J. PERFORMANCE EVALUATION

## *1) Limit of Detection (LoD) - Analytical Sensitivity:*

The LoD study established the lowest concentration of SARS-CoV-2 (genome copies(cp)/mL) that can be detected by the Diagnovital SARS-CoV-2 test at least 95% of the time. The preliminary LoD was established by testing 10-fold dilutions of a positive patient sample extracted using RTA Viral RNA Isolation Kit and quantitated by Droplet Digital PCR (QX200 Droplet Digital PCR System, BioRad). The extracted RNA was tested in triplicate by Diagnovital SARS-CoV-2.

| **SARS-CoV-2 - Tentative LoD** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Target Level** | **Valid results** | **E-Gene** | | | **RdRp** | | | **RNase P** | | |
| | | **n** | **Mean Ct** | **Detection Rate** | **n** | **Mean Ct** | **Detection Rate** | **n** | **Mean Ct** | **Detection Rate** |
| 100.000 cp/mL | 3 | 3 | 25.5 | 100% | 3 | 24.8 | 100% | 3 | 25.4 | 100% |
| 10.000 cp/mL | 3 | 3 | 29.2 | 100% | 3 | 28.3 | 100% | 3 | 27.8 | 100% |
| 1.000 cp/mL | 3 | 3 | 33.0 | 100% | 3 | 31.7 | 100% | 3 | 32.2 | 100% |
| **100 cp/mL** | **3** | **3** | **35.9** | **100%** | **3** | **34.5** | **100%** | **3** | **35.5** | **100%** |
| 10 cp/mL | 3 | 2 | 40.5 | 66.6% | 2 | 38.1 | 66.6% | 3 | 38.8 | 100% |
| 1 cp/mL | 3 | 0 | NA | 0% | 0 | NA | 0% | 0 | NA | 0% |
| Negative | 3 | 0 | NA | 0% | 0 | NA | 0% | 0 | NA | 0% |
| **Tentative LoD: 100 cp/mL** [lowest target level demonstrating >95% detection rate of both targets] | | | | | | | | | | |

The concentration range between 100 cp/ml and 10 cp/ml was further broken down to confirm the LoD by testing 24 replicates of 100 cp/mL, 30 cp/mL, and 10 cp/mL. The nasopharyngeal samples were prepared by spiking the quantified SARS-CoV-2 RNA into VTM. Using TRA Viral RNA Isolation Kit, 150 µl of VTM was extracted. The extracted RNA was tested by BIO-RAD CFX96-IVD Real-Time PCR Detection System and QuantStudio™ 5 Dx.

| **SARS-CoV-2 - Confirmatory LoD (BIO-RAD CFX96-IVD)** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Target Level** | **Valid results** | **E-Gene** | | | **RdRp** | | | **RNase P** | | |
| | | **n** | **Mean Ct** | **Detection Rate** | **n** | **Mean Ct** | **Detection Rate** | **n** | **Mean Ct** | **Detection Rate** |
| 100 cp/mL | 24 | 20 | 33.85 | 100% | 24 | 33.92 | 100% | 24 | 33.40 | 100% |
| 30 cp/mL | 24 | 18 | 33.91 | 75% | 20 | 34.64 | 65% | 24 | 34.04 | 100% |
| 10 cp/mL | 24 | 3 | 35.81 | 12.5% | 6 | 35.73 | 25% | 10 | 35.19 | 42% |

| SARS-CoV-2 - Confirmatory LoD (QuantStudio™ 5 Dx) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Target Level | Valid results | E-Gene | | | RdRp | | | RNase P | | |
| | | n | Mean Ct | Detection Rate | n | Mean Ct | Detection Rate | n | Mean Ct | Detection Rate |
| 100 cp/mL | 24 | 20 | 33.52 | 100% | 24 | 33.58 | 100% | 24 | 33.51 | 100% |
| 30 cp/mL | 24 | 19 | 34.01 | 75% | 20 | 34.23 | 65% | 20 | 34.44 | 83% |
| 10 cp/mL | 24 | 4 | 35.20 | 17% | 8 | 35.37 | 33% | 17 | 34.84 | 70% |

The final LoD for the Diagnovital SARS-CoV-2 is calculated to be 38 copies/mL, which is the lowest concentration at which equal or above 95% of replicates were detected (i.e., 24/24 for the E gene and 24/24 for the RdRp gene).

## 2) ***Inclusivity (Analytical Sensitivity):***

Primer/probe inclusivity was evaluated by BLAST analysis against 389 publicly available SARS-CoV-2 sequences in the Betacoronavirus database on April 5, 2020. The Primers E_Sarbeco_F1, E_Sarbeco_R2, RdRp_SARSr-F2, RdRp_SARSr-R1, and probes E_Sarbeco_P1 and RdRp_SARSr-P2 exhibited 100% homology with all the available sequences.

The Primers and Probes from WHO were used during the studies. Please refer to the following link : https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045).

## 3) ***Cross-reactivity (Analytical Specificity):***

### *a. Wet Testing*

In this study, the specificity of the Diagnovital SARS-CoV-2 Kit was evaluated by testing the organisms listed in the table below. In the absence of SARS-CoV-2, 9 reference organisms and 11 clinical specimens were tested. The potential cross-reactive organisms were tested at concentrations between $1x10^3$ – $1x10^5$ copies/ml. Exact concentrations for the cross reactants was not available. Cross-reactivity with other coronaviruses cell culture supernatants containing human coronaviruses (HCoV)-229E, -NL63, -OC43, and -HKU1, as well as MERS-CoV, were tested in all three assays.
For the non-cultivable HCoV-HKU1, a supernatant from human airway culture was used. Virus RNA concentration in all samples was determined by specific real-time RT-PCRs and in-vitro transcribed RNA standards designed for absolute viral load quantification.

Samples were extracted by RTA Viral RNA Isolation Kit according to the RTA Viral RNA Isolation Kit Handbook. Starting sample volumes were 150 µl and elution volumes were 50 µl. Then, PCR reactions were setup by Diagnovital SARS-CoV-2 Real Time PCR Kit according to the Diagnovital SARS-CoV-2 Kit Handbook. BIO-RAD CFX96-IVD Real-Time PCR Detection System was used for amplification, detection, and analysis. Amplification Ct values of the study are provided in the table below. Diagnovital SARS-

CoV-2 Kit does not show any cross-reactivity with other potential cross-reactive markers at the tested concentration for the organisms listed in the table below.

**Table 4:** Potential cross-reactive markers tested in the study.

| Sample | Source | Sample ID | Replicates Detected/Total | Result |
|---|---|---|---|---|
| Human Adenovirus | NIBSC | 16/324 | 0/3 | Negative |
| Parainfluenza virus | ATCC | VR-93 | 0/3 | Negative |
| Influenza A | ATCC | VR-95 | 0/3 | Negative |
| Influenza A H5N1 | ATCC | VR-1609 | 0/3 | Negative |
| Influenza A H1N1 | ATCC | VR-1672 | 0/3 | Negative |
| Influenza A H3N2 | ATCC | VR-822 | 0/3 | Negative |
| Influenza A H7N7 | ATCC | VR-1641 | 0/3 | Negative |
| Influenza B | ATCC | VR-101 | 0/3 | Negative |
| Parainfluenza 1 | ATCC | VR-94 | 0/3 | Negative |
| Parainfluenza 2 | ATCC | VR-92 | 0/3 | Negative |
| Parainfluenza 3 | ATCC | VR-93 | 0/3 | Negative |
| Parainfluenza 4 | ATCC | VR-579 | 0/3 | Negative |
| Human Metapneumovirus (hMPV) | ATCC | VR-3250SD | 0/3 | Negative |
| Human Enterovirus V71 | ATCC | VR-1432 | 0/3 | Negative |
| Human respiratory syncytial virus | ATCC | VR-154 | 0/3 | Negative |
| Human Coronavirus NL63 | ATCC | VR-3263SD | 0/3 | Negative |
| Human Coronavirus HKU1 | ATCC | VR-3262SD | 0/3 | Negative |
| Human Coronavirus 229E | ATCC | VR-740 | 0/3 | Negative |
| Betacoronavirus 1 OC43 | ATCC | VR-1558D | 0/3 | Negative |
| MERS Coronavirus | ATCC | VR-3248SD | 0/3 | Negative |
| TPC | | | 0/3 | 20,91 |
| NTC | | | 0/3 | Negative |

### *b. In Silico Analysis:*

BLAST analysis showed no homology with primers and probes of the Diagnovital SARS-CoV-2 Kit for the organisms listed in the table below.

The *in-silico* analysis for possible cross-reactions with all the organisms listed in Table 2 was conducted by mapping primers in Diagnovital SARS-CoV-2 Real Time PCR Kit individually to the sequences downloaded from NCBI database. No potential cross reactivity was observed with analyzed pathogens.

**Table 5.** In-Silico Analysis for Primers and Probes

| Pathogen | Strain | GenBank Accession # | % Homology Forward E Primer | % Homology Reverse E Primer | % Homology E Probe | % Homology Forward RdRp Primer | % Homology Reverse RdRp Primer | % Homology RdRp Probe |
|---|---|---|---|---|---|---|---|---|
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome | NC_045512.2 | 100% | 100% | 100% | 100% | 100% | 100% |
| Human coronavirus 229E | Human coronavirus 229E strain 229E/human/USA/932-72/1993, complete genome | KF514432.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| | Human coronavirus 229E strain 229E/human/USA/933-40/1993, complete genome | KF514433.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Human coronavirus OC43 | Human coronavirus OC43 strain OC43/human/USA/971-5/1997, complete genome | KF530099.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| | Human coronavirus OC43 isolate LRTI_238, complete genome | KX344031.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Human coronavirus HKU1 | Human coronavirus HKU1 strain HKU1/human/USA/HKU1-18/2010, complete genome | KF430201.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| | Human coronavirus HKU1 isolate SI17244, complete genome | MH940245.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Human coronavirus NL63 | Human coronavirus NL63 strain NL63/human/USA/905-25/1990, complete genome | KF530113.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| | Human coronavirus NL63 strain NL63/human/USA/891-4/1989, complete genome | KF530114.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| SARS-coronavirus | SARS coronavirus CUHK-AG01, complete genome | AY345986.1 | 100% | 100% | 100% | 100% | 100% | 52% |
| | SARS coronavirus A022, complete genome | AY686863.1 | 100% | 100% | 100% | 100% | 100% | 52% |
| MERS-Coronavirus | Middle East respiratory syndrome-related coronavirus strain HCoV-EMC, complete genome | MH013216.1 | <50% | <50% | <50% | <50% | 78% | <50% |
| Adenovirus | Human adenovirus type 1, complete genome | AC_000017.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Human Metapneumovirus (hMPV) | Human metapneumovirus strain HMPV/Homo sapiens/PER/FPP00726/2011/A, complete genome | KJ627437.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Parainfluenza 1 | Human parainfluenza virus 1 isolate NM001, complete genome | KX639498.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Parainfluenza 2 | Human parainfluenza virus 2 isolate VIROAF10, complete genome | KM190939.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Parainfluenza 3 | Human parainfluenza virus 3 strain HPIV3/AUS/3/2007, complete genome | KF530243.1 | <50% | <50% | <50% | <50% | <50% | <50% |

| Pathogen | Strain | GenBank Accession # | % Homology Forward E Primer | % Homology Reverse E Primer | % Homology E Probe | % Homology Forward RdRp Primer | % Homology Reverse RdRp Primer | % Homology RdRp Probe |
|---|---|---|---|---|---|---|---|---|
| Parainfluenza 4 | Human parainfluenza virus 4a isolate HPIV4_DK(459), complete genome | KF483663.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Influenza A | Influenza A virus (A/New York/PV305/2017(H1N1)) segment 2 polymerase PB1 (PB1) gene, complete cds; and nonfunctional PB1-F2 protein (PB1-F2) gene, complete sequence | MH798556.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Influenza B | Influenza B virus (B/Nicaragua/8689_13/2017) segment 2 polymerase PB2 (PB2) gene, complete cds | MK969560.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Enterovirus | Human enterovirus 68 isolate EV68_NL_201013421 VP1 protein gene, partial cds | JF896312.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Respiratory syncytial virus | Respiratory syncytial virus strain B/WI/629-Q0190/10, complete genome | JN032120.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Rhinovirus | Human rhinovirus 14, complete genome | NC_001490.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Chlamydia pneumoniae | Chlamydia pneumoniae genome assembly PB2, chromosome : 1 | NZ_LN847241.1 | <50% | 77% | 50% | <50% | <50% | 52% |
| Haemophilus influenzae | Haemophilus influenzae PittGG, complete genome | CP000672.1 | <50% | 59% | <50% | <50% | <50% | <50% |
| Legionella pneumophila | Legionella pneumophila strain Philadelphia_1_CDC, complete genome | CP015928.1 | <50% | 54% | 50% | 59% | 50% | 56% |
| Mycobacterium tuberculosis | Mycobacterium tuberculosis DNA, complete genome, strain: HN-506 | AP018036.1 | <50% | 63% | 50% | 59% | <50% | <50% |
| Streptococcus pneumoniae | Streptococcus pneumoniae strain D39V chromosome, complete genome | CP027540.1 | <50% | <50% | 54% | <50% | 50% | 56% |
| Streptococcus pyogene | Streptococcus pyogenes MGAS8232, complete genome | AE009949.1 | 53% | 59% | <50% | <50% | 50% | 64% |
| Bordetella pertussis | Bordetella pertussis strain B3921, complete genome | CP011448.1 | <50% | 63% | <50% | <50% | <50% | 52% |
| Mycoplasma pneumoniae | Mycoplasma pneumoniae strain 14-637 chromosome, complete genome | CP039772.1 | <50% | 54% | <50% | <50% | <50% | <50% |
| Pneumocystis jirovecii | Pneumocystis jirovecii isolate SW7_full mitochondrion, complete genome | MH010446.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Candida albicans | Candida albicans strain L757 mitochondrion, complete genome | NC_018046.1 | <50% | <50% | <50% | <50% | <50% | <50% |
| Pseudomonas aeruginosa | Pseudomonas aeruginosa UCBPP-PA14, complete genome | CP000438.1 | 50% | 77% | <50% | 59% | <50% | <50% |
| Staphylococcus epidermidis | Staphylococcus epidermidis strain SP3 16S ribosomal RNA gene, partial sequence | KY750253.1 | <50% | <50% | <50% | <50% | <50% | <50% |

| Pathogen | Strain | GenBank Accession # | % Homology Forward E Primer | % Homology Reverse E Primer | % Homology E Probe | % Homology Forward RdRp Primer | % Homology Reverse RdRp Primer | % Homology RdRp Probe |
|---|---|---|---|---|---|---|---|---|
| Streptococcus salivarius | Streptococcus salivarius strain LAB813 chromosome, complete genome | CP040804.1 | 65% | 54% | <50% | 59% | 50% | <50% |

**b)** ***Microbial Interference Studies****:*

Microbial Interference Studies were not performed because no homology above 80 % was determined in the in-silico analysis with the test's primers and probes for any of the targets.

***c) Endogenous Interference Substances Studies:***

We tested potential endogenous interference substances which may interfere with PCR using the Diagnovital SARS-CoV-2 Kit. The substances were tested at the concentrations indicated in the table below. UTM was spiked with the substances indicated below. In the sampled matrixes, RNA was extracted using the RTA RNA Viral Isolation Kit. The extracted RNA was tested in triplicates using the Diagnovital SARS-CoV-2 Kit.

In the table below, the results show that the PCR was not affected by the potential endogenous interfering substances.

**Table 6:** Interference Study

| Potential Interfering Substance | Conc. | Positive Samples | | Negative Samples |
|---|---|---|---|---|
| | | Viral Strain Level | Results | Results |
| Mucin: bovine submaxillary gland, type I-S | 2.5 mg/ml | 2.5X LoD | 3/3 | 0/3 |
| Blood (human) | 2.5% v/v | 2.5X LoD | 3/3 | 0/3 |
| Afrin Original nasal spray | 15% v/v | 2.5X LoD | 3/3 | 0/3 |
| Basic Care allergy relief nasal spray (Gluococorticoid) | 5% v/v | 2.5X LoD | 3/3 | 0/3 |
| NeilMed Nasal gel | 1.25% | 2.5X LoD | 3/3 | 0/3 |
| GoodSense All Day Allergy, Cetirizine HCl Tablets 10 mg | 1mg/mL | 2.5X LoD | 3/3 | 0/3 |
| Cepacol Sore Throat (benzocaine/menthol lozenges) | 5 mg/mL | 2.5X LoD | 3/3 | 0/3 |
| Zanamivir | 3.3 mg/mL | 2.5X LoD | 3/3 | 0/3 |
| Tamiflu | 2.2 µg/mL | 2.5X LoD | 3/3 | 0/3 |
| Mupirocin ointment | 5mg/mL | 2.5X LoD | 3/3 | 0/3 |
| Tobramycin | 4ug/mL | 2.5X LoD | 3/3 | 0/3 |

## *4) Clinical Evaluation:*

### a. Specificity

Clinical specimens that were characterized as negative for SARS-CoV-2 by the Roche Cobas SARS-CoV-2 Test were used in clinical evaluation studies. They were collected from patients with signs and symptoms of an upper respiratory infection and by qualified personnel according to the package insert of the collection device of the Copan swabs and Copan UTM. Specimens were handled as described in the package insert of the collection device and were stored frozen until use. Samples were tested to be negative also for common upper respiratory tract infections. The following samples were obtained: 30 oropharyngeal, 10 nasal, 30 nasopharyngeal swabs, and 30 bronchoalveolar lavage (BAL) specimens. Aliquots of the samples were extracted and tested in a blinded manner together with the positive spiked samples described below and according to the Diagnovital SARS-CoV-2 Instructions for Use using the BIO-RAD CFX96-IVD Real-Time PCR Detection System and QuantStudio™ 5 Dx for amplification, detection, and analysis.

Individual Ct values of these samples for the SARS-CoV-2 targets and RNase P are provided in Appendix 2, tables 1-4. The negative percent agreement was calculated based on the result obtained from the prior testing at a government laboratory. None of the 100 SARS-CoV-2 negative clinical specimens gave positive test result for SARS-CoV-2. Diagnostic specificity of Diagnovital SARS-CoV-2 is 100 % (see combined performance tables below).

### b. Sensitivity

A second aliquot of the negative samples described above was tested in a contrived clinical study. Positive samples were generated by spiking the negative aliquots of the 30 NP swabs and 30 BALs with a quantified clinical specimen positive for SARS-CoV-2 (see LoD above) at 1.5X LOD (20 samples), 2X LOD (5 samples), and 80X LOD (5 samples) SARS-CoV-2 RNA. Positive specimens were tested in a blinded manner with the negative specimen from section **a.** above.

The positive percent agreement was calculated based on the agreement of the Diagnovital SARS-CoV-2 result with the expected spiked results in NP swabs and BALs. Results are shown below.

**Table 7**. Clinical Performance of the Diagnovital SARS-CoV-2 Kit against the expected results (spiking status) in NP swab specimens are:

| Sample Concentration | n | Target 1 (E Gene) | | Target 2 (RdRp Gene) | | RNase P | |
|---|---|---|---|---|---|---|---|
| | | % positive (two-sided 95% CI) | Mean Ct | % positive (two-sided 95% CI) | Mean Ct | % positive | Mean Ct |
| **NASOPHARYNGEAL-SWABS** | | | | | | | |
| 150 c/mL<br>1.5X LoD | 20 | 100<br>(80.6 – 99.9) | 33.8 | 100<br>(80.6 – 99.9) | 34.3 | 100<br>(80.6 – 99.9) | 26.1 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 200 c/mL<br>2X LoD | 5 | 100<br>(65.8 – 99.9) | 33.9 | 100<br>(65.8 – 99.9) | 34.2 | 100<br>(65.8 – 99.9) | 26.1 |
| 8000c/mL<br>80X LoD | 5 | 100<br>(65.8 – 99.9) | 25.0 | 100<br>(65.8 – 99.9) | 25.2 | 100<br>(65.8 – 99.9) | 25.5 |
| Negative | 30 | 0<br>(n/a) | N/A | 0<br>(n/a) | N/A | 100<br>(88.7 - 100) | 25.4 |
| **Positive Percent Agreement: 30/30 = 100% (95% CI: 88.7% - 100%)**<br>**Negative Percent Agreement: 10/10 = 100% (95% CI: 72.1% - 100%)** | | | | | | | |
| **NASAL-SWABS** | | | | | | | |
| Negative | 10 | 0<br>(n/a) | N/A | 0<br>(n/a) | N/A | 100<br>(72.1 – 99.9) | 26.5 |
| **OROPHARYNGEAL SWABS** | | | | | | | |
| Negative | 30 | 0<br>(n/a) | N/A | 0<br>(n/a) | N/A | 100<br>(88.7 - 100) | 25.7 |
| **Negative Percent Agreement (Nasal Swabs): 10/10 = 100% (95% CI: 72.1% - 100%)**<br>**Negative Percent Agreement (Oropharyngeal Swabs): 10/10 = 100% (95% CI: 72.1% - 100%)** | | | | | | | |
| **BAL** | | | | | | | |
| 150 c/mL<br>1.5X LoD | 20 | 100<br>(80.6 – 99.9) | 33.2 | 100<br>(80.6 – 99.9) | 33.8 | 100<br>(80.6 – 99.9) | 25.8 |
| 200 c/mL<br>2X LoD | 5 | 100<br>(65.8 – 99.9) | 33.4 | 100<br>(65.8 – 99.9) | 33.7 | 100<br>(65.8 – 99.9) | 25.9 |
| 8000 c/mL<br>80X LoD | 5 | 100<br>(65.8 – 99.9) | 24.4 | 100<br>(65.8 – 99.9) | 24.7 | 100<br>(65.8 – 99.9) | 26.0 |
| Negative | 30 | 0<br>(n/a) | N/A | 0<br>(n/a) | N/A | 100<br>(88.7 - 100) | 26.2 |
| **Positive Percent Agreement: 30/30 = 100% (95% CI: 88.7% - 100%)**<br>**Negative Percent Agreement: 30/30 = 100% (95% CI: 88.7% - 100%)** | | | | | | | |

**c. Additional Clinical Information**
**(not to be used for the Instructions for Use Document)**:

The Diagnovital SARS-CoV-2 Real-Time PCR Kit was conducted using clinical samples collected on nasopharyngeal swabs.

A total of 169 samples were tested, 160 of which were clinically negative and 9 of them were positive.

The number of tested samples and the name of the test centers are given in the table below. As shown in the table, all clinically positive samples were found to be positive and all clinically negative samples were found to be negative.

**The Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA) were both 100%.**

**Table 8.** Additional Clinical Evidence

| Country | Customer | Negative by Reference Method* | Negative by Diagnovital | Positive by Reference Method* | Positive by Diagnovital |
|---|---|---|---|---|---|
| **Austria** | **Pathologielabor Dr. Obrist Dr. Brunhuber OG, Klostergasse 1, 6511 Zams, Tirol** | **37** | **37** | **2** | **2** |
| **Austria** | **Med. Universitätsklinikum Innsbruck; Abteilung Virologie, Schöpfstrasse 41, 2.Stock, A-6020 Innsbruck** | **14** | **14** | **1** | **1** |
| **Austria** | **Labor Confidence DNA-Analysen, Formanekgasse 14/1, A-1190 Wien** | **41** | **41** | **0** | **0** |
| **Germany** | **Bioactiva Diagnostica, Louisenstrasse 137, D-61348 Bad Homburg** | **7** | **7** | **1** | **1** |
| **Germany** | **Dietrich Bonhoeffer Klinikum Salvador- Allende Str. 30 17036 Neubrandenburg** | **26** | **26** | **0** | **0** |
| **Iran** | **Bahman Hospital, Shahrgharb, Nourth Iran zamin, Tehran** | **35** | **35** | **5** | **5** |

* Reference Method could not be identified