

External Quality Assessment Scheme

SARS-CoV-2, nucleic acid detection Round 1, 2023

Specimens

Please find enclosed 3 simulated swab samples S001, S002 and S003.

Caution

Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. According to the sample manufacturer the specimens do not contain viable microbes. However, no known test method can offer complete assurance that the specimens will not transmit any infectious diseases.

Not for patient use.

Examinations

SARS-CoV-2 NAT

Additional information (e.g. suspected variant) may be reported in the comments section of the result form. Reporting Ct values is optional.

Storage and use

The samples should be stored at +2...30 °C and used as soon as possible.

1. Open the foil package. Pay attention to avoid contamination.
2. Remove the swab from the foil package and place the swab into a sample collection tube / transport media (1-3 mL). We recommend a volume of 1 mL, as problems with internal control may occur when using higher dilutions. Rotate the swab to dislodge as much material as possible. Remove the swab by pressing it towards the walls of the elution vial. You can also cut the swab into the sample collection tube.
3. Recap the collection tube and mix thoroughly.
4. Follow the test manufacturer's instructions for sample extraction and detection.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your test from the registry, please contact the EQA Coordinator. This round has the possibility to report three results from the same sample, if the sample volume is sufficient for several analyses. To open a new result form, press the "Add result +" button on the right side of the blue bar for each sample in LabScala. Only the qualitative results are scored.

S001



S002



S003



2023-01-24

INSTRUCTIONS

Product no. 5676
LQ775723011-013/CA

Subcontracting: Sample pretesting

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **February 20, 2023.**

The expected results of the round are published in LabScala in the View Reports section by February 24, 2023.

Inquiries

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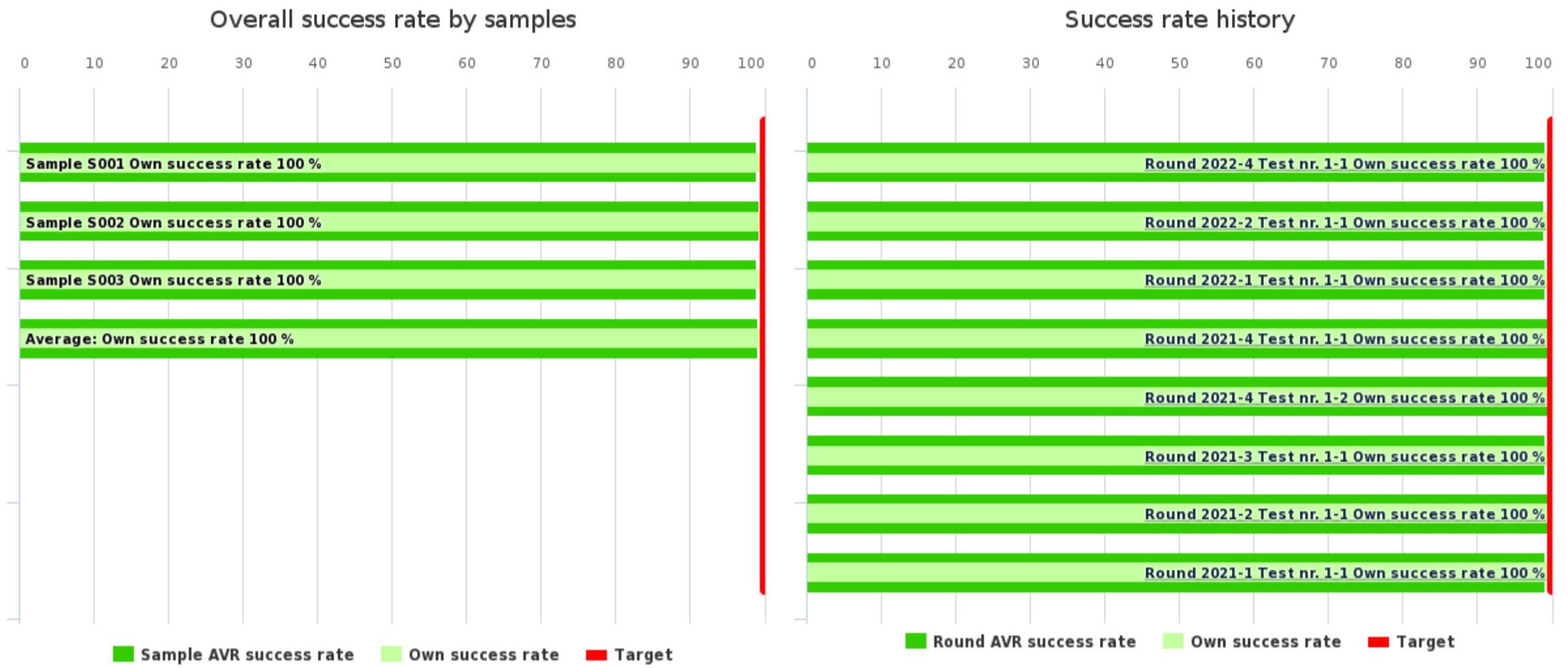
Only the qualitative analysis is accredited.



Client report

| | No of participants | No of responded participants | Response percentage |
|---|--------------------|------------------------------|---------------------|
| SARS-CoV-2, nucleic acid detection, January, 1-2023 | 208 | 199 | 95.7 % |

Summary

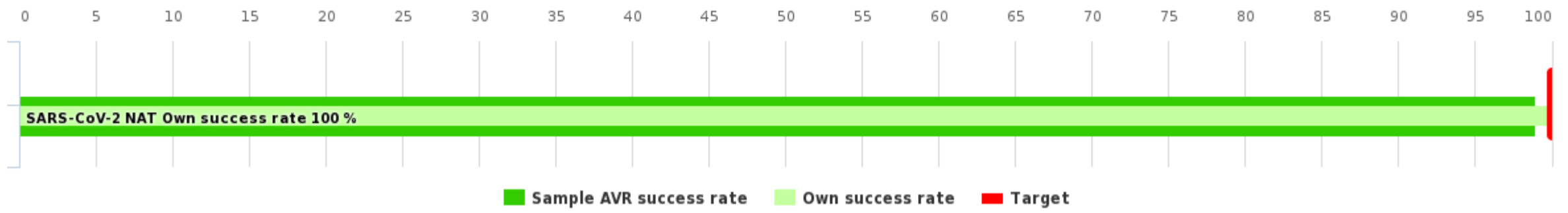


| Summary | Own score | Max score | Own success rate | Difference | AVR success rate |
|-------------|-----------|-----------|------------------|------------|------------------|
| Sample S001 | 2 | 2 | 100 % | 1 % | 99 % |
| Sample S002 | 2 | 2 | 100 % | 0.7 % | 99.3 % |
| Sample S003 | 2 | 2 | 100 % | 1 % | 99 % |
| Average: | | | 100 % | 0.9 % | 99.1 % |

| History | Test nr. | Own success rate | Difference | AVR success rate |
|--------------|----------|------------------|------------|------------------|
| Round 2022-4 | 1-1 | 100 % | 0.8 % | 99.2 % |
| Round 2022-2 | 1-1 | 100 % | 1.1 % | 98.9 % |
| Round 2022-1 | 1-1 | 100 % | 0.8 % | 99.2 % |
| Round 2021-4 | 1-1 | 100 % | 0.3 % | 99.7 % |
| Round 2021-4 | 1-2 | 100 % | 0.3 % | 99.7 % |
| Round 2021-3 | 1-1 | 100 % | 0.9 % | 99.1 % |
| Round 2021-2 | 1-1 | 100 % | 0.6 % | 99.4 % |
| Round 2021-1 | 1-1 | 100 % | 0.9 % | 99.1 % |

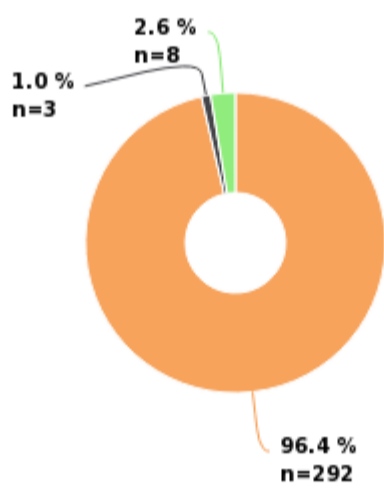
Sample S001

Sample S001 success rate



| Sample S001 results | Responded | Own score | Max score | Own success rate | Difference | AVR success rate | Count |
|---------------------|----------------|-----------|-----------|------------------|------------|------------------|-------|
| | SARS-CoV-2 NAT | 2 | 2 | 100 % | 1 % | 99 % | 303 |
| Total: | | 2 | 2 | 100 % | 1 % | 99 % | 303 |

Sample S001 SARS-CoV-2 NAT



■ Negative
 ■ Positive
 ■ Invalid result

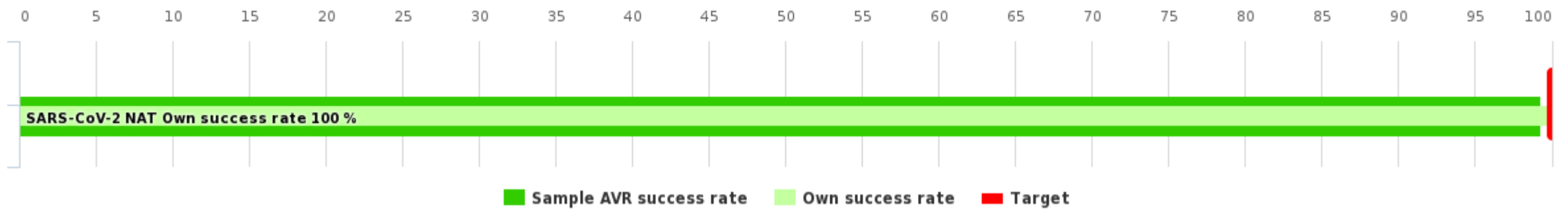
| SARS-CoV-2 NAT | Qualitative interpretation | Method | Qualitative interpretation count | Method count | Own score | Max score | Own success rate | Difference | AVR success rate |
|----------------|---|--|----------------------------------|--------------|-----------|-----------|------------------|------------|------------------|
| | <input checked="" type="radio"/> Negative | | 292 | | 2 | 2 | 100 % | 0 % | 100 % |
| | | 1drop Inc. 1copy COVID-19 qPCR 4plex Kit | | 1 | | | | | |
| | | 3DMed ANDiS Fast SARS-CoV-2 RT-qPCR Detection Kit | | 7 | | | | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 | | 6 | | | | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 2.0 | | 3 | | | | | |
| | | Abbott Alinity m Resp-4-Plex assay | | 3 | | | | | |
| | | Abbott Alinity m SARS-CoV-2 assay | | 4 | | | | | |
| | | Abbott ID NOW COVID-19 2.0 | | 27 | | | | | |
| | | ACON Promotor SARS-CoV-2 RT PCR Test Kit | | 1 | | | | | |
| | | Adaltis MOLgen SARS-COV2 Real Time RT PCR Kit | | 1 | | | | | |
| | | Amplicon AmpliTest SARS-CoV-2 RdRp/E (Real Time PCR) | | 1 | | | | | |
| | | Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit | | 4 | | | | | |
| | | BD SARS-CoV-2 Reagents for BD MAX System | | 2 | | | | | |
| | | BD SARS-CoV-2/Flu for BD MAX System | | 6 | | | | | |
| | | BioFire Diagnostics BioFire Respiratory Panel 2.1 | | 9 | | | | | |
| | | Biosynex AMPLIQUICK SARS-CoV-2 | | 2 | | | | | |
| | | <input checked="" type="radio"/> Cepheid Xpert Xpress CoV-2 plus | | 28 | | | | | |
| | | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | | 16 | | | | | |
| | | Cepheid Xpert Xpress SARS-CoV-2 test | | 20 | | | | | |

| | | | | | | |
|--|---|----|--|--|--|--|
| | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | 2 | | | | |
| | CerTest VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit for BD MAX | 1 | | | | |
| | CerTest VIASURE SARS-CoV-2 Real Time PCR Detection Kit | 4 | | | | |
| | Co-Diagnostics Logix Smart Coronavirus 2019 (COVID-19) Test Kit | 1 | | | | |
| | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | 24 | | | | |
| | DiaSorin Simplexa COVID-19 Direct Kit | 1 | | | | |
| | DNA-Technology SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit | 1 | | | | |
| | ELITechGroup SARS-CoV-2 ELITe MGB Kit | 3 | | | | |
| | ELITechGroup SARS-CoV-2 PLUS ELITe MGB Kit | 3 | | | | |
| | Eurobio Scientific EurobioPlex FluCoSyn | 5 | | | | |
| | Eurobio Scientific EurobioPlex SARS-CoV-2 Fast-SVD | 2 | | | | |
| | Euroimmun EURORealTime SARS-CoV-2 | 3 | | | | |
| | Fast-track Diagnostics FTD SARS-CoV-2 Assay | 1 | | | | |
| | GeneProof SARS-CoV-2 Advanced PCR Kit | 1 | | | | |
| | HEMA SARS-CoV-2 Real time PCR | 2 | | | | |
| | Hologic Panther Fusion SARS-CoV-2 Assay | 1 | | | | |
| | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | 7 | | | | |
| | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | 4 | | | | |
| | ID-Solutions IDNCOV2q | 2 | | | | |
| | In-house PCR for SARS-CoV-2 | 1 | | | | |
| | Jiangsu Biopertectus Technologies COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | 1 | | | | |
| | Laboratoire OBO OSANTYS SARS-CoV-2 RT-qPCR Kit | 1 | | | | |
| | Luminex ARIES SARS-CoV-2 Assay | 1 | | | | |
| | MIKROGEN ampliCube Coronavirus SARS-CoV-2 | 1 | | | | |
| | Mobidiag Amplidiag COVID-19 | 3 | | | | |
| | Mobidiag Amplidiag RESP-4 | 2 | | | | |
| | Mobidiag Novodiag COVID-19 | 3 | | | | |
| | NeuMoDx SARS-CoV-2 Assay | 3 | | | | |
| | NovaTec Immundiagnostica GSD NovaPrime TSP SARS-CoV-2 RT-PCR | 3 | | | | |
| | PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR | 1 | | | | |
| | PerkinElmer SARS-CoV-2 Nucleic Acid Detection Kit | 2 | | | | |
| | Primerdesign genesig Real-Time PCR Coronavirus (COVID-19) | 1 | | | | |
| | Primerdesign PROMate COVID-19 | 1 | | | | |
| | Qiagen QIAstat-Dx Respiratory SARS-CoV-2 Panel | 1 | | | | |
| | Qiagen SARS-CoV-2 N1+N2 Assay Kit | 2 | | | | |
| | Roche cobas SARS-CoV-2 & Influenza A/B Test | 3 | | | | |
| | Roche cobas SARS-CoV-2 Test | 3 | | | | |
| | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | 6 | | | | |
| | Roche Liat cobas SARS-CoV-2 Assay | 9 | | | | |
| | Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit | 2 | | | | |
| | SD Biosensor STANDARD M10 SARS-CoV-2 Test | 8 | | | | |
| | Seegene Allplex SARS-CoV-2 Assay | 6 | | | | |
| | Seegene Allplex SARS-CoV-2 fast PCR Assay | 3 | | | | |
| | Seegene Allplex SARS-CoV-2 Master Assay | 2 | | | | |

| | | | | | | | | | |
|--|----------------|--|-----|---|---|---|-------|-----|------|
| | | Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay | | 2 | | | | | |
| | | Shenzhen Lifotronic Technology SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | | | | |
| | | Siemens FTD SARS-CoV-2 Assay | | 1 | | | | | |
| | | Tib Molbiol LightMix Modular SARS and Wuhan CoV E-gene | | 1 | | | | | |
| | | Ustar Biotechnologies EasyNAT SARS-CoV-2 | | 1 | | | | | |
| | | Vitassay qPCR SARS-CoV-2 | | 4 | | | | | |
| | | Xiamen Zeesan Biotech SARS-CoV-2 Test Kit (Real-time PCR) | | 1 | | | | | |
| | | Zybio SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | | | | |
| | Positive | | 3 | | - | | | | 0 % |
| | | Cepheid Xpert Xpress CoV-2 plus | | 1 | | | | | |
| | | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 1 | | | | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 1 | | | | | |
| | Invalid result | | 8 | | - | | | | - |
| | | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | | 2 | | | | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | | 2 | | | | | |
| | | In-house PCR for SARS-CoV-2 | | 1 | | | | | |
| | | Mobidiag Amplidiag COVID-19 | | 1 | | | | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 1 | | | | | |
| | | Seegene Allplex SARS-CoV-2 Master Assay | | 1 | | | | | |
| | Total: | | 303 | | 2 | 2 | 100 % | 1 % | 99 % |

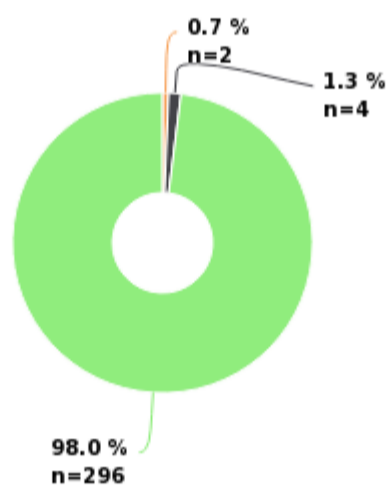
Sample S002

Sample S002 success rate



| Sample S002 results | Responded | Own score | Max score | Own success rate | Difference | AVR success rate | Count |
|---------------------|----------------|-----------|-----------|------------------|------------|------------------|-------|
| | SARS-CoV-2 NAT | 2 | 2 | 100 % | 0.7 % | 99.3 % | 302 |
| Total: | | 2 | 2 | 100 % | 0.7 % | 99.3 % | 302 |

Sample S002 SARS-CoV-2 NAT



■ Negative
 ■ Weak positive
 ■ Positive

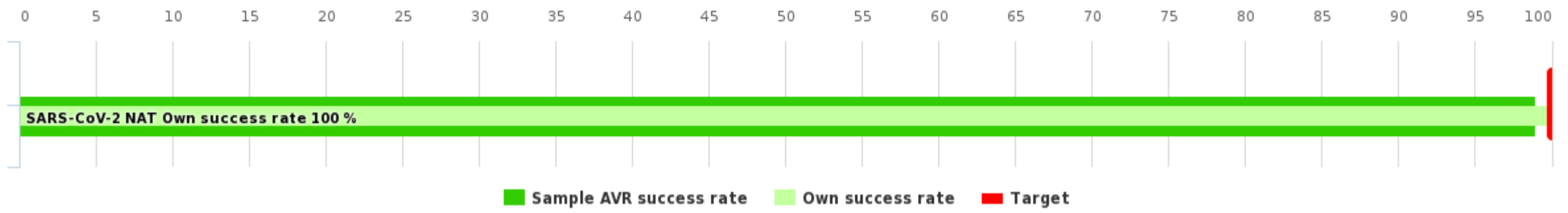
| SARS-CoV-2 NAT | Qualitative interpretation | Method | Qualitative interpretation count | Method count | Own score | Max score | Own success rate | Difference | AVR success rate |
|----------------|---|---|----------------------------------|--------------|-----------|-----------|------------------|------------|------------------|
| | Negative | | 2 | | - | | | | 0 % |
| | | CerTest VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit for BD MAX | | 1 | | | | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 1 | | | | | |
| | Weak positive | | 4 | | - | | | | 100 % |
| | | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | | 2 | | | | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | | 1 | | | | | |
| | | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | | 1 | | | | | |
| | <input checked="" type="radio"/> Positive | | 296 | | 2 | 2 | 100 % | 0 % | 100 % |
| | | 1drop Inc. 1copy COVID-19 qPCR 4plex Kit | | 1 | | | | | |
| | | 3DMed ANDiS Fast SARS-CoV-2 RT-qPCR Detection Kit | | 7 | | | | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 | | 6 | | | | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 2.0 | | 3 | | | | | |
| | | Abbott Alinity m Resp-4-Plex assay | | 3 | | | | | |
| | | Abbott Alinity m SARS-CoV-2 assay | | 3 | | | | | |
| | | Abbott ID NOW COVID-19 2.0 | | 26 | | | | | |
| | | Abbott RealTime SARS-CoV-2 assay | | 1 | | | | | |
| | | ACON Promotor SARS-CoV-2 RT PCR Test Kit | | 1 | | | | | |
| | | Adaltis MOLgen SARS-COV2 Real Time RT PCR Kit | | 1 | | | | | |
| | | Amplicon AmpliTest SARS-CoV-2 RdRp/E (Real Time PCR) | | 1 | | | | | |

| | | | | | | |
|--|---|----|--|--|--|--|
| | Applied Biosystems TaqMan 2019-nCoV Assay Kit v1 | 1 | | | | |
| | Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit | 3 | | | | |
| | BD SARS-CoV-2 Reagents for BD MAX System | 2 | | | | |
| | BD SARS-CoV-2/Flu for BD MAX System | 5 | | | | |
| | BioFire Diagnostics BioFire Respiratory Panel 2.1 | 9 | | | | |
| | Biosynex AMPLIQUICK SARS-CoV-2 | 2 | | | | |
| | ● Cepheid Xpert Xpress CoV-2 plus | 28 | | | | |
| | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | 15 | | | | |
| | Cepheid Xpert Xpress SARS-CoV-2 test | 19 | | | | |
| | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | 2 | | | | |
| | CerTest VIASURE SARS-CoV-2 Real Time PCR Detection Kit | 4 | | | | |
| | Co-Diagnostics Logix Smart Coronavirus 2019 (COVID-19) Test Kit | 1 | | | | |
| | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | 26 | | | | |
| | DiaSorin Simplexa COVID-19 Direct Kit | 1 | | | | |
| | DNA-Technology SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit | 1 | | | | |
| | ELITechGroup SARS-CoV-2 ELITe MGB Kit | 4 | | | | |
| | ELITechGroup SARS-CoV-2 PLUS ELITe MGB Kit | 4 | | | | |
| | Eurobio Scientific EurobioPlex FluCoSyn | 5 | | | | |
| | Eurobio Scientific EurobioPlex SARS-CoV-2 Fast-SVD | 2 | | | | |
| | Euroimmun EURORealTime SARS-CoV-2 | 3 | | | | |
| | Fast-track Diagnostics FTD SARS-CoV-2 Assay | 1 | | | | |
| | GeneProof SARS-CoV-2 Advanced PCR Kit | 1 | | | | |
| | HEMA SARS-CoV-2 Real time PCR | 2 | | | | |
| | Hologic Panther Fusion SARS-CoV-2 Assay | 1 | | | | |
| | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | 7 | | | | |
| | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | 3 | | | | |
| | ID-Solutions IDNCOV2q | 2 | | | | |
| | In-house PCR for SARS-CoV-2 | 2 | | | | |
| | Jiangsu Bioperfectus Technologies COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | 1 | | | | |
| | Laboratoire OBO OSANTYS SARS-CoV-2 RT-qPCR Kit | 1 | | | | |
| | Luminex ARIES SARS-CoV-2 Assay | 1 | | | | |
| | MIKROGEN ampliCube Coronavirus SARS-CoV-2 | 1 | | | | |
| | Mobidiag Amplidiag COVID-19 | 4 | | | | |
| | Mobidiag Amplidiag RESP-4 | 2 | | | | |
| | Mobidiag Novodiag COVID-19 | 4 | | | | |
| | NeuMoDx SARS-CoV-2 Assay | 3 | | | | |
| | NovaTec Immundiagnostica GSD NovaPrime TSP SARS-CoV-2 RT-PCR | 3 | | | | |
| | PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR | 1 | | | | |
| | PerkinElmer SARS-CoV-2 Nucleic Acid Detection Kit | 2 | | | | |
| | Primerdesign genesig Real-Time PCR Coronavirus (COVID-19) | 1 | | | | |
| | Primerdesign PROMate COVID-19 | 1 | | | | |
| | Qiagen QIAstat-Dx Respiratory SARS-CoV-2 Panel | 1 | | | | |
| | Qiagen SARS-CoV-2 N1+N2 Assay Kit | 2 | | | | |
| | Roche cobas SARS-CoV-2 & Influenza A/B Test | 3 | | | | |
| | Roche cobas SARS-CoV-2 Test | 3 | | | | |

| | | | | | | | | | |
|--|--------|--|-----|---|---|---|-------|-------|--------|
| | | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 7 | | | | | |
| | | Roche Liat cobas SARS-CoV-2 Assay | | 9 | | | | | |
| | | Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit | | 2 | | | | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 9 | | | | | |
| | | Seegene Allplex SARS-CoV-2 Assay | | 6 | | | | | |
| | | Seegene Allplex SARS-CoV-2 fast PCR Assay | | 3 | | | | | |
| | | Seegene Allplex SARS-CoV-2 Master Assay | | 3 | | | | | |
| | | Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay | | 2 | | | | | |
| | | Shenzhen Lifotronic Technology SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | | | | |
| | | Siemens FTD SARS-CoV-2 Assay | | 1 | | | | | |
| | | Tib Molbiol LightMix Modular SARS and Wuhan CoV E-gene | | 1 | | | | | |
| | | Ustar Biotechnologies EasyNAT SARS-CoV-2 | | 1 | | | | | |
| | | Vitassay qPCR SARS-CoV-2 | | 4 | | | | | |
| | | Xiamen Zeesan Biotech SARS-CoV-2 Test Kit (Real-time PCR) | | 1 | | | | | |
| | | Zybio SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | | | | |
| | Total: | | 302 | | 2 | 2 | 100 % | 0.7 % | 99.3 % |

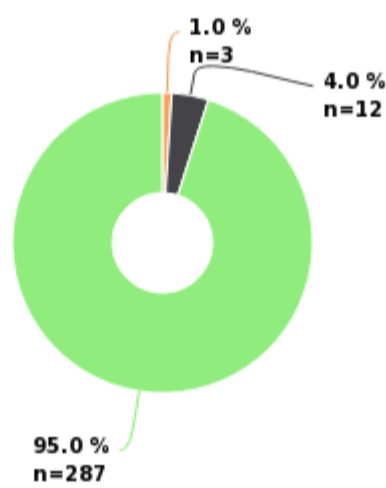
Sample S003

Sample S003 success rate



| Sample S003 results | Responded | Own score | Max score | Own success rate | Difference | AVR success rate | Count |
|---------------------|----------------|-----------|-----------|------------------|------------|------------------|-------|
| | SARS-CoV-2 NAT | 2 | 2 | 100 % | 1 % | 99 % | 302 |
| Total: | | 2 | 2 | 100 % | 1 % | 99 % | 302 |

Sample S003 SARS-CoV-2 NAT



■ Negative
 ■ Weak positive
 ■ Positive

| SARS-CoV-2 NAT | Qualitative interpretation | Method | Qualitative interpretation count | Method count | Own score | Max score | Own success rate | Difference | AVR success rate |
|----------------|---|---|----------------------------------|--------------|-----------|-----------|------------------|------------|------------------|
| | Negative | | 3 | | - | | | | 0 % |
| | | Cepheid Xpert Xpress CoV-2 plus | | 1 | | | | | |
| | | CerTest VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit for BD MAX | | 1 | | | | | |
| | | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 1 | | | | | |
| | Weak positive | | 12 | | - | | | | 100 % |
| | | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | | 2 | | | | | |
| | | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | | 1 | | | | | |
| | | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | | 1 | | | | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | | 3 | | | | | |
| | | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | | 2 | | | | | |
| | | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | | 1 | | | | | |
| | | Luminex ARIES SARS-CoV-2 Assay | | 1 | | | | | |
| | | Seegene Allplex SARS-CoV-2 Assay | | 1 | | | | | |
| | <input checked="" type="radio"/> Positive | | 287 | | 2 | 2 | 100 % | 0 % | 100 % |
| | | 1drop Inc. 1copy COVID-19 qPCR 4plex Kit | | 1 | | | | | |
| | | 3DMed ANDiS Fast SARS-CoV-2 RT-qPCR Detection Kit | | 8 | | | | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 | | 7 | | | | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 2.0 | | 2 | | | | | |
| | | Abbott Alinity m Resp-4-Plex assay | | 3 | | | | | |

| | | | | | | |
|--|---|----|--|--|--|--|
| | Abbott Alinity m SARS-CoV-2 assay | 4 | | | | |
| | Abbott ID NOW COVID-19 2.0 | 25 | | | | |
| | ACON Promotor SARS-CoV-2 RT PCR Test Kit | 1 | | | | |
| | Adaltis MOLgen SARS-COV2 Real Time RT PCR Kit | 1 | | | | |
| | Amplicon AmpliTest SARS-CoV-2 RdRp/E (Real Time PCR) | 1 | | | | |
| | Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit | 4 | | | | |
| | BD SARS-CoV-2 Reagents for BD MAX System | 2 | | | | |
| | BD SARS-CoV-2/Flu for BD MAX System | 5 | | | | |
| | BioFire Diagnostics BioFire Respiratory Panel 2.1 | 9 | | | | |
| | Biosynex AMPLIQUICK SARS-CoV-2 | 2 | | | | |
| | <input checked="" type="radio"/> Cepheid Xpert Xpress CoV-2 plus | 28 | | | | |
| | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | 13 | | | | |
| | Cepheid Xpert Xpress SARS-CoV-2 test | 19 | | | | |
| | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | 3 | | | | |
| | CerTest VIASURE SARS-CoV-2 Real Time PCR Detection Kit | 3 | | | | |
| | CerTest VIASURE SARS-CoV-2 S gene Real Time PCR | 1 | | | | |
| | Co-Diagnostics Logix Smart Coronavirus 2019 (COVID-19) Test Kit | 1 | | | | |
| | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | 25 | | | | |
| | DiaSorin Simplexa COVID-19 Direct Kit | 1 | | | | |
| | DNA-Technology SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit | 1 | | | | |
| | ELITechGroup SARS-CoV-2 ELITE MGB Kit | 4 | | | | |
| | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | 2 | | | | |
| | Eurobio Scientific EurobioPlex FluCoSyn | 5 | | | | |
| | Eurobio Scientific EurobioPlex SARS-CoV-2 Fast-SVD | 2 | | | | |
| | Euroimmun EURORealTime SARS-CoV-2 | 3 | | | | |
| | Fast-track Diagnostics FTD SARS-CoV-2 Assay | 1 | | | | |
| | GeneProof SARS-CoV-2 Advanced PCR Kit | 1 | | | | |
| | HEMA SARS-CoV-2 Real time PCR | 2 | | | | |
| | Hologic Panther Fusion SARS-CoV-2 Assay | 1 | | | | |
| | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | 5 | | | | |
| | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | 3 | | | | |
| | ID-Solutions IDNCOV2q | 2 | | | | |
| | In-house PCR for SARS-CoV-2 | 2 | | | | |
| | Jiangsu Bioperfectus Technologies COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | 1 | | | | |
| | Laboratoire OBO OSANTYS SARS-CoV-2 RT-qPCR Kit | 1 | | | | |
| | MIKROGEN ampliCube Coronavirus SARS-CoV-2 | 1 | | | | |
| | Mobidiag Amplidiag COVID-19 | 4 | | | | |
| | Mobidiag Amplidiag RESP-4 | 2 | | | | |
| | Mobidiag Novodiag COVID-19 | 3 | | | | |
| | NeuMoDx SARS-CoV-2 Assay | 3 | | | | |
| | NovaTec Immundiagnostica GSD NovaPrime TSP SARS-CoV-2 RT-PCR | 3 | | | | |
| | PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR | 1 | | | | |
| | PerkinElmer SARS-CoV-2 Nucleic Acid Detection Kit | 2 | | | | |
| | Primerdesign genesig Real-Time PCR Coronavirus (COVID-19) | 1 | | | | |
| | Primerdesign PROMate COVID-19 | 1 | | | | |

| | | | | | | | | | |
|--|--|--|------------|--|----------|----------|--------------|------------|-------------|
| | Qiagen QIAstat-Dx Respiratory SARS-CoV-2 Panel | | 1 | | | | | | |
| | Qiagen SARS-CoV-2 N1+N2 Assay Kit | | 2 | | | | | | |
| | Roche cobas SARS-CoV-2 & Influenza A/B Test | | 4 | | | | | | |
| | Roche cobas SARS-CoV-2 Test | | 3 | | | | | | |
| | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 5 | | | | | | |
| | Roche Liat cobas SARS-CoV-2 Assay | | 9 | | | | | | |
| | Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit | | 2 | | | | | | |
| | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 10 | | | | | | |
| | Seegene Allplex SARS-CoV-2 Assay | | 5 | | | | | | |
| | Seegene Allplex SARS-CoV-2 fast PCR Assay | | 3 | | | | | | |
| | Seegene Allplex SARS-CoV-2 Master Assay | | 3 | | | | | | |
| | Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay | | 2 | | | | | | |
| | Shenzhen Lifotronic Technology SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | | | | | |
| | Siemens FTD SARS-CoV-2 Assay | | 1 | | | | | | |
| | Tib Molbiol LightMix Modular SARS and Wuhan CoV E-gene | | 1 | | | | | | |
| | Ustar Biotechnologies EasyNAT SARS-CoV-2 | | 1 | | | | | | |
| | Vitassay qPCR SARS-CoV-2 | | 4 | | | | | | |
| | Xiamen Zeesan Biotech SARS-CoV-2 Test Kit (Real-time PCR) | | 1 | | | | | | |
| | Zybio SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | | | | | |
| | Total: | | 302 | | 2 | 2 | 100 % | 1 % | 99 % |

Report Info

PARTICIPANTS

Altogether 208 laboratories from 23 countries participated in this EQA round.

REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button . In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

SCORING

The round is scored based on test results when 60% or more of the participants report the expected result and when at least three results are reported. The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

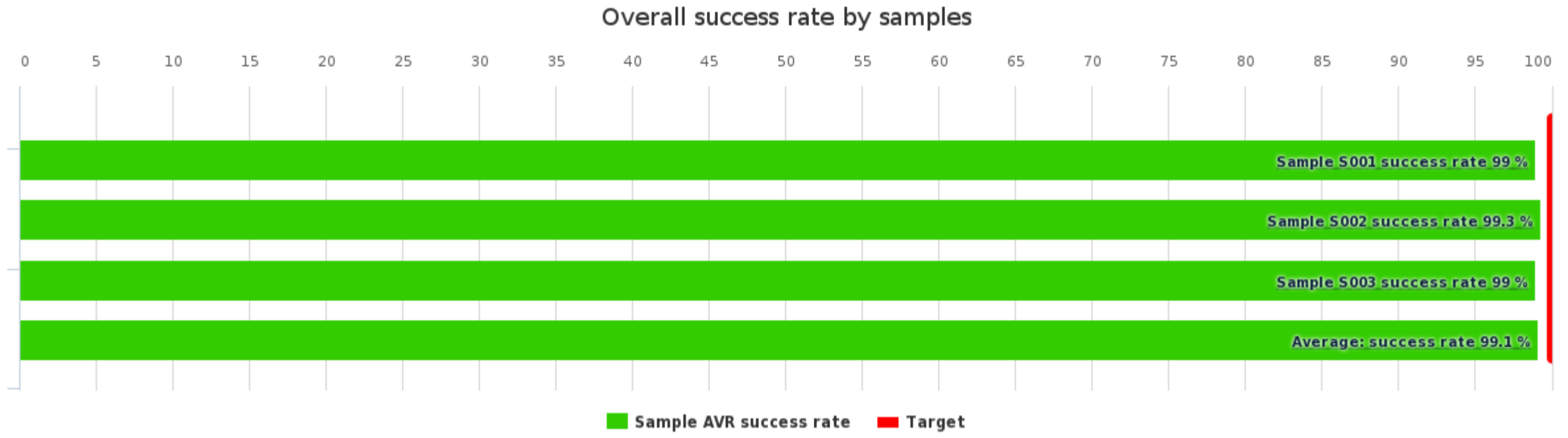
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample success rates.

The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

GLOBAL REPORT

| | No of participants | No of responded participants | Response percentage |
|---|--------------------|------------------------------|---------------------|
| SARS-CoV-2, nucleic acid detection, January, 1-2023 | 208 | 199 | 95.7 % |

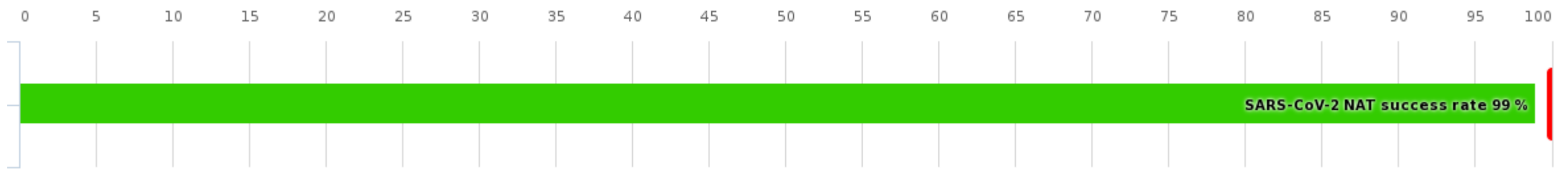
Summary



| Summary | AVR success rate |
|-------------|------------------|
| Sample S001 | 99 % |
| Sample S002 | 99.3 % |
| Sample S003 | 99 % |
| Average: | 99.1 % |

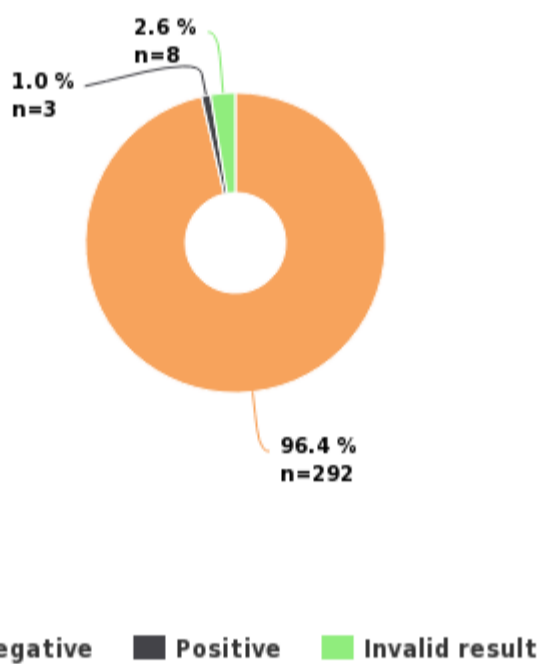
Sample S001

Sample S001 success rate



| Sample S001 results | Responded | AVR success rate | Count |
|---------------------|----------------|------------------|-------|
| | SARS-CoV-2 NAT | 99 % | 303 |
| Total: | | 99 % | 303 |

Sample S001 SARS-CoV-2 NAT



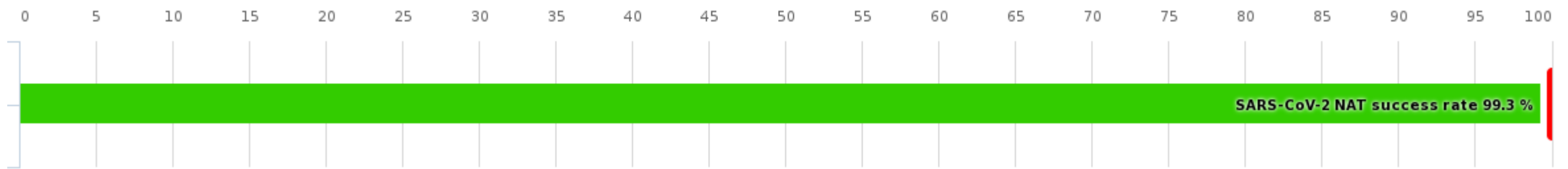
| SARS-CoV-2 NAT | Qualitative interpretation | Method | Qualitative interpretation count | Method count | AVR success rate | Qualitative interpretation Score |
|----------------|----------------------------|---|----------------------------------|--------------|------------------|----------------------------------|
| | Negative | | 292 | | 100 % | 2 |
| | | 1drop Inc. 1copy COVID-19 qPCR 4plex Kit | | 1 | | |
| | | 3DMed ANDiS Fast SARS-CoV-2 RT-qPCR Detection Kit | | 7 | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 | | 6 | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 2.0 | | 3 | | |
| | | Abbott Alinity m Resp-4-Plex assay | | 3 | | |
| | | Abbott Alinity m SARS-CoV-2 assay | | 4 | | |
| | | Abbott ID NOW COVID-19 2.0 | | 27 | | |
| | | ACON Promotor SARS-CoV-2 RT PCR Test Kit | | 1 | | |
| | | Adaltis MOLgen SARS-COV2 Real Time RT PCR Kit | | 1 | | |
| | | Amplicon AmpliTest SARS-CoV-2 RdRp/E (Real Time PCR) | | 1 | | |
| | | Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit | | 4 | | |
| | | BD SARS-CoV-2 Reagents for BD MAX System | | 2 | | |
| | | BD SARS-CoV-2/Flu for BD MAX System | | 6 | | |
| | | BioFire Diagnostics BioFire Respiratory Panel 2.1 | | 9 | | |
| | | Biosynex AMPLIQUICK SARS-CoV-2 | | 2 | | |
| | | Cepheid Xpert Xpress CoV-2 plus | | 28 | | |
| | | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | | 16 | | |
| | | Cepheid Xpert Xpress SARS-CoV-2 test | | 20 | | |
| | | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | | 2 | | |
| | | CerTest VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit for BD MAX | | 1 | | |
| | | CerTest VIASURE SARS-CoV-2 Real Time PCR Detection Kit | | 4 | | |
| | | Co-Diagnostics Logix Smart Coronavirus 2019 (COVID-19) Test Kit | | 1 | | |

| | | | | | | |
|--|----------------|---|--|----|-----|---|
| | | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | | 24 | | |
| | | DiaSorin Simplexa COVID-19 Direct Kit | | 1 | | |
| | | DNA-Technology SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit | | 1 | | |
| | | ELITechGroup SARS-CoV-2 ELITE MGB Kit | | 3 | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | | 3 | | |
| | | Eurobio Scientific EurobioPlex FluCoSyn | | 5 | | |
| | | Eurobio Scientific EurobioPlex SARS-CoV-2 Fast-SVD | | 2 | | |
| | | Euroimmun EURORealTime SARS-CoV-2 | | 3 | | |
| | | Fast-track Diagnostics FTD SARS-CoV-2 Assay | | 1 | | |
| | | GeneProof SARS-CoV-2 Advanced PCR Kit | | 1 | | |
| | | HEMA SARS-CoV-2 Real time PCR | | 2 | | |
| | | Hologic Panther Fusion SARS-CoV-2 Assay | | 1 | | |
| | | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | | 7 | | |
| | | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | | 4 | | |
| | | ID-Solutions IDNCOV2q | | 2 | | |
| | | In-house PCR for SARS-CoV-2 | | 1 | | |
| | | Jiangsu Biopertectus Technologies COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | | 1 | | |
| | | Laboratoire OBO OSANTYS SARS-CoV-2 RT-qPCR Kit | | 1 | | |
| | | Luminex ARIES SARS-CoV-2 Assay | | 1 | | |
| | | MIKROGEN ampliCube Coronavirus SARS-CoV-2 | | 1 | | |
| | | Mobidiag Amplidiag COVID-19 | | 3 | | |
| | | Mobidiag Amplidiag RESP-4 | | 2 | | |
| | | Mobidiag Novodiag COVID-19 | | 3 | | |
| | | NeuMoDx SARS-CoV-2 Assay | | 3 | | |
| | | NovaTec Immundiagnostica GSD NovaPrime TSP SARS-CoV-2 RT-PCR | | 3 | | |
| | | PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR | | 1 | | |
| | | PerkinElmer SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | |
| | | Primerdesign genesig Real-Time PCR Coronavirus (COVID-19) | | 1 | | |
| | | Primerdesign PROMate COVID-19 | | 1 | | |
| | | Qiagen QIAstat-Dx Respiratory SARS-CoV-2 Panel | | 1 | | |
| | | Qiagen SARS-CoV-2 N1+N2 Assay Kit | | 2 | | |
| | | Roche cobas SARS-CoV-2 & Influenza A/B Test | | 3 | | |
| | | Roche cobas SARS-CoV-2 Test | | 3 | | |
| | | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 6 | | |
| | | Roche Liat cobas SARS-CoV-2 Assay | | 9 | | |
| | | Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit | | 2 | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 8 | | |
| | | Seegene Allplex SARS-CoV-2 Assay | | 6 | | |
| | | Seegene Allplex SARS-CoV-2 fast PCR Assay | | 3 | | |
| | | Seegene Allplex SARS-CoV-2 Master Assay | | 2 | | |
| | | Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay | | 2 | | |
| | | Shenzhen Lifotronic Technology SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | |
| | | Siemens FTD SARS-CoV-2 Assay | | 1 | | |
| | | Tib Molbiol LightMix Modular SARS and Wuhan CoV E-gene | | 1 | | |
| | | Ustar Biotechnologies EasyNAT SARS-CoV-2 | | 1 | | |
| | | Vitassay qPCR SARS-CoV-2 | | 4 | | |
| | | Xiamen Zeesan Biotech SARS-CoV-2 Test Kit (Real-time PCR) | | 1 | | |
| | | Zybio SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | |
| | Positive | | | 3 | 0 % | 0 |
| | | Cepheid Xpert Xpress CoV-2 plus | | 1 | | |
| | | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 1 | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 1 | | |
| | Invalid result | | | 8 | - | - |

| | | | | | | |
|--|--------|---|-----|---|------|--|
| | | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | | 2 | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | | 2 | | |
| | | In-house PCR for SARS-CoV-2 | | 1 | | |
| | | Mobidiag Amplidiag COVID-19 | | 1 | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 1 | | |
| | | Seegene Allplex SARS-CoV-2 Master Assay | | 1 | | |
| | Total: | | 303 | | 99 % | |

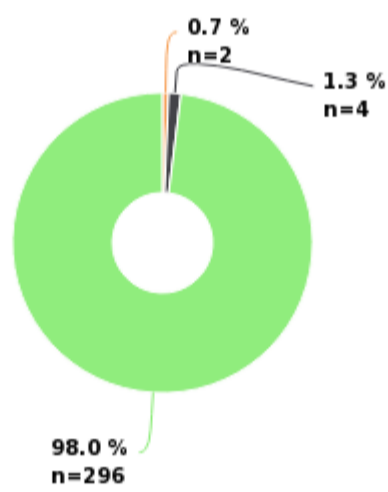
Sample S002

Sample S002 success rate



| Sample S002 results | Responded | AVR success rate | Count |
|---------------------|----------------|------------------|-------|
| | SARS-CoV-2 NAT | 99.3 % | 302 |
| Total: | | 99.3 % | 302 |

Sample S002 SARS-CoV-2 NAT



■ Negative
 ■ Weak positive
 ■ Positive

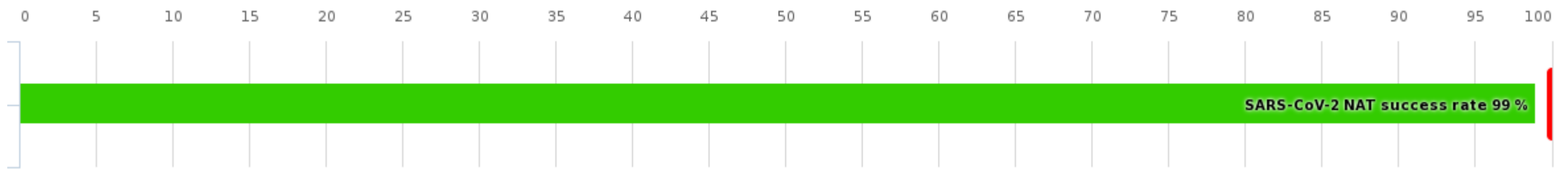
| SARS-CoV-2 NAT | Qualitative interpretation | Method | Qualitative interpretation count | Method count | AVR success rate | Qualitative interpretation Score |
|----------------|----------------------------|---|----------------------------------|--------------|------------------|----------------------------------|
| | Negative | | 2 | | 0 % | 0 |
| | | CerTest VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit for BD MAX | | 1 | | |
| | | SD Biosensor STANDARD M10 SARS-CoV-2 Test | | 1 | | |
| | Weak positive | | 4 | | 100 % | 2 |
| | | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | | 2 | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | | 1 | | |
| | | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | | 1 | | |
| | Positive | | 296 | | 100 % | 2 |
| | | 1drop Inc. 1copy COVID-19 qPCR 4plex Kit | | 1 | | |
| | | 3DMed ANDiS Fast SARS-CoV-2 RT-qPCR Detection Kit | | 7 | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 | | 6 | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 2.0 | | 3 | | |
| | | Abbott Alinity m Resp-4-Plex assay | | 3 | | |
| | | Abbott Alinity m SARS-CoV-2 assay | | 3 | | |
| | | Abbott ID NOW COVID-19 2.0 | | 26 | | |
| | | Abbott RealTime SARS-CoV-2 assay | | 1 | | |
| | | ACON Promotor SARS-CoV-2 RT PCR Test Kit | | 1 | | |
| | | Adaltis MOLgen SARS-COV2 Real Time RT PCR Kit | | 1 | | |
| | | Amplicon AmpliTest SARS-CoV-2 RdRp/E (Real Time PCR) | | 1 | | |
| | | Applied Biosystems TaqMan 2019-nCoV Assay Kit v1 | | 1 | | |
| | | Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit | | 3 | | |
| | | BD SARS-CoV-2 Reagents for BD MAX System | | 2 | | |
| | | BD SARS-CoV-2/Flu for BD MAX System | | 5 | | |

| | | | |
|--|---|----|--|
| | BioFire Diagnostics BioFire Respiratory Panel 2.1 | 9 | |
| | Biosynex AMPLIQUICK SARS-CoV-2 | 2 | |
| | Cepheid Xpert Xpress CoV-2 plus | 28 | |
| | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | 15 | |
| | Cepheid Xpert Xpress SARS-CoV-2 test | 19 | |
| | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | 2 | |
| | CerTest VIASURE SARS-CoV-2 Real Time PCR Detection Kit | 4 | |
| | Co-Diagnostics Logix Smart Coronavirus 2019 (COVID-19) Test Kit | 1 | |
| | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | 26 | |
| | DiaSorin Simplexa COVID-19 Direct Kit | 1 | |
| | DNA-Technology SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit | 1 | |
| | ELITechGroup SARS-CoV-2 ELITe MGB Kit | 4 | |
| | ELITechGroup SARS-CoV-2 PLUS ELITe MGB Kit | 4 | |
| | Eurobio Scientific EurobioPlex FluCoSyn | 5 | |
| | Eurobio Scientific EurobioPlex SARS-CoV-2 Fast-SVD | 2 | |
| | Euroimmun EURORealTime SARS-CoV-2 | 3 | |
| | Fast-track Diagnostics FTD SARS-CoV-2 Assay | 1 | |
| | GeneProof SARS-CoV-2 Advanced PCR Kit | 1 | |
| | HEMA SARS-CoV-2 Real time PCR | 2 | |
| | Hologic Panther Fusion SARS-CoV-2 Assay | 1 | |
| | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | 7 | |
| | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | 3 | |
| | ID-Solutions IDNCOV2q | 2 | |
| | In-house PCR for SARS-CoV-2 | 2 | |
| | Jiangsu Bioperfectus Technologies COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | 1 | |
| | Laboratoire OBO OSANTYS SARS-CoV-2 RT-qPCR Kit | 1 | |
| | Luminex ARIES SARS-CoV-2 Assay | 1 | |
| | MIKROGEN ampliCube Coronavirus SARS-CoV-2 | 1 | |
| | Mobidiag Amplidiag COVID-19 | 4 | |
| | Mobidiag Amplidiag RESP-4 | 2 | |
| | Mobidiag Novodiag COVID-19 | 4 | |
| | NeuMoDx SARS-CoV-2 Assay | 3 | |
| | NovaTec Immundiagnostica GSD NovaPrime TSP SARS-CoV-2 RT-PCR | 3 | |
| | PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR | 1 | |
| | PerkinElmer SARS-CoV-2 Nucleic Acid Detection Kit | 2 | |
| | Primerdesign genesig Real-Time PCR Coronavirus (COVID-19) | 1 | |
| | Primerdesign PROmate COVID-19 | 1 | |
| | Qiagen QIAstat-Dx Respiratory SARS-CoV-2 Panel | 1 | |
| | Qiagen SARS-CoV-2 N1+N2 Assay Kit | 2 | |
| | Roche cobas SARS-CoV-2 & Influenza A/B Test | 3 | |
| | Roche cobas SARS-CoV-2 Test | 3 | |
| | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | 7 | |
| | Roche Liat cobas SARS-CoV-2 Assay | 9 | |
| | Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit | 2 | |
| | SD Biosensor STANDARD M10 SARS-CoV-2 Test | 9 | |
| | Seegene Allplex SARS-CoV-2 Assay | 6 | |
| | Seegene Allplex SARS-CoV-2 fast PCR Assay | 3 | |
| | Seegene Allplex SARS-CoV-2 Master Assay | 3 | |
| | Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay | 2 | |
| | Shenzhen Lifotronic Technology SARS-CoV-2 Nucleic Acid Detection Kit | 2 | |
| | Siemens FTD SARS-CoV-2 Assay | 1 | |
| | Tib Molbiol LightMix Modular SARS and Wuhan CoV E-gene | 1 | |
| | Ustar Biotechnologies EasyNAT SARS-CoV-2 | 1 | |

| | | | | | | |
|--|--------|---|-----|---|--------|--|
| | | Vitassay qPCR SARS-CoV-2 | | 4 | | |
| | | Xiamen Zeesan Biotech SARS-CoV-2 Test Kit (Real-time PCR) | | 1 | | |
| | | Zybio SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | |
| | Total: | | 302 | | 99.3 % | |

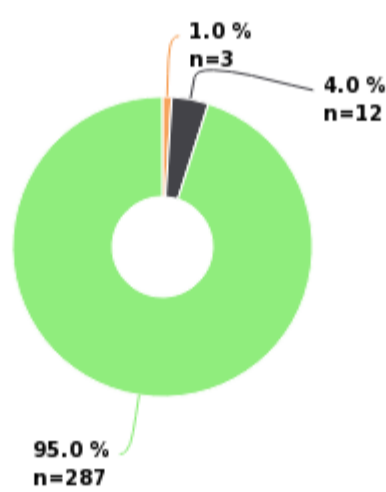
Sample S003

Sample S003 success rate



| Sample S003 results | Responded | AVR success rate | Count |
|---------------------|----------------|------------------|-------|
| | SARS-CoV-2 NAT | 99 % | 302 |
| Total: | | 99 % | 302 |

Sample S003 SARS-CoV-2 NAT



■ Negative
 ■ Weak positive
 ■ Positive

| SARS-CoV-2 NAT | Qualitative interpretation | Method | Qualitative interpretation count | Method count | AVR success rate | Qualitative interpretation Score |
|----------------|----------------------------|---|----------------------------------|--------------|------------------|----------------------------------|
| | Negative | | 3 | | 0 % | 0 |
| | | Cepheid Xpert Xpress CoV-2 plus | | 1 | | |
| | | CerTest VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit for BD MAX | | 1 | | |
| | | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | | 1 | | |
| | Weak positive | | 12 | | 100 % | 2 |
| | | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | | 2 | | |
| | | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | | 1 | | |
| | | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | | 1 | | |
| | | ELITechGroup SARS-CoV-2 PLUS ELITe MGB Kit | | 3 | | |
| | | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | | 2 | | |
| | | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | | 1 | | |
| | | Luminex ARIES SARS-CoV-2 Assay | | 1 | | |
| | | Seegene Allplex SARS-CoV-2 Assay | | 1 | | |
| | Positive | | 287 | | 100 % | 2 |
| | | 1drop Inc. 1copy COVID-19 qPCR 4plex Kit | | 1 | | |
| | | 3DMed ANDiS Fast SARS-CoV-2 RT-qPCR Detection Kit | | 8 | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 | | 7 | | |
| | | Abacus Diagnostica GenomEra SARS-CoV-2 2.0 | | 2 | | |
| | | Abbott Alinity m Resp-4-Plex assay | | 3 | | |
| | | Abbott Alinity m SARS-CoV-2 assay | | 4 | | |
| | | Abbott ID NOW COVID-19 2.0 | | 25 | | |
| | | ACON Promotor SARS-CoV-2 RT PCR Test Kit | | 1 | | |
| | | Adaltis MOLgen SARS-COV2 Real Time RT PCR Kit | | 1 | | |

| | | | |
|--|---|----|--|
| | Amplicon AmpliTest SARS-CoV-2 RdRp/E (Real Time PCR) | 1 | |
| | Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR Kit | 4 | |
| | BD SARS-CoV-2 Reagents for BD MAX System | 2 | |
| | BD SARS-CoV-2/Flu for BD MAX System | 5 | |
| | BioFire Diagnostics BioFire Respiratory Panel 2.1 | 9 | |
| | Biosynex AMPLIQUICK SARS-CoV-2 | 2 | |
| | Cepheid Xpert Xpress CoV-2 plus | 28 | |
| | Cepheid Xpert Xpress CoV-2/Flu/RSV plus | 13 | |
| | Cepheid Xpert Xpress SARS-CoV-2 test | 19 | |
| | Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV | 3 | |
| | CerTest VIASURE SARS-CoV-2 Real Time PCR Detection Kit | 3 | |
| | CerTest VIASURE SARS-CoV-2 S gene Real Time PCR | 1 | |
| | Co-Diagnostics Logix Smart Coronavirus 2019 (COVID-19) Test Kit | 1 | |
| | Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay | 25 | |
| | DiaSorin Simplexa COVID-19 Direct Kit | 1 | |
| | DNA-Technology SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit | 1 | |
| | ELITechGroup SARS-CoV-2 ELITE MGB Kit | 4 | |
| | ELITechGroup SARS-CoV-2 PLUS ELITE MGB Kit | 2 | |
| | Eurobio Scientific EurobioPlex FluCoSyn | 5 | |
| | Eurobio Scientific EurobioPlex SARS-CoV-2 Fast-SVD | 2 | |
| | Euroimmun EURORealTime SARS-CoV-2 | 3 | |
| | Fast-track Diagnostics FTD SARS-CoV-2 Assay | 1 | |
| | GeneProof SARS-CoV-2 Advanced PCR Kit | 1 | |
| | HEMA SARS-CoV-2 Real time PCR | 2 | |
| | Hologic Panther Fusion SARS-CoV-2 Assay | 1 | |
| | ID-Solutions ID SARS-CoV-2 / Influenza Triplex | 5 | |
| | ID-Solutions ID SARS-CoV-2 / VOC Revolution Pentaplex | 3 | |
| | ID-Solutions IDNCOV2q | 2 | |
| | In-house PCR for SARS-CoV-2 | 2 | |
| | Jiangsu Bioperfectus Technologies COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | 1 | |
| | Laboratoire OBO OSANTYS SARS-CoV-2 RT-qPCR Kit | 1 | |
| | MIKROGEN ampliCube Coronavirus SARS-CoV-2 | 1 | |
| | Mobidiag Amplidiag COVID-19 | 4 | |
| | Mobidiag Amplidiag RESP-4 | 2 | |
| | Mobidiag Novodiag COVID-19 | 3 | |
| | NeuMoDx SARS-CoV-2 Assay | 3 | |
| | NovaTec Immundiagnostica GSD NovaPrime TSP SARS-CoV-2 RT-PCR | 3 | |
| | PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR | 1 | |
| | PerkinElmer SARS-CoV-2 Nucleic Acid Detection Kit | 2 | |
| | Primerdesign genesig Real-Time PCR Coronavirus (COVID-19) | 1 | |
| | Primerdesign PROmate COVID-19 | 1 | |
| | Qiagen QIAstat-Dx Respiratory SARS-CoV-2 Panel | 1 | |
| | Qiagen SARS-CoV-2 N1+N2 Assay Kit | 2 | |
| | Roche cobas SARS-CoV-2 & Influenza A/B Test | 4 | |
| | Roche cobas SARS-CoV-2 Test | 3 | |
| | Roche Liat cobas SARS-CoV-2 & Influenza A/B Assay | 5 | |
| | Roche Liat cobas SARS-CoV-2 Assay | 9 | |
| | Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit | 2 | |
| | SD Biosensor STANDARD M10 SARS-CoV-2 Test | 10 | |
| | Seegene Allplex SARS-CoV-2 Assay | 5 | |
| | Seegene Allplex SARS-CoV-2 fast PCR Assay | 3 | |
| | Seegene Allplex SARS-CoV-2 Master Assay | 3 | |
| | Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay | 2 | |

| | | | | | | |
|--|--------|--|-----|---|------|--|
| | | Shenzhen Lifotronic Technology SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | |
| | | Siemens FTD SARS-CoV-2 Assay | | 1 | | |
| | | Tib Molbiol LightMix Modular SARS and Wuhan CoV E-gene | | 1 | | |
| | | Ustar Biotechnologies EasyNAT SARS-CoV-2 | | 1 | | |
| | | Vitassay qPCR SARS-CoV-2 | | 4 | | |
| | | Xiamen Zeesan Biotech SARS-CoV-2 Test Kit (Real-time PCR) | | 1 | | |
| | | Zybio SARS-CoV-2 Nucleic Acid Detection Kit | | 2 | | |
| | Total: | | 302 | | 99 % | |

Report Info

PARTICIPANTS

Altogether 208 laboratories from 23 countries participated in this EQA round.

REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button . In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

SCORING

The round is scored based on test results when 60% or more of the participants report the expected result and when at least three results are reported. The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample success rates.

The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

External Quality Assessment Scheme

SARS-CoV-2, nucleic acid detection Round 1, 2023

Specimens

Samples of this EQA round were simulated samples, which included the whole genome of SARS-CoV-2 virus. The sample lots were tested in an accredited Finnish reference laboratory and the results were consistent with the certificates provided by the sample manufacturer. Based on the quality controls conducted by the sample material manufacturer, pre-testing and the results obtained in the round, the sample lots are to be considered as homogeneous, stable and suitable for external quality assessment. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ775723011)
SARS-CoV-2 NAT negative

Sample S002 (LQ775723012)
SARS-CoV-2 NAT positive
Strain: NC_045512 (original strain)
Pre-test laboratory C_t values: 28.46 (E gene), 28.20 (S gene)

Sample S003 (LQ775723013)
SARS-CoV-2 NAT positive
Strain: B.1.1.529 (Omicron variant)
Pre-test laboratory C_t values: 29.41 (E gene), 30.19 (S gene)

C_t values reported by participants are now available in LabScala. The results are sorted by genes in tables.

Pre-test method: Laboratory-developed multiplex RT-PCR test with WHO recommended E gene specific target and S gene specific target with S/S(del69–70) differentiation.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – Expert

The success rate was very high, 99.1% on this EQA round. Both virus strains were detected equally well. The average C_t values reported by participants were very close to pre-testing values. Standard deviations are expectably rather large when many different methods are used. According to published reports on infectivity, an upper C_t value of 25–35 correlate with culture of viable virus from a sample. Average C_t values reported by the participants were between 27.99–30.70 for samples S002 and S003. Thus, a C_t value ≥ 35 from these samples could be considered a poor result from the clinical point of view. Participants reported 8 (2.6%) unclear results for the negative sample S001, possibly because of a low concentration of human cellular material in it. This will be corrected in the next round.

Exceptions in scoring

Invalid test results reported from the negative sample (S001) were excluded from the scoring, because the concentration of human cells was possibly too low for some methods.

2023-03-08

FINAL REPORT

Product no. 5676

Subcontracting: Sample pretesting

| | |
|------------------|------------|
| Samples sent | 2023-01-24 |
| Round closed | 2023-02-20 |
| Expected results | 2023-02-21 |
| Final report | 2023-03-08 |

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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Only the qualitative analysis phase is accredited.



End of report

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