UK NEQAS
International Quality Expertise

Microbiology

UK NEQAS for Microbiology, P O Box 63003, NW9 1GH
Tel: +44 (0)20 8905 9890 Fax: +44 (0)20 8205 1488 email: organiser@ukneqasmicro.org.uk web: http://www.ukneqasmicro.org.uk

# Molecular detection of SARS-CoV-2 EQA

External Quality Assessment (EQA) scheme for the Molecular detection of SARS-CoV-2 to help **testing laboratories to monitor, evaluate and improve their performance.**

- ✓ This EQA is supported by DHSC and NHS England
- ✓ Monthly distribution of 2 specimens, scheduled from August 2020:
  - Eight distributions scheduled between August 2020 to March 2021
- ✓ Specimens supplied as freeze-dried samples
- ✓ Country-specific performance available if greater than 10 participants
- ✓ Two weeks period for examination and reporting results
- ✓ Helps identify performance issues in a prompt manner
- ✓ Scheme supported by qualified and experienced professionals
- ✓ Educational
- ✓ Intended results will appear on our website https://ukneqasmicro.org.uk/ the day after the closing date and reports issued within 10 days.
- ✓ **For further information on how to register, please contact the Virology Scheme Manager by email:** organiser@ukneqasmicro.org.uk

  Please include Molecular detection of SARS-CoV-2 EQA in your email header

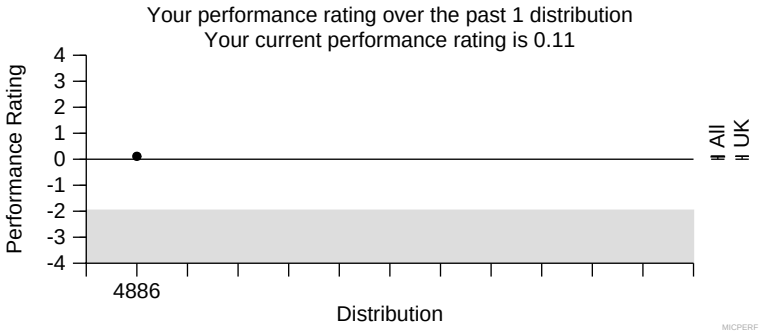
| Intended Result | | Your Report | Your Score |
|---|---|---|---|
| Specimen 6333 | SARS-CoV-2 negative | SARS-CoV-2 negative | 2 |
| Specimen 6334 | SARS-CoV-2 positive | SARS-CoV-2 positive | 2 |

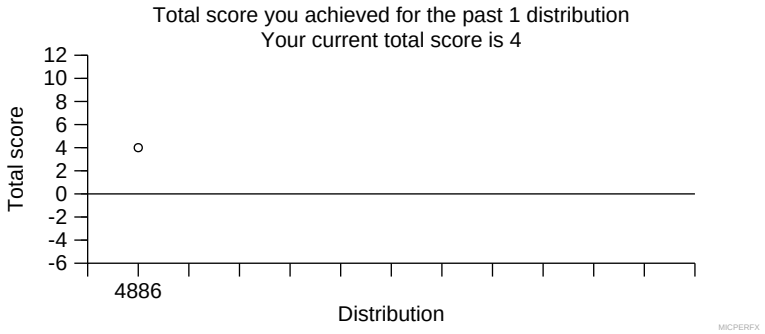
**Cumulative score information**
Total number of specimens sent to you for **Molecular Detection of SARS- CoV-2** over the last 1 distributions is 2
For these distributions specimen numbers 6333 6334 have been analysed and scored.

Number of reports analysed 1
Number of specimens reported as not examined (not scored) 0
Number of specimens received too late for analysis (not scored) 0
Number of specimens for which no report was received (not scored) 0
Your cumulative score for these specimens was 4 out of a possible total of 4

The mean score calculated from the reports returned by **UK** laboratories was 3.88 (with a standard error of 1.06)

**Performance rating**
Your performance rating for **Molecular Detection of SARS- CoV-2** (i.e. the number of standard errors by which your cumulative score lies above or below the mean) for **UK** laboratories is 0.11.
A performance rating of more than 1.96 standard errors below the mean indicates possible poor performance.
Please note your performance rating may alter if other participants' results are amended.
No score penalty is incurred for non return of reports. However non return of results may be used as a measure of poor performance.




**Comments:**
A total of 103 specimen sets were distributed with 92 participants returning results within the specified period. Overall performance for this distribution was excellent with 100% of participants returning the intended result for specimen 6333 and 96.7% of participants returning the intended result for specimen 6334.

**Specimen comments:**
**Specimen 6333**
Represented a simulated nasopharyngeal swab from a 45-year-old diabetic female complaining of tiredness and cough.
The specimen was **negative** for SARS-CoV-2 and only contained HEp-2 cells. 100% of participants reported the intended result.

**Specimen 6334**
Represented a simulated nasopharyngeal swab from a febrile 47-year-old male virologist with myalgia for 1 week.
The specimen was **positive** for SARS-CoV-2 and also contained HEp-2 cells. 96.7% of participants reported the intended result.

Histograms on page 2 and subsequent pages display results from a maximum of 12 nucleic acid detection methods, nucleic acid extraction methods, and amplification platforms. These include the most commonly used methods and the method used in laboratory indicated by an arrow. The figures in the histograms and those in the overall result tables may differ due to exclusion of kits displayed in the histograms resulting in apparently lower number of data sets in the histograms.

**Please see pages 6 to 8 for further comments**

**Turn around time:** The time taken to report your results was 1-days. This information is provided for your own use and does not form part of your performance assessment.

**Enquiries:** Pre-distribution test results are available should you experience a technical failure and wish to discuss the results. Written enquiries about this distribution should be addressed to Dr. Marit Orav at **organiser@ukneqasmicro.org.uk** .

**Acknowledgements:** We would like to thank NIBSC for the provision of SARS-CoV-2 material.

**Report authorised by:** Dr. Sanjiv Rughooputh, Scheme Organiser for UK NEQAS Microbiology

Operated by Public Health England
National Infection Service
61 Colindale Avenue
Colindale
London NW9 5EQ

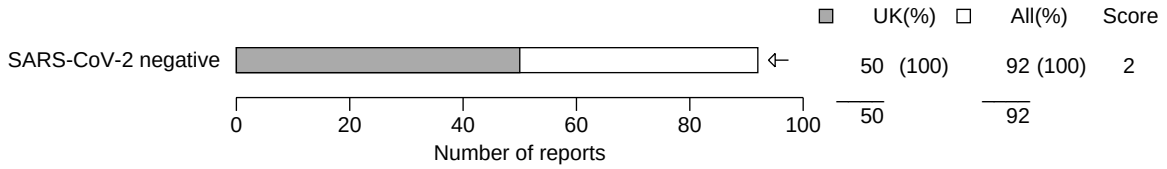

UK NEQAS for Microbiology
PO Box 63003
London NW9 1GH

Published at 16:24 on Tuesday 8 September 2020

Two freeze-dried simulated nasopharyngeal swab samples were dispatched with a request to report on the presence or absence of SARS-CoV-2 nucleic acid in specimens. Specimen 6333 was a negative specimen and only contained HEp-2 cells. Specimen 6334 was positive for SARS-CoV-2.

## Specimen : 6333

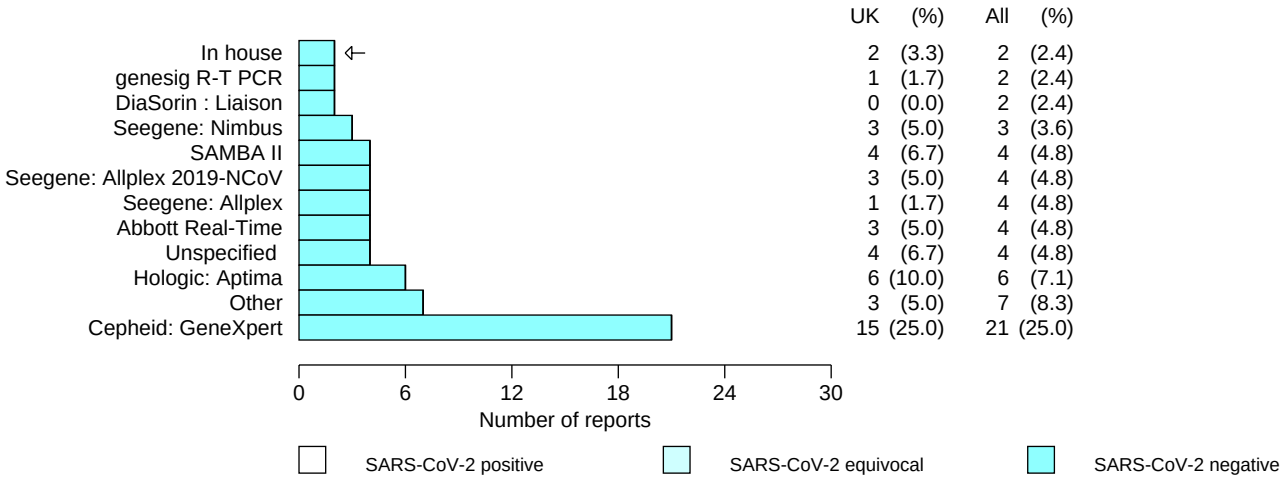
**Clinical details: Nasopharyngeal swab from a 45-year-old diabetic female complaining of tiredness and cough**
**Intended result: SARS-CoV-2 negative**




## Specimen : 6333

**Clinical details: Nasopharyngeal swab from a 45-year-old diabetic female complaining of tiredness and cough**
**Intended result: SARS-CoV-2 negative**

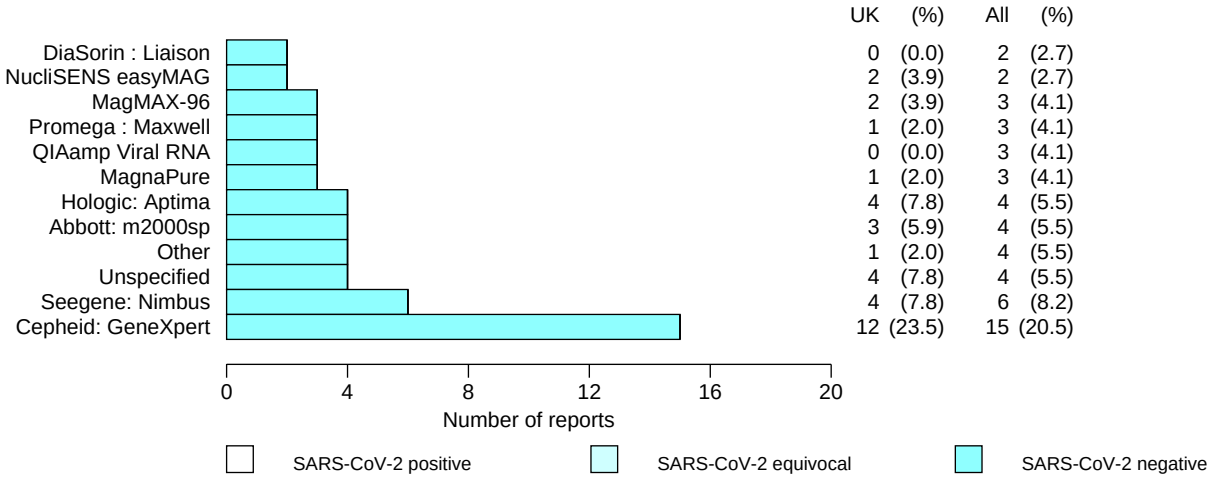
**Virus detection method (PCR amplification kit)**




## Specimen : 6333

**Clinical details: Nasopharyngeal swab from a 45-year-old diabetic female complaining of tiredness and cough**
**Intended result: SARS-CoV-2 negative**

**Nucleic acid extraction method**

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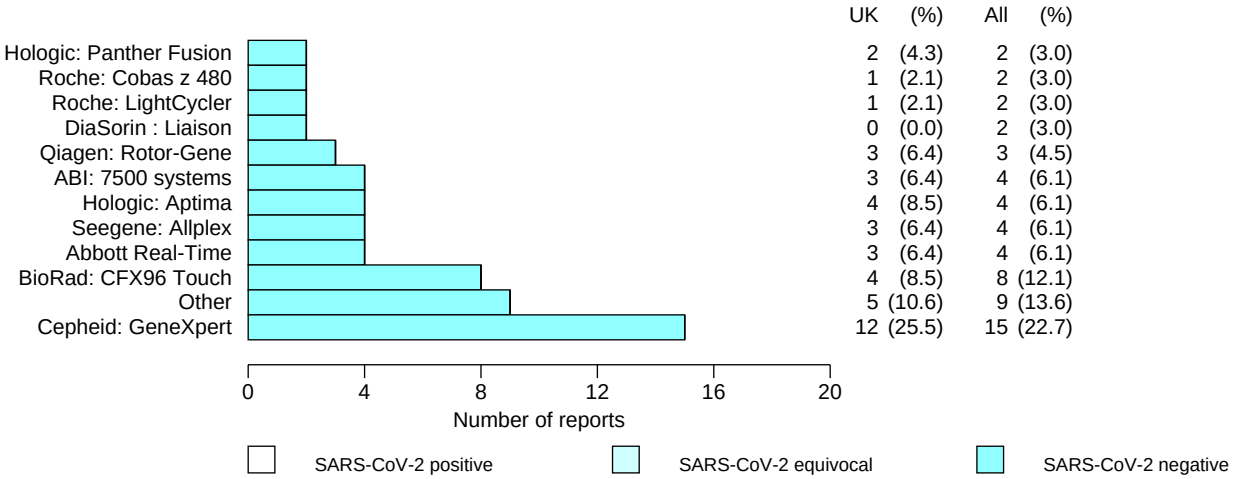
## Specimen : 6333

**Clinical details: Nasopharyngeal swab from a 45-year-old diabetic female complaining of tiredness and cough**
**Intended result: SARS-CoV-2 negative**

**Amplification platform**




| | UK | (%) | All | (%) |
|---|---|---|---|---|
| Hologic: Panther Fusion | 2 | (4.3) | 2 | (3.0) |
| Roche: Cobas z 480 | 1 | (2.1) | 2 | (3.0) |
| Roche: LightCycler | 1 | (2.1) | 2 | (3.0) |
| DiaSorin : Liaison | 0 | (0.0) | 2 | (3.0) |
| Qiagen: Rotor-Gene | 3 | (6.4) | 3 | (4.5) |
| ABI: 7500 systems | 3 | (6.4) | 4 | (6.1) |
| Hologic: Aptima | 4 | (8.5) | 4 | (6.1) |
| Seegene: Allplex | 3 | (6.4) | 4 | (6.1) |
| Abbott Real-Time | 3 | (6.4) | 4 | (6.1) |
| BioRad: CFX96 Touch | 4 | (8.5) | 8 | (12.1) |
| Other | 5 | (10.6) | 9 | (13.6) |
| Cepheid: GeneXpert | 12 | (25.5) | 15 | (22.7) |





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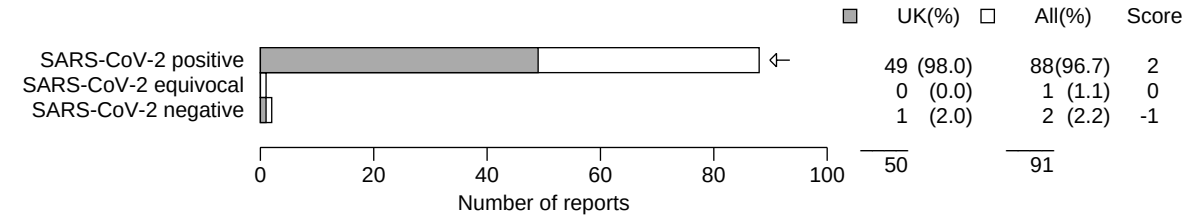
Two freeze-dried simulated nasopharyngeal swab samples were dispatched with a request to report on the presence or absence of SARS-CoV-2 nucleic acid in specimens. Specimen 6333 was a negative specimen and only contained HEp-2 cells. Specimen 6334 was positive for SARS-CoV-2.

## Specimen : 6334

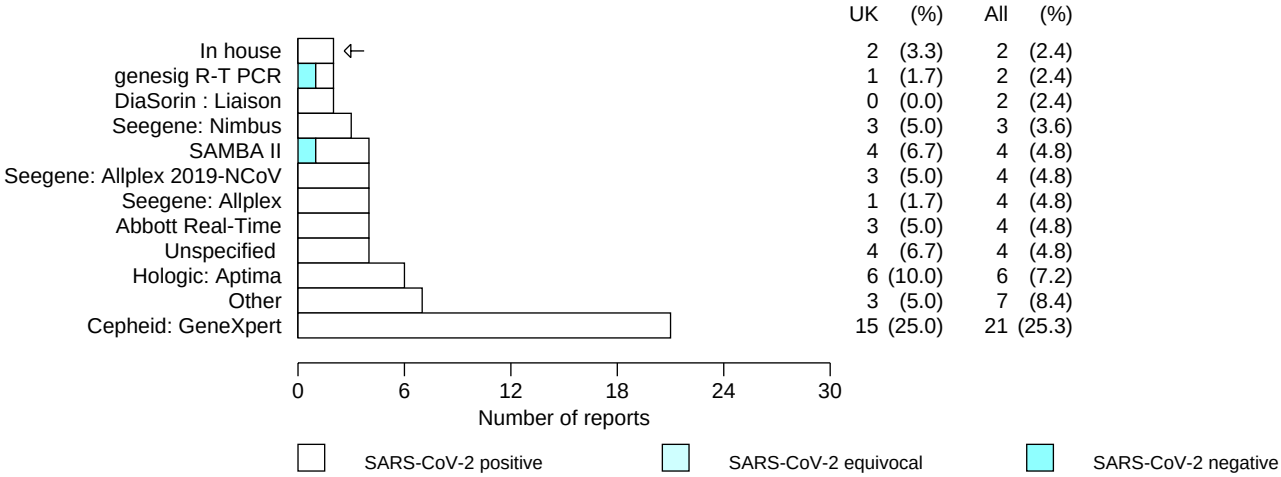
**Clinical details: Nasopharyngeal swab from a febrile 47-year-old male virologist with myalgia for 1 week**
**Intended result: SARS-CoV-2 positive**




## Specimen : 6334

**Clinical details: Nasopharyngeal swab from a febrile 47-year-old male virologist with myalgia for 1 week**
**Intended result: SARS-CoV-2 positive**

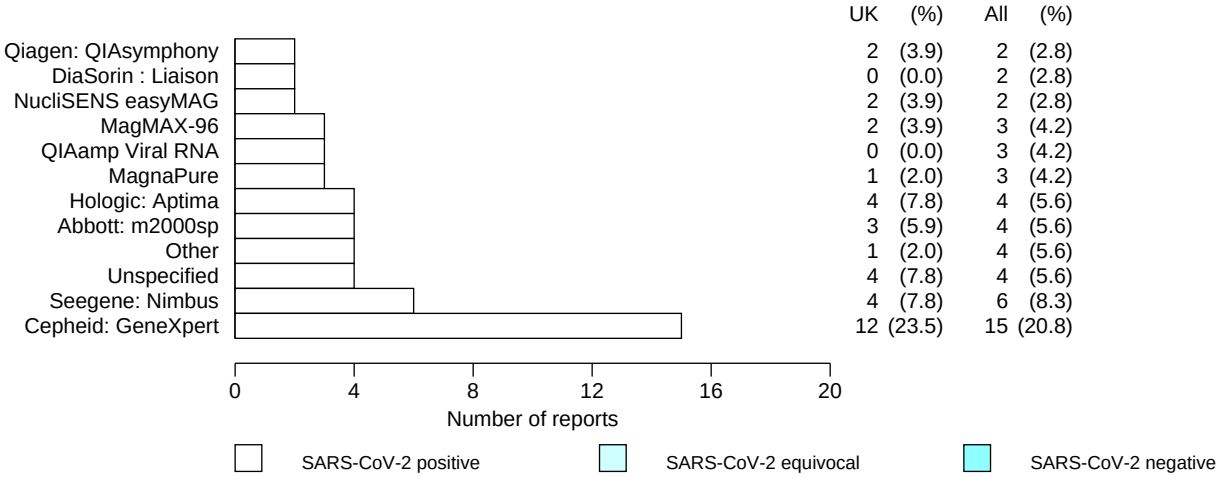
**Virus detection method (PCR amplification kit)**




## Specimen : 6334

**Clinical details: Nasopharyngeal swab from a febrile 47-year-old male virologist with myalgia for 1 week**
**Intended result: SARS-CoV-2 positive**

**Nucleic acid extraction method**

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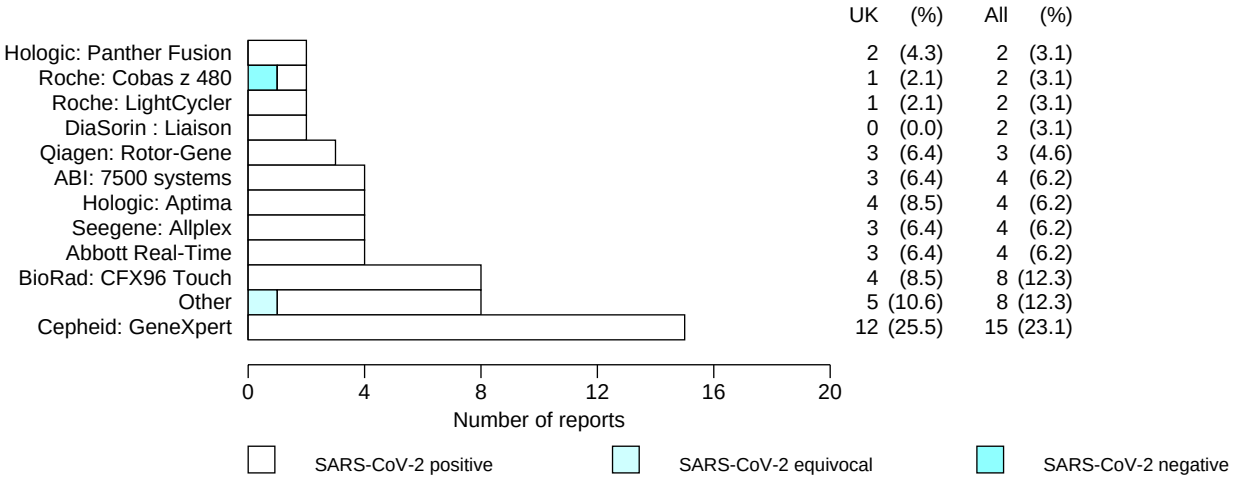
## Specimen : 6334

**Clinical details: Nasopharyngeal swab from a febrile 47-year-old male virologist with myalgia for 1 week**
**Intended result: SARS-CoV-2 positive**

**Amplification platform**




| | UK | (%) | All | (%) |
|---|---|---|---|---|
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| Qiagen: Rotor-Gene | 3 | (6.4) | 3 | (4.6) |
| ABI: 7500 systems | 3 | (6.4) | 4 | (6.2) |
| Hologic: Aptima | 4 | (8.5) | 4 | (6.2) |
| Seegene: Allplex | 3 | (6.4) | 4 | (6.2) |
| Abbott Real-Time | 3 | (6.4) | 4 | (6.2) |
| BioRad: CFX96 Touch | 4 | (8.5) | 8 | (12.3) |
| Other | 5 | (10.6) | 8 | (12.3) |
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## Comments on Distribution 4886

This is the first live distribution of the UK NEQAS Molecular Detection of SARS-CoV-2 EQA after two successful pilot studies. From this distribution onwards, scoring and performance monitoring will be applicable.

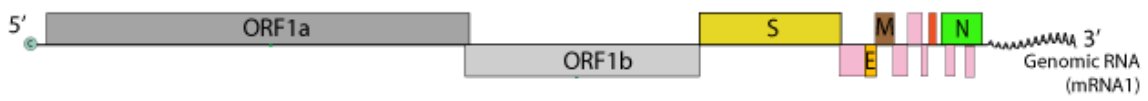
Distribution 4886 consisted of 2 specimens; 6333: negative for SARS-CoV-2 nucleic acid and 6334 which was positive. Overall performance for this distribution was excellent with 100% of participants returning the intended result for specimen 6333 and 96.7% of participants returning the intended result for specimen 6334.

103 sets of specimens were sent to participating laboratories. 92 participants returned their results by the closing date, representing a participation rate of 89.3%. 63 participants provided a test result reading for specimen 6334 which was either Cycle threshold (Ct) or Relative Light Units (RLU) value. Of these, five participants using Hologic platforms provided the following RLU values: 1075, 1239, 1270, 1283 and 1328. Fifty eight participants provided a Ct value for their real time PCR assays. The Ct values have been rounded to the nearest one decimal place and are illustrated in table 1.

The Ct values ranged from a minimum of 22.0 to a maximum of 43.5. The mean Ct value reported was 33.3 with a standard deviation of 3.62 and a median of 33.9. 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).

Targets for amplification reported by participants were *E gene* ( n = 20), the ORF region (n = 8), *RDRP gene* (n = 8), *N gene* (n = 9) and *S gene* ( n = 4). Figure 1 illustrates the genome map of SARS-CoV-2 and the different targets that participants have reported.

***Figure 1: Genome map of SARS-CoV-2***




(Source: Swiss Institute of Bioinformatics https://viralzone.expasy.org/9076)





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***Table 1: Ct values reported by participants for specimen 6334.***

| Lab | Ct Value | Lab | Ct Value |
|---|---|---|---|
| 1 | 34.9 | 30 | 34.4 |
| 2 | 29.0 | 31 | 33.0 |
| 3 | 35.1 | 32 | 40.6 |
| 4 | 35.1 | 33 | 36.3 |
| 5 | 34.2 | 34 | 33.3 |
| 6 | 31.7 | 35 | 37.0 |
| 7 | 39.6 | 36 | 35.4 |
| 8 | 32.8 | 37 | 37.3 |
| 9 | 31.8 | 38 | 28.1 |
| 10 | 35.0 | 39 | 22.0 |
| 11 | 24.3 | 40 | 33.8 |
| 12 | 35.2 | 41 | 34.0 |
| 13 | 33.7 | 42 | 43.5 |
| 14 | 30.7 | 43 | 26.7 |
| 15 | 35.2 | 44 | 31.7 |
| 16 | 26.4 | 45 | 28.2 |
| 17 | 30.7 | 46 | 32.7 |
| 18 | 33.5 | 47 | 32.0 |
| 19 | 32.3 | 48 | 31.5 |
| 20 | 36.1 | 49 | 32.0 |
| 21 | 33.0 | 50 | 29.5 |
| 22 | 34.1 | 51 | 34.4 |
| 23 | 35.5 | 52 | 36.0 |
| 24 | 31.9 | 53 | 31.5 |
| 25 | 37.0 | 54 | 35.9 |
| 26 | 33.9 | 55 | 32.2 |
| 27 | 36.8 | 56 | 34.3 |
| 28 | 34.2 | 57 | 32.0 |
| 29 | 35.2 | 58 | 34.3 |

According to the latest World Health Organization (WHO) Coronavirus Disease (COVID-19) Dashboard (7th September 2020) (https://covid19.who.int/), the number of confirmed COVID-19 cases globally is now above 27 million with almost 900,000 deaths. The majority of cases are through community transmission, hence the importance of testing and participating in an EQA on a regular basis.





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The UK NEQAS Molecular Detection of SARS-CoV-2 EQA now runs on a monthly basis. Table 2 provides tentative dates when the distributions will be dispatched with their respective closing dates. If there are changes to these dates, a communication will be sent to you.

| Scheduled distributions | 31-Aug | 28-Sep | 26-Oct | 23-Nov | 04-Jan | 01-Feb | 01-Mar |
|---|---|---|---|---|---|---|---|
| Closing dates | 14-Sep | 12-Oct | 09-Nov | 07-Dec | 18-Jan | 15-Feb | 15-Mar |

***Table 2: Scheduled distribution and closing dates for the Molecular detection of SARS-CoV-2 EQA.***

We encourage our participants to provide as much information as possible when returning their results on their testing protocols including Ct, RLU or any other units used to report their results as well as inform us of any challenges they encounter when dealing with their EQA specimens.

If you have any comments or suggestions, please feel free to contact us.

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