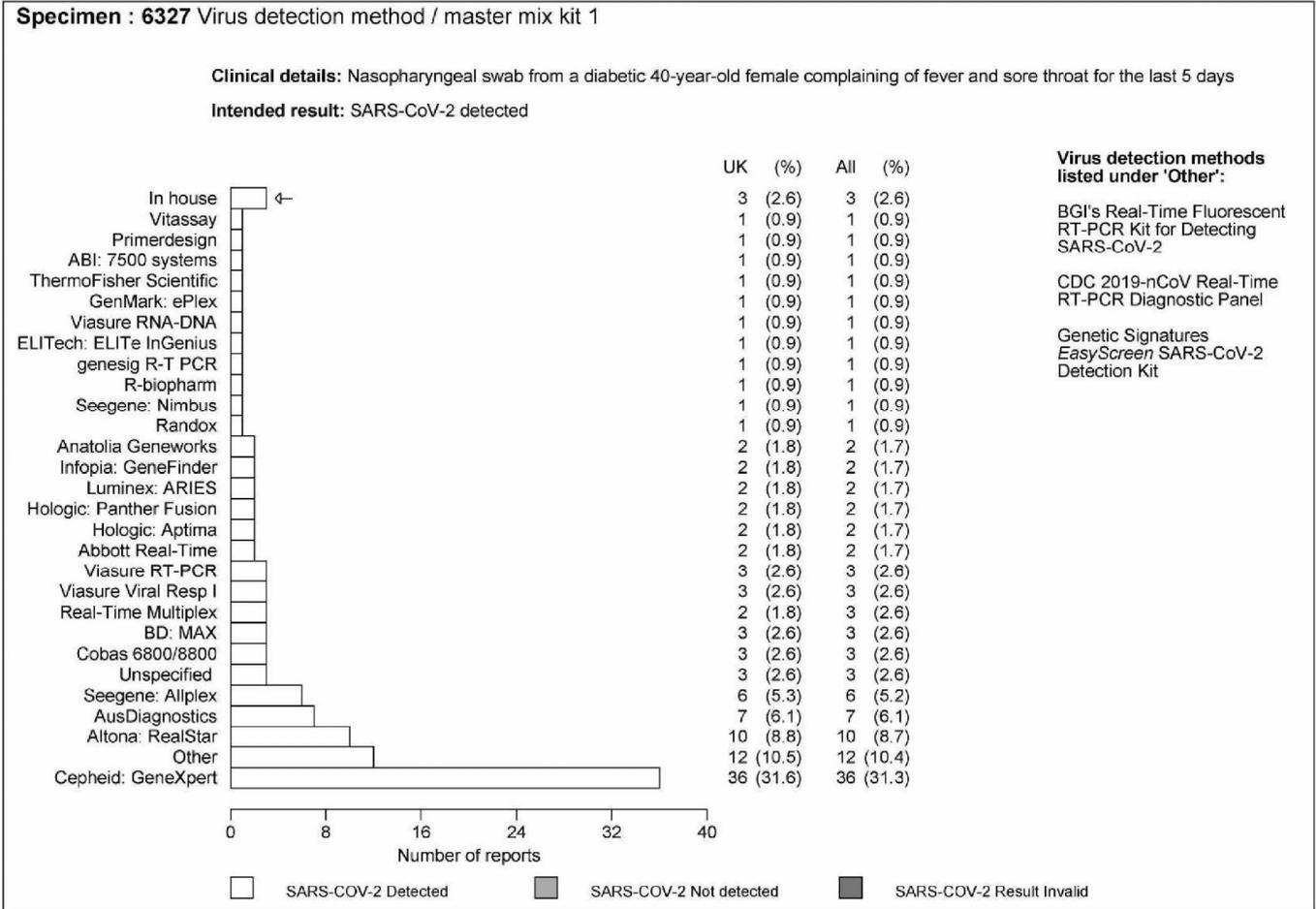
**Acknowledgements:** This pilot was ran as a collaboration between the UK NEQAS consortium and National Institute for Biological Standards and Control (NIBSC). We thank colleagues across UK NEQAS centres and NIBSC for their work on this pilot.

**Report authorised by:** 5.1.2e for UK NEQAS Microbiology



	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 2 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.



	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 3 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

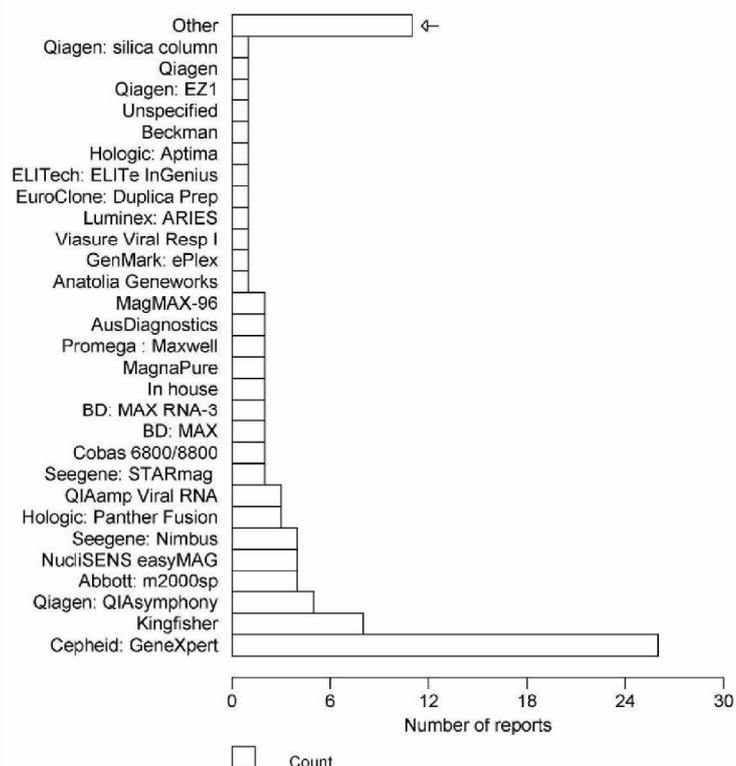
### Specimen : 6327 Virus extraction method 1

**Clinical details:** Nasopharyngeal swab from a diabetic 40-year-old female complaining of fever and sore throat for the last 5 days

**Intended result:** SARS-CoV-2 detected

#### Virus extraction methods listed under 'Other':

MagPurix  
PerkinElmer chemagic Prepito  
molg3n PurePrep Pathogens Kit  
altona Diagnostics AltoStar  
IndiMag Pathogen Kit  
Zymo Research Quick-DNA/RNA Viral Kit  
SAMBA II  
MGI Nucleic Acid Extraction Solution



Organised jointly by UK NEQAS Consortium and NIBSC

© Copyright. The data in UK NEQAS reports are confidential. Participants must consult the scheme organiser before quoting data from the scheme.  
UK NEQAS for Microbiology  
PO Box 63003  
London NW9 1GH

Published at 15:11 on Friday 5 June 2020

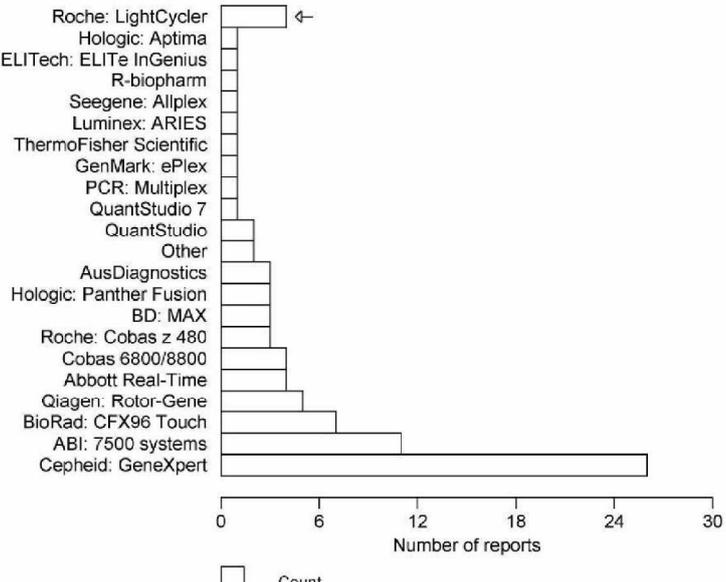
	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 4 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

**Specimen : 6327** Amplification platform 1

**Clinical details:** Nasopharyngeal swab from a diabetic 40-year-old female complaining of fever and sore throat for the last 5 days

**Intended result:** SARS-CoV-2 detected



Platform	Number of reports
Roche: LightCycler	4
Hologic: Aptima	1
ELITech: ELITe InGenius	1
R-biopharm	1
Seegene: Allplex	1
Luminex: ARIES	1
ThermoFisher Scientific	1
GenMark: ePlex	1
PCR: Multiplex	1
QuantStudio 7	1
QuantStudio	1
Other	1
AusDiagnostics	2
Hologic: Panther Fusion	2
BD: MAX	2
Roche: Cobas z 480	2
Cobas 6800/8800	3
Abbott Real-Time	3
Qiagen: Rotor-Gene	4
BioRad: CFX96 Touch	6
ABI: 7500 systems	10
Cepheid: GeneXpert	25

**Virus amplification platforms listed under 'Other':**

- bio molecular systems Mic qPCR Cycler
- SAMBA II



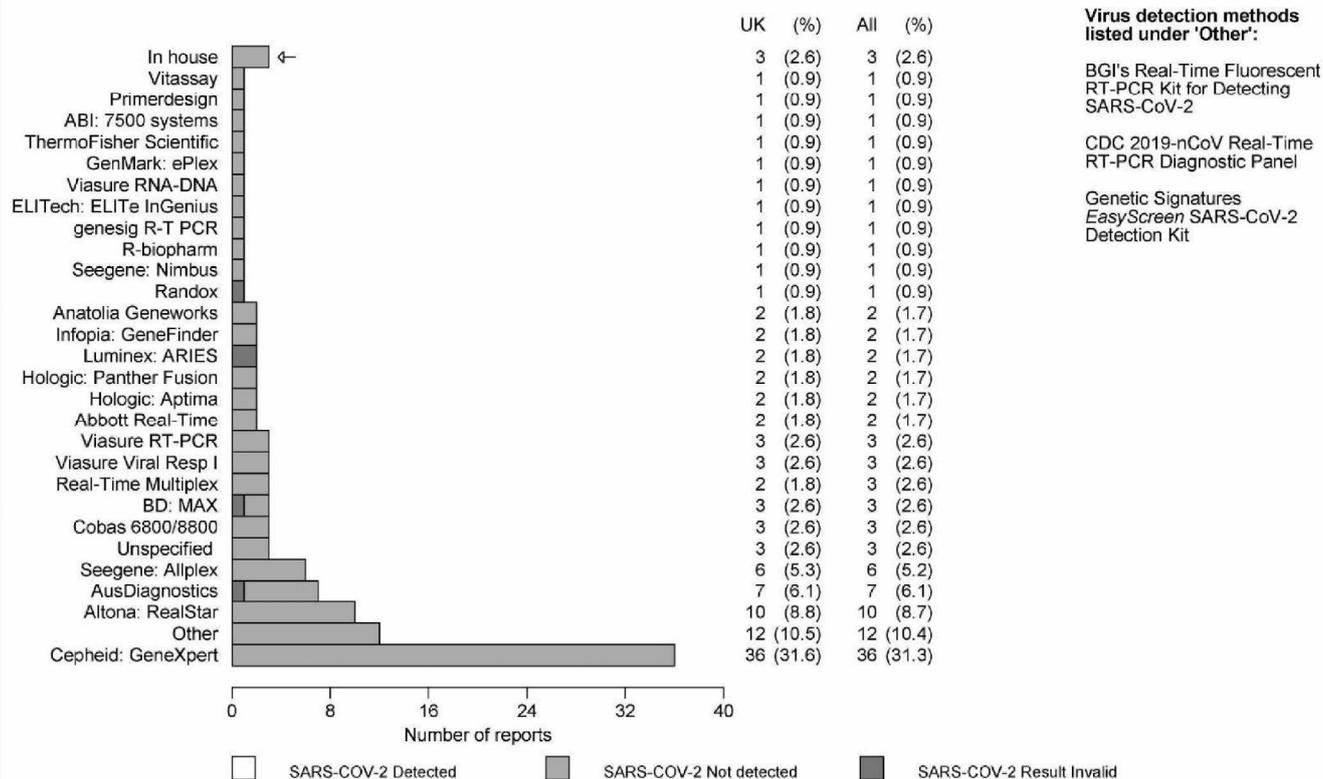
	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 5 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

**Specimen : 6328** Virus detection method / master mix kit 1

**Clinical details:** Nasopharyngeal swab from a 82-year-old male in a residential home with cough, headache and exhaustion for the last 7 days

**Intended result:** SARS-CoV-2 not detected



Organised jointly by UK NEQAS Consortium and NIBSC

© Copyright. The data in UK NEQAS reports are confidential. Participants must consult the scheme organiser before quoting data from the scheme.  
UK NEQAS for Microbiology  
PO Box 63003  
London NW9 1GH

Published at 15:11 on Friday 5 June 2020

	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 6 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

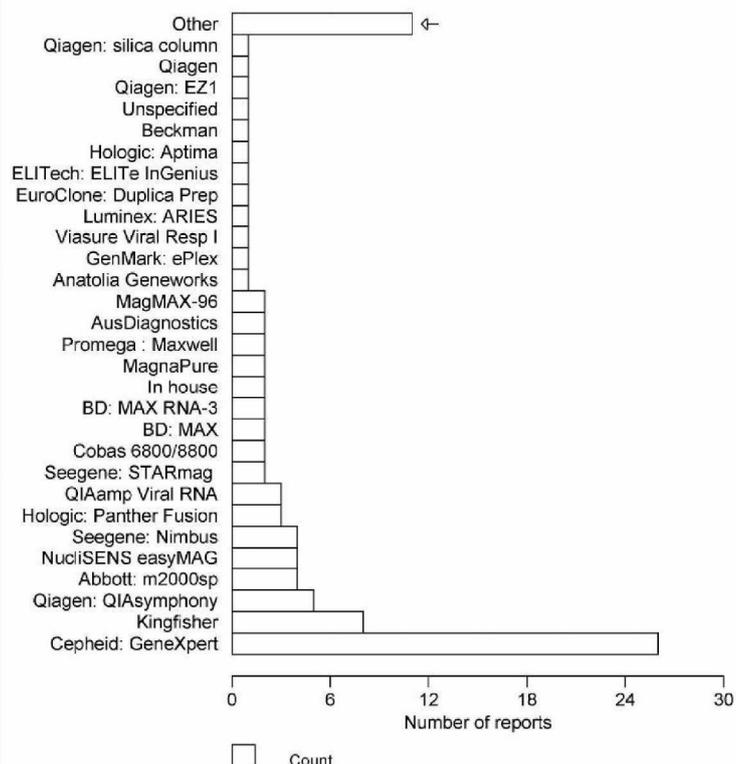
### Specimen : 6328 Virus extraction method 1

**Clinical details:** Nasopharyngeal swab from a 82-year-old male in a residential home with cough, headache and exhaustion for the last 7 days

**Intended result:** SARS-CoV-2 not detected

#### Virus extraction methods listed under 'Other':

MagPurix  
PerkinElmer chemagic Prepito  
molg3n PurePrep Pathogens Kit  
altona Diagnostics AltoStar  
IndiMag Pathogen Kit  
Zymo Research *Quick* -DNA/RNA Viral Kit  
SAMBA II  
MGI Nucleic Acid Extraction Solution



Organised jointly by UK NEQAS Consortium and NIBSC

© Copyright. The data in UK NEQAS reports are confidential. Participants must consult the scheme organiser before quoting data from the scheme.  
UK NEQAS for Microbiology  
PO Box 63003  
London NW9 1GH

Published at 15:11 on Friday 5 June 2020

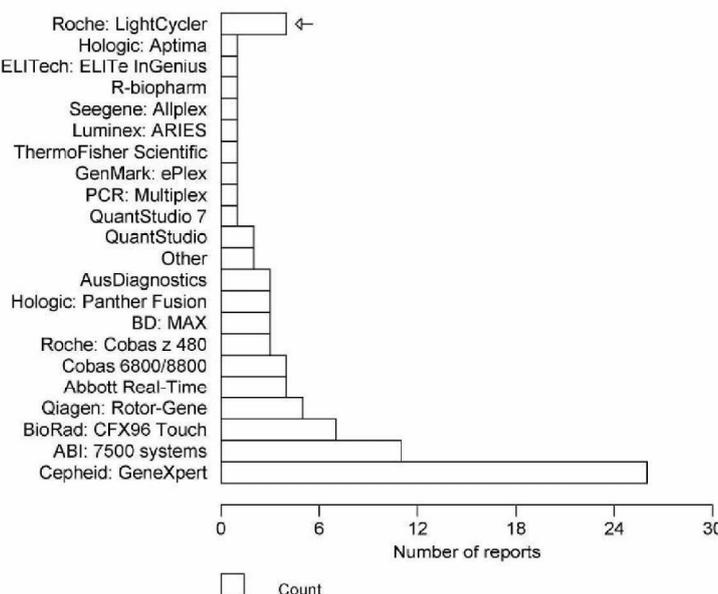
	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 7 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

**Specimen : 6328** Amplification platform 1

**Clinical details:** Nasopharyngeal swab from a 82-year-old male in a residential home with cough, headache and exhaustion for the last 7 days

**Intended result:** SARS-CoV-2 not detected



Platform	Number of reports
Roche: LightCycler	1
Hologic: Aptima	1
ELITech: ELITe InGenius	1
R-biopharm	1
Seegene: Allplex	1
Luminex: ARIES	1
ThermoFisher Scientific	1
GenMark: ePlex	1
PCR: Multiplex	1
QuantStudio 7	1
QuantStudio	2
Other	3
AusDiagnostics	4
Hologic: Panther Fusion	4
BD: MAX	4
Roche: Cobas z 480	5
Cobas 6800/8800	5
Abbott Real-Time	6
Qiagen: Rotor-Gene	7
BioRad: CFX96 Touch	8
ABI: 7500 systems	12
Cepheid: GeneXpert	25

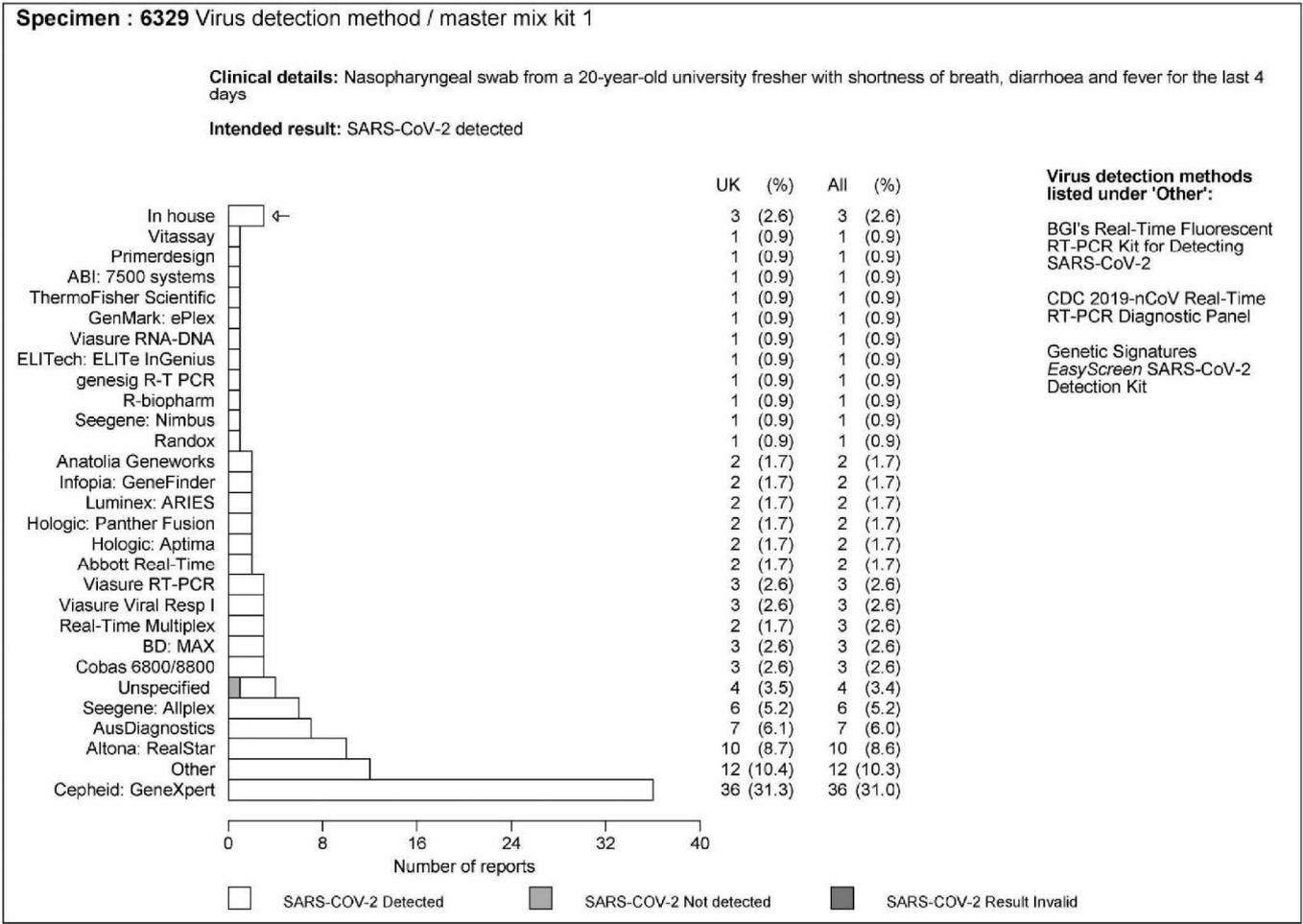
**Virus amplification platforms listed under 'Other':**

- bio molecular systems Mic
- qPCR Cyclor
- SAMBA II



	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 8 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.



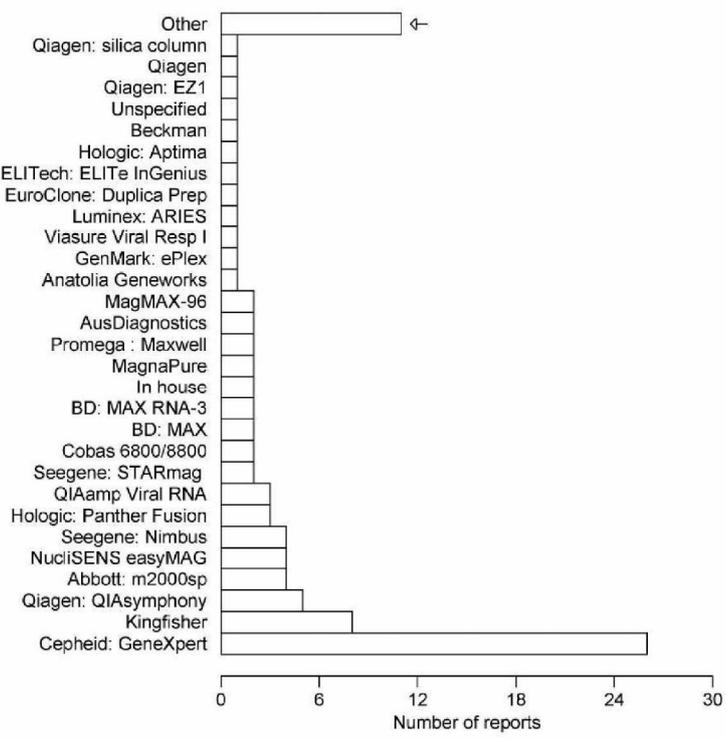
	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 9 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

**Specimen : 6329** Virus extraction method 1

**Clinical details:** Nasopharyngeal swab from a 20-year-old university fresher with shortness of breath, diarrhoea and fever for the last 4 days

**Intended result:** SARS-CoV-2 detected



Method	Number of reports
Other	29
Cepheid: GeneXpert	25
Kingfisher	8
QIAsymphony	7
Abbott: m2000sp	6
NucliSENS easyMAG	5
Seegene: Nimbus	4
Hologic: Panther Fusion	3
QIAamp Viral RNA	2
Seegene: STARmag	2
Cobas 6800/8800	2
BD: MAX	2
BD: MAX RNA-3	2
In house	2
MagnaPure	2
Promega : Maxwell	2
AusDiagnostics	2
MagMAX-96	2
Anatolia Geneworks	2
GenMark: ePlex	2
Viasure Viral Resp I	2
Luminex: ARIES	2
EuroClone: Duplica Prep	2
ELITech: ELITe InGenius	2
Hologic: Aptima	2
Beckman	2
Unspecified	2
Qiagen: EZ1	2
Qiagen	2
Qiagen: silica column	2

**Virus extraction methods listed under 'Other':**

- MagPurix
- PerkinElmer chemagic Prepito
- molg3n PurePrep Pathogens Kit
- altona Diagnostics AltoStar
- IndiMag Pathogen Kit
- Zymo Research Quick-DNA/RNA Viral Kit
- SAMBA II
- MGI Nucleic Acid Extraction Solution



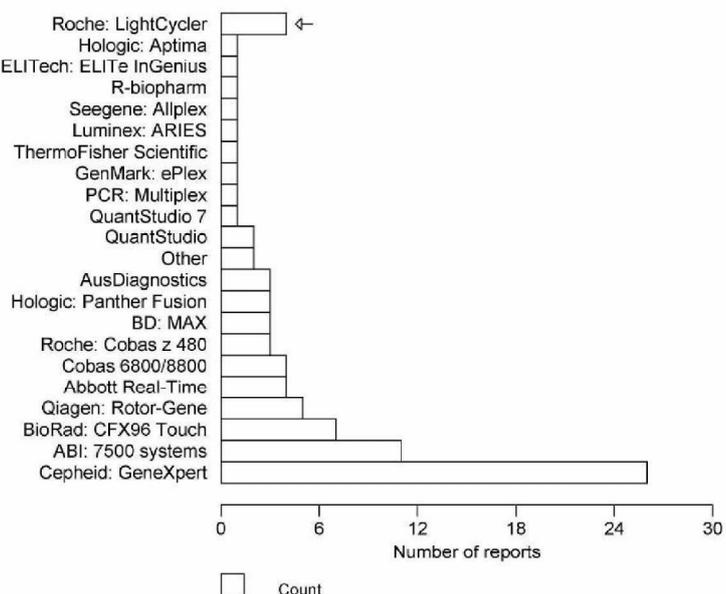
	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 10 of 14
	Dispatch Date : 21-May-2020	

Three frozen simulated nasopharyngeal swabs were dispatched with a request to test each for the presence of SARS-CoV-2 using molecular methods. Specimen 6328 was a negative specimen containing only the specimen matrix. Specimens 6327 and 6329 were both positive for SARS-CoV-2.

**Specimen : 6329** Amplification platform 1

**Clinical details:** Nasopharyngeal swab from a 20-year-old university fresher with shortness of breath, diarrhoea and fever for the last 4 days

**Intended result:** SARS-CoV-2 detected



Platform	Number of reports
Roche: LightCycler	4
Hologic: Aptima	1
ELITech: ELITe InGenius	1
R-biopharm	1
Seegene: Allplex	1
Luminex: ARIES	1
ThermoFisher Scientific	1
GenMark: ePlex	1
PCR: Multiplex	1
QuantStudio 7	1
QuantStudio	1
Other	1
AusDiagnostics	2
Hologic: Panther Fusion	2
BD: MAX	2
Roche: Cobas z 480	3
Cobas 6800/8800	3
Abbott Real-Time	4
Qiagen: Rotor-Gene	4
BioRad: CFX96 Touch	6
ABI: 7500 systems	10
Cepheid: GeneXpert	25

**Virus amplification platforms listed under 'Other':**

- bio molecular systems Mic
- qPCR Cyclor
- SAMBA II



### Comments on distribution 4884

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing COVID-19 was first reported in 5.1.2a in December, 2019 and subsequently declared as a “Public Health Emergency of International Concern” by WHO in January 2020.

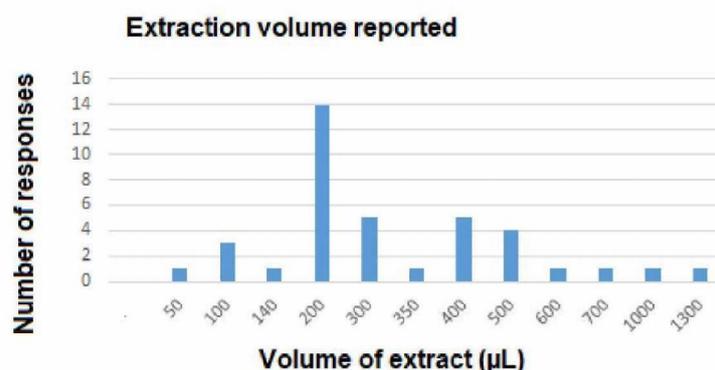
Since, more than 250,000 deaths worldwide have been associated with COVID-19 and the number of deaths is increasing on a daily basis. This unprecedented pandemic caused by SARS-CoV-2 is posing challenges to testing laboratories due to high testing demand, but also availability of reliable and sensitive diagnostic tests.

This first pilot studies distribution for the Molecular Detection of SARS-CoV-2 EQA has been introduced to assist laboratories performing molecular testing to monitor, evaluate and improve on their performance.

The overall performance in this distribution was excellent with 98.3 % of participants returning the intended results.

Of the 110 laboratories that were sent a set of specimens 85 (77.3%) returned their results within the specified time. Considering that this was the first pilot and the closing date was within 7 days, the return rate was good.

Thirty eight participants provided the volume of clinical material used for nucleic acid extraction. The volume of clinical material extracted ranged from 50µL to 1300 µL, with 200 µL being the most popular extraction volume (36.9%)

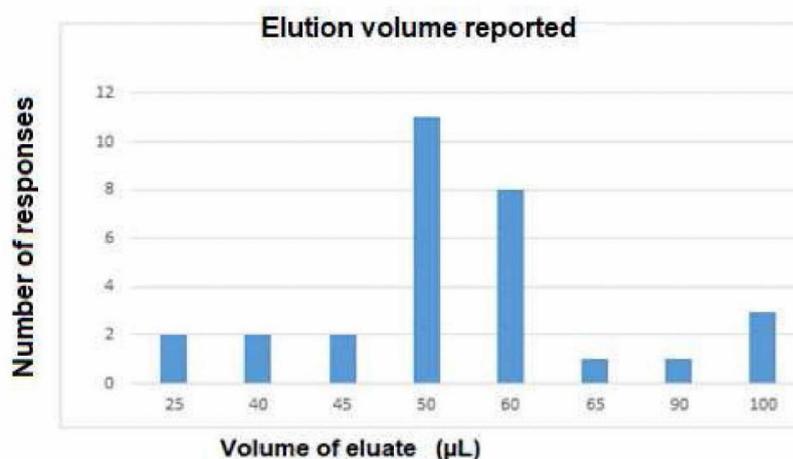


One participant did not know the extraction volume, as an automated platform was used.



<b>UK NEQAS</b> International Quality Expertise	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 12 of 14

Thirty participants provided the elution volume of their nucleic acid extraction method.



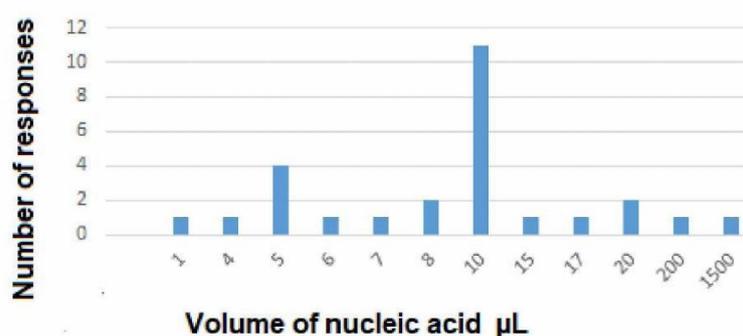
The volume of elution ranged from 25 to 100 µL. Eleven (37%) participants eluted in 50 µL and 8 (27%) eluted in 60 µL.



	Molecular Detection of SARS- CoV-2	Laboratory : 5.1.1c
	Distribution : 4884	Page 13 of 14

Twenty seven responses were received for the volume of nucleic acid template used for amplification. One participant did not know what volume was used as the system was automated.

#### Nucleic acid template used by participants

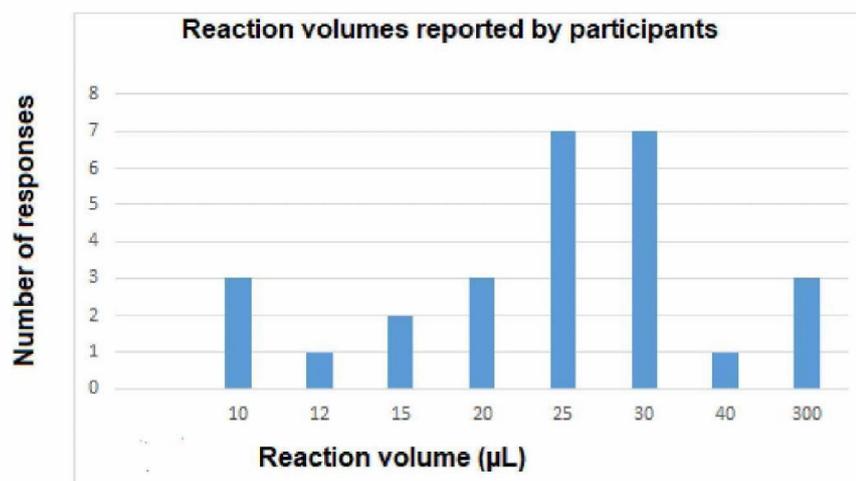


40.7% of responders used 10 µL nucleic acid template in their amplification reaction.

One participant reported using 200 µL and another one 1500 µL.



Twenty seven participants provided the reaction volume that they use for their amplification.



The reaction volume reported ranged between 10 to 300 µL. 25 µL and 30 µL were most popular with approximately 26% (7) participants using each volume.

From the data reported on extraction volume, elution volume, nucleic acid template used and reaction volume for amplification, it is apparent that laboratories have different procedures in place for testing their specimens.

The different combinations of the 4 parameters will influence the sensitivities and limit of detection of assays used by laboratories.

Specimens for a second pilot will be dispatched on the 25<sup>th</sup> June, where additional data will be collected, analysed and presented in the distribution report.

If you are interested to participate in the 2<sup>nd</sup> pilot, please register using the following link: <http://ukneqasmicro.org.uk/cov-reg/>

As part of your registration process you are required to fill in a questionnaire.

