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Analytical Specificity Study Test Report (Cross-reactivity)

- **Product Name:** nCoV-QS
- **Lot No.:** M224220AT10
- **Manufacturing date:** 31.January.2020

| | Name | Date | Signature |
|---------------------|-------------|--------------|---|
| Created by: | Eunkyung Yu | 2020. 02. 05 |  |
| Reviewed by: | Jihye Yoon | 2020. 02. 05 |  |
| Approved by: | HyonSun Kim | 2020. 02. 05 |  |

Revision History

| Revision No. | Rev. Date | Revision Description |
|--------------|--------------|-------------------------------------|
| 0.0 | 2020. 02. 05 | First issue for design verification |
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1. Purpose

Using VERI-Q™PCR 316 COVID-19 Detection System, This study is designed to evaluate the cross-reactivity of nCoV-QS.

2. References

CLSI, EP7-3rd ed.: 2018: Interference Testing in Clinical Chemistry

3. Time schedule

3.1 Test period

- 2020. 01. 31

4. Device information

- Veri-Q PCR 316 (S/N: 18F017, 18A008, 18F018, 19A009, 18F005)
- Bio-Rad, CFX96 (S/N: CT035611, CT012021)

5. Test information

5.1 Sample

5.1.1 Sample information

| | |
|-----------------------------|--|
| Test organisms | Different genomic DNA or RNA extracted from other pathogens. |
| Sample concentration | At least 5×10^5 copies/reaction |
| PCR positive control | Cloned positive control within product |

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5.2 Test organisms list

| No. | Organism | No. | Organism |
|-----|-------------------------------|-----|----------------------------------|
| 1 | Human gDNA | 23 | Bordetella pertussis |
| 2 | Influenza virus A. H1 | 24 | Malaria(Plasmodium falciparum) |
| 3 | Influenza virus A. H3N2 | 25 | Dengue virus type1 |
| 4 | Influenza virus B | 26 | Dengue virus type2 |
| 5 | Respiratory syncytial virus A | 27 | Dengue virus type3 |
| 6 | Respiratory syncytial virus B | 28 | Dengue virus type4 |
| 7 | Parainfluenza virus Type1 | 29 | Haemophilus influenzae |
| 8 | Parainfluenza virus Type2 | 30 | Streptococcus pneumoniae |
| 9 | Parainfluenza virus Type3 | 31 | Streptococcus pyogenes |
| 10 | Adenovirus B-3 | 32 | Seoul virus |
| 11 | Adenovirus C-1 | 33 | West Nile virus |
| 12 | Adenovirus C-2 | 34 | Yellow fever virus |
| 13 | Enterovirus | 35 | Lassa virus (LASV) |
| 14 | Rhinovirus | 36 | Rift valley fever virus(RVFV) |
| 15 | Metapneumovirus | 37 | Hantaan virus |
| 16 | Coronavirus NL63 | 38 | Rickettsia powazekii |
| 17 | Coronavirus 229E | 39 | Rickettsia typhi |
| 18 | Coronavirus OC43 | 40 | Salmonella typhi |
| 19 | Coronavirus HKU-1 | 41 | Staphylococcus aureus |
| 20 | Coronavirus SARS | 42 | Yersinia enterocolitica |
| 21 | Coronavirus MERS | - | Positive control |
| 22 | Chlamydia pneumoniae | - | Negative Control |

5.3 Test procedure

- Testing each sample for 1 run a day
- Following the instruction for use of the product (MCTF-2242-IFU-EN)

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5.4 Acceptance criteria

- No reaction with the tested organisms.
- Set the threshold line as shown in the table before checking the Ct value.

| | Target | Fluorophore | Threshold | Cut-off Ct value for positive |
|--------------|------------------|--------------------|------------------|--------------------------------------|
| nCoV-QS-PPM1 | SARS-CoV-2/ORF3a | FAM | 1000 | < 40 |
| | IPC | Cy5 | 1500 | < 40 |
| nCoV-QS-PPM2 | SARS-CoV-2/N | Cy5 | 1500 | < 40 |
| | IPC | HEX | 500 | < 40 |

5.5 Data analysis

- Confirm the reactivity with tested organisms.
- The Ct values of positive PCR controls are confirmed as shown in the table.

| Sample | Target Ct value | IPC Ct value |
|------------------|------------------------|---------------------|
| Positive control | <40 | < 40 |
| Negative control | Not detect | < 40 |

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6. Result

6.1 Veri-Q PCR316

| No. | Organism | PPM1 | | PPM2 | |
|-----|----------------------------------|--------|-------|--------|-------|
| | | Target | IPC | Target | IPC |
| 1 | Human gDNA | N/D | 26.88 | N/D | 25.06 |
| 2 | Influenza virus A. H1 | N/D | 26.68 | N/D | 25.12 |
| 3 | Influenza virus A. H3N2 | N/D | 26.83 | N/D | 25.09 |
| 4 | Influenza virus B | N/D | 27.05 | N/D | 25.44 |
| 5 | Respiratory syncytial virus A | N/D | 26.86 | N/D | 25.9 |
| 6 | Respiratory syncytial virus B | N/D | 26.98 | N/D | 25.33 |
| 7 | Parainfluenza virus Type1 | N/D | 27.15 | N/D | 25.69 |
| 8 | Parainfluenza virus Type2 | N/D | 26.85 | N/D | 25.29 |
| 9 | Parainfluenza virus Type3 | N/D | 26.32 | N/D | 25.35 |
| 10 | Adenovirus B-3 | N/D | 26.44 | N/D | 24.87 |
| 11 | Adenovirus C-1 | N/D | 26.54 | N/D | 25.35 |
| 12 | Adenovirus C-2 | N/D | 26.48 | N/D | 25.11 |
| 13 | Enterovirus | N/D | 26.37 | N/D | 25.12 |
| 14 | Rhinovirus | N/D | 26.15 | N/D | 24.99 |
| 15 | Metapneumovirus | N/D | 26.6 | N/D | 25.36 |
| 16 | Coronavirus NL63 | N/D | 26.16 | N/D | 25 |
| 17 | Coronavirus 229E | N/D | 26.03 | N/D | 25.05 |
| 18 | Coronavirus OC43 | N/D | 25.91 | N/D | 25.03 |
| 19 | Coronavirus HKU-1 | N/D | 25.72 | N/D | 25.18 |
| 20 | Coronavirus SARS | N/D | 26.06 | N/D | 25.1 |
| 21 | MERS | N/D | 26.05 | N/D | 25.08 |
| 22 | Chlamydia pneumoniae | N/D | 26.12 | N/D | 25.32 |
| 23 | Bordetella pertussis | N/D | 26.18 | N/D | 25.22 |
| 24 | Malaria(Plasmodium falciparum) | N/D | 26.17 | N/D | 24.83 |
| 25 | Dengue virus type1 | N/D | 26.2 | N/D | 25.32 |
| 26 | Dengue virus type2 | N/D | 26.06 | N/D | 25.19 |
| 27 | Dengue virus type3 | N/D | 26.26 | N/D | 24.98 |
| 28 | Dengue virus type4 | N/D | 26.05 | N/D | 24.94 |
| 29 | Haemophilus influenzae | N/D | 25.99 | N/D | 25.56 |
| 30 | Streptococcus pneumoniae | N/D | 26.12 | N/D | 25.46 |
| 31 | Streptococcus pyogenes | N/D | 26.13 | N/D | 25.48 |
| 32 | Seoul virus | N/D | 25.99 | N/D | 25.36 |
| 33 | West Nile virus | N/D | 25.94 | N/D | 25.18 |
| 34 | Yellow fever virus | N/D | 26.18 | N/D | 25.27 |
| 35 | Lassa virus (LASV) | N/D | 26.04 | N/D | 25.3 |

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|----|--------------------------------|-------|-------|-------|-------|
| 36 | Rift vally fever virus(RVFV) | N/D | 25.93 | N/D | 25.57 |
| 37 | Hantaan virus | N/D | 25.93 | N/D | 25.67 |
| 38 | Rickettsia powazekii | N/D | 25.77 | N/D | 25.66 |
| 39 | Rickettsia typhi | N/D | 26.11 | N/D | 25.4 |
| 40 | Salmonella typhi | N/D | 25.92 | N/D | 25.5 |
| 41 | Stapylococcus aureus | N/D | 26.05 | N/D | 25.19 |
| 42 | Yersinia enterocolitica | N/D | 26.05 | N/D | 25.11 |
| - | Positive control | 26.08 | 27.02 | 24.84 | 25.28 |
| | | 25.73 | 25.97 | 24.57 | 25.22 |
| | | 25.61 | 26.31 | 25.04 | 25.77 |
| - | Negative Control | N/D | 26.48 | N/D | 24.57 |
| | | N/D | 27.02 | N/D | 25.07 |
| | | N/D | 25.83 | N/D | 25.26 |

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6.2 Bio-rad, CFX96

| No. | Organism | PPM1 | | PPM2 | |
|-----|----------------------------------|--------|-------|--------|-------|
| | | Target | IPC | Target | IPC |
| 1 | Human gDNA | N/A | 28.12 | N/A | 26.38 |
| 2 | Influenza virus A. H1 | N/A | 27.81 | N/A | 26.36 |
| 3 | Influenza virus A. H3N2 | N/A | 27.87 | N/A | 26.21 |
| 4 | Influenza virus B | N/A | 27.97 | N/A | 26.47 |
| 5 | Respiratory syncytial virus A | N/A | 27.96 | N/A | 26.41 |
| 6 | Respiratory syncytial virus B | N/A | 27.94 | N/A | 26.35 |
| 7 | Parainfluenza virus Type1 | N/A | 27.96 | N/A | 26.16 |
| 8 | Parainfluenza virus Type2 | N/A | 27.93 | N/A | 26.19 |
| 9 | Parainfluenza virus Type3 | N/A | 27.79 | N/A | 26.07 |
| 10 | Adenovirus B-3 | N/A | 28.51 | N/A | 25.8 |
| 11 | Adenovirus C-1 | N/A | 27.92 | N/A | 27.19 |
| 12 | Adenovirus C-2 | N/A | 28.42 | N/A | 26.79 |
| 13 | Enterovirus | N/A | 28.49 | N/A | 26.21 |
| 14 | Rhinovirus | N/A | 27.7 | N/A | 26.21 |
| 15 | Metapneumovirus | N/A | 28.32 | N/A | 26.65 |
| 16 | Coronavirus NL63 | N/A | 28.08 | N/A | 26.4 |
| 17 | Coronavirus 229E | N/A | 27.94 | N/A | 26.38 |
| 18 | Coronavirus OC43 | N/A | 28.02 | N/A | 26.28 |
| 19 | Coronavirus HKU-1 | N/A | 27.95 | N/A | 26.32 |
| 20 | Coronavirus SARS | N/A | 27.91 | N/A | 26.28 |
| 21 | MERS | N/A | 27.82 | N/A | 26.17 |
| 22 | Chlamydia pneumoniae | N/A | 28.87 | N/A | 26.47 |
| 23 | Bordetella pertussis | N/A | 27.79 | N/A | 26.37 |
| 24 | Malaria(Plasmodium falciparum) | N/A | 28.04 | N/A | 26.07 |
| 25 | Dengue virus type1 | N/A | 27.43 | N/A | 26.21 |
| 26 | Dengue virus type2 | N/A | 28.04 | N/A | 26.38 |
| 27 | Dengue virus type3 | N/A | 27.98 | N/A | 26.24 |
| 28 | Dengue virus type4 | N/A | 27.81 | N/A | 26.41 |
| 29 | Haemophilus influenzae | N/A | 27.94 | N/A | 26.26 |
| 30 | Streptococcus pneumoniae | N/A | 27.86 | N/A | 25.18 |
| 31 | Streptococcus pyogenes | N/A | 27.91 | N/A | 26.25 |
| 32 | Seoul virus | N/A | 27.8 | N/A | 26.62 |
| 33 | West nile virus | N/A | 27.59 | N/A | 27.98 |
| 34 | Yellow fever virus | N/A | 27.8 | N/A | 26.21 |
| 35 | Lassa virus (LASV) | N/A | 27.99 | N/A | 25.69 |
| 36 | Rift vally fever virus(RVFV) | N/A | 27.97 | N/A | 26.38 |

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|----|-------------------------|-------|-------|-------|-------|
| 37 | Hantaan virus | N/A | 28 | N/A | 26.57 |
| 38 | Rickettsia powazekii | N/A | 28.24 | N/A | 26.51 |
| 39 | Rickettsia typhi | N/A | 27.82 | N/A | 26.47 |
| 40 | Salmonella typhi | N/A | 27.75 | N/A | 26.34 |
| 41 | Stapylococcus aureus | N/A | 27.88 | N/A | 26.38 |
| 42 | Yersinia enterocolitica | N/A | 27.79 | N/A | 26.22 |
| - | Positive control | 28.23 | 27.99 | 26.84 | 26.27 |
| - | Negative Control | N/A | 27.58 | N/A | 28.81 |

7. Conclusion

- The analytical specificity of the nCoV-QS was tested against 42 organisms including bacteria and virus that can be isolated from the reference DNA or RNA material and cultured medium samples.
- Each isolated sample was tested at a concentration at least 5×10^5 copies/reaction.
- It was confirmed that nCoV-QS was specifically detected in positive control.