

## **Clinical Study Report**

On the purpose of test the sensitivity and specificity, and then test whether the kit can realize the clinical use, the following study is carried out:

Product : COVID-19 Antigen Rapid Test Kit

On behalf of

**BEIJING BEIER BIOENGINEERING CO., LTD**

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Version No A /1

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## 1. Evaluation methods of clinical samples

### 1.1 Sample source and confirmation method

For the same patient, two swabs were taken at the same time. One is used for RT-PCR detection, and the other is used for our company's kit detection.

All samples used in the performance evaluation report are provided by the hospital and confirmed by clinical diagnosis. Clinical diagnosis was confirmed by clinical symptoms and PCR results. All samples were homologous to the samples tested by RT-PCR.

Samples of other respiratory pathogens were confirmed by NMPA approved kit or virus culture method.

The PCR reagent information used is below:

Product Name: Novel Coronavirus (2019-nCoV) Real Time RT-PCR Kit (Real-time Fluorescent PCR method)

Manufacturer: Shanghai ZJ Bio-Tech Co., Ltd.

NMPA approval No: 20203400057

### 1.2 Test report procedure

The homologous swab was used for comparative test. And then calculate sensitivity, specificity, PPV and NPV.

### 1.3 Results of comparison

Table 1 Source and test results of positive samples

| No | Sample Type | Ct value | Beier's Kit |
|----|-------------|----------|-------------|
| 1  | Swab        | 28       | +++         |
| 2  | Swab        | 28       | +++         |
| 3  | Swab        | 36       | +           |
| 4  | Swab        | 31       | +++         |
| 5  | Swab        | 31       | ++          |
| 6  | Swab        | 31       | ++          |
| 7  | Swab        | 32       | ++          |
| 8  | Swab        | 29       | +++         |
| 9  | Swab        | 36       | -           |
| 10 | Swab        | 30       | +++         |

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|    |      |    |     |
|----|------|----|-----|
| 11 | Swab | 34 | +   |
| 12 | Swab | 29 | +++ |
| 13 | Swab | 35 | +   |
| 14 | Swab | 32 | ++  |
| 15 | Swab | 31 | ++  |
| 16 | Swab | 29 | +++ |
| 17 | Swab | 33 | ++  |
| 18 | Swab | 28 | +++ |
| 19 | Swab | 28 | +++ |
| 20 | Swab | 34 | ++  |
| 21 | Swab | 32 | ++  |
| 22 | Swab | 35 | +   |
| 23 | Swab | 35 | +   |
| 24 | Swab | 30 | +++ |
| 25 | Swab | 32 | ++  |
| 26 | Swab | 35 | +   |
| 27 | Swab | 30 | +++ |
| 28 | Swab | 34 | +   |
| 29 | Swab | 35 | +   |
| 30 | Swab | 34 | +   |
| 31 | Swab | 34 | +   |
| 32 | Swab | 36 | +   |
| 33 | Swab | 34 | +   |
| 34 | Swab | 36 | -   |
| 35 | Swab | 30 | +++ |
| 36 | Swab | 34 | +   |
| 37 | Swab | 29 | +++ |
| 38 | Swab | 33 | +   |

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|    |      |    |     |
|----|------|----|-----|
| 39 | Swab | 36 | +   |
| 40 | Swab | 29 | +++ |
| 41 | Swab | 36 | -   |
| 42 | Swab | 28 | +++ |
| 43 | Swab | 29 | +++ |
| 44 | Swab | 28 | +++ |
| 45 | Swab | 33 | +   |
| 46 | Swab | 35 | +   |
| 47 | Swab | 36 | +   |
| 48 | Swab | 30 | +++ |
| 49 | Swab | 34 | +   |
| 50 | Swab | 29 | +++ |
| 51 | Swab | 30 | +++ |
| 52 | Swab | 32 | ++  |
| 53 | Swab | 33 | +   |
| 54 | Swab | 32 | ++  |
| 55 | Swab | 36 | -   |
| 56 | Swab | 29 | +++ |
| 57 | Swab | 28 | +++ |
| 58 | Swab | 32 | ++  |
| 59 | Swab | 31 | ++  |
| 60 | Swab | 36 | +   |
| 61 | Swab | 28 | +++ |
| 62 | Swab | 30 | +++ |
| 63 | Swab | 33 | ++  |
| 64 | Swab | 32 | ++  |
| 65 | Swab | 30 | +++ |
| 66 | Swab | 28 | +++ |

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|    |      |    |     |
|----|------|----|-----|
| 67 | Swab | 35 | +   |
| 68 | Swab | 34 | +   |
| 69 | Swab | 30 | +++ |
| 70 | Swab | 36 | -   |
| 71 | Swab | 34 | +   |
| 72 | Swab | 33 | ++  |
| 73 | Swab | 31 | ++  |
| 74 | Swab | 29 | +++ |
| 75 | Swab | 31 | ++  |
| 76 | Swab | 31 | ++  |
| 77 | Swab | 30 | +++ |
| 78 | Swab | 28 | +++ |
| 79 | Swab | 33 | +   |
| 80 | Swab | 29 | +++ |
| 81 | Swab | 35 | +   |
| 82 | Swab | 28 | +++ |
| 83 | Swab | 34 | +   |
| 84 | Swab | 31 | ++  |
| 85 | Swab | 36 | +   |
| 86 | Swab | 33 | +   |
| 87 | Swab | 35 | +   |
| 88 | Swab | 35 | +   |
| 89 | Swab | 36 | +   |
| 90 | Swab | 34 | +   |
| 91 | Swab | 34 | +   |
| 92 | Swab | 35 | +   |
| 93 | Swab | 30 | +++ |
| 94 | Swab | 31 | ++  |

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|     |      |    |     |
|-----|------|----|-----|
| 95  | Swab | 29 | +++ |
| 96  | Swab | 35 | +   |
| 97  | Swab | 35 | +   |
| 98  | Swab | 31 | ++  |
| 99  | Swab | 31 | ++  |
| 100 | Swab | 29 | +++ |
| 101 | Swab | 32 | +   |
| 102 | Swab | 32 | ++  |
| 103 | Swab | 31 | ++  |
| 104 | Swab | 30 | +++ |
| 105 | Swab | 31 | ++  |
| 106 | Swab | 34 | +   |
| 107 | Swab | 32 | ++  |
| 108 | Swab | 28 | +++ |
| 109 | Swab | 33 | +   |
| 110 | Swab | 29 | +++ |
| 111 | Swab | 28 | +++ |
| 112 | Swab | 34 | +   |
| 113 | Swab | 28 | +++ |
| 114 | Swab | 30 | +++ |
| 115 | Swab | 33 | +   |
| 116 | Swab | 36 | +   |
| 117 | Swab | 31 | ++  |
| 118 | Swab | 28 | +++ |
| 119 | Swab | 29 | +++ |
| 120 | Swab | 30 | +++ |
| 121 | Swab | 31 | ++  |
| 122 | Swab | 33 | +   |

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|     |      |    |     |
|-----|------|----|-----|
| 123 | Swab | 32 | ++  |
| 124 | Swab | 34 | +   |
| 125 | Swab | 34 | +   |
| 126 | Swab | 36 | +   |
| 127 | Swab | 30 | +++ |
| 128 | Swab | 36 | +   |
| 129 | Swab | 35 | +   |
| 130 | Swab | 28 | +++ |
| 131 | Swab | 35 | +   |
| 132 | Swab | 31 | ++  |
| 133 | Swab | 29 | +++ |
| 134 | Swab | 36 | +   |
| 135 | Swab | 32 | ++  |
| 136 | Swab | 29 | +++ |
| 137 | Swab | 36 | +   |
| 138 | Swab | 33 | +   |
| 139 | Swab | 36 | +   |
| 140 | Swab | 32 | ++  |
| 141 | Swab | 36 | +   |
| 142 | Swab | 36 | +   |
| 143 | Swab | 31 | ++  |
| 144 | Swab | 36 | +   |
| 145 | Swab | 34 | +   |
| 146 | Swab | 29 | +++ |
| 147 | Swab | 31 | ++  |
| 148 | Swab | 32 | +   |
| 149 | Swab | 32 | +   |
| 150 | Swab | 28 | +++ |

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|     |      |    |     |
|-----|------|----|-----|
| 151 | Swab | 28 | +++ |
| 152 | Swab | 28 | +++ |
| 153 | Swab | 30 | +++ |
| 154 | Swab | 32 | ++  |
| 155 | Swab | 30 | +++ |
| 156 | Swab | 34 | +   |
| 157 | Swab | 31 | ++  |
| 158 | Swab | 28 | +++ |
| 159 | Swab | 35 | +   |
| 160 | Swab | 29 | +++ |
| 161 | Swab | 34 | +   |
| 162 | Swab | 29 | +++ |
| 163 | Swab | 35 | +   |
| 164 | Swab | 31 | ++  |
| 165 | Swab | 34 | +   |
| 166 | Swab | 32 | +   |
| 167 | Swab | 36 | -   |
| 168 | Swab | 35 | +   |
| 169 | Swab | 31 | +   |
| 170 | Swab | 28 | +++ |
| 171 | Swab | 28 | +++ |

\*Note: "+++" strong positive color; "++"middle positive color; "+" weak positive color; "-" negative;

Table 2 Source and test results of positive samples

| No | Sample Type | Pathogen types | Beier's Kit |
|----|-------------|----------------|-------------|
| 1  | Swab        | Parainfluenza  | -           |
| 2  | Swab        | Influenza A    | -           |



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|    |      |                             |   |
|----|------|-----------------------------|---|
| 3  | Swab | Respiratory syncytial virus | - |
| 4  | Swab | Influenza A                 | - |
| 5  | Swab | Influenza A                 | - |
| 6  | Swab | Adenovirus                  | - |
| 7  | Swab | Influenza A                 | - |
| 8  | Swab | Influenza A                 | - |
| 9  | Swab | Parainfluenza               | - |
| 10 | Swab | Influenza A                 | - |
| 11 | Swab | Influenza A                 | - |
| 12 | Swab | Chlamydia pneumoniae        | - |
| 13 | Swab | Chlamydia pneumoniae        | - |
| 14 | Swab | Chlamydia pneumoniae        | - |
| 15 | Swab | Chlamydia pneumoniae        | - |
| 16 | Swab | Parainfluenza               | - |
| 17 | Swab | Parainfluenza               | - |
| 18 | Swab | Adenovirus                  | - |
| 19 | Swab | Parainfluenza               | - |
| 20 | Swab | Parainfluenza               | - |
| 21 | Swab | Adenovirus                  | - |
| 22 | Swab | Parainfluenza               | - |
| 23 | Swab | Parainfluenza               | - |
| 24 | Swab | Parainfluenza               | - |
| 25 | Swab | Human Metapneumovirus       | - |
| 26 | Swab | Influenza A                 | - |
| 27 | Swab | Influenza A                 | - |
| 28 | Swab | Influenza A                 | - |
| 29 | Swab | Influenza A                 | + |
| 30 | Swab | Influenza A                 | - |

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|    |      |                             |   |
|----|------|-----------------------------|---|
| 31 | Swab | Influenza A                 | - |
| 32 | Swab | Influenza A                 | - |
| 33 | Swab | Influenza A                 | - |
| 34 | Swab | Influenza A                 | - |
| 35 | Swab | Influenza A                 | - |
| 36 | Swab | Influenza A                 | - |
| 37 | Swab | Parainfluenza               | - |
| 38 | Swab | Influenza A                 | - |
| 39 | Swab | Chlamydia pneumoniae        | - |
| 40 | Swab | Chlamydia pneumoniae        | - |
| 41 | Swab | Chlamydia pneumoniae        | - |
| 42 | Swab | Chlamydia pneumoniae        | - |
| 43 | Swab | Chlamydia pneumoniae        | - |
| 44 | Swab | Chlamydia pneumoniae        | - |
| 45 | Swab | Influenza A                 | - |
| 46 | Swab | Haemophilus influenza       | - |
| 47 | Swab | Influenza A                 | - |
| 48 | Swab | Influenza A                 | - |
| 49 | Swab | Parainfluenza               | - |
| 50 | Swab | Respiratory syncytial virus | - |
| 51 | Swab | Respiratory syncytial virus | - |
| 52 | Swab | Respiratory syncytial virus | - |
| 53 | Swab | Respiratory syncytial virus | - |
| 54 | Swab | Respiratory syncytial virus | - |
| 55 | Swab | Respiratory syncytial virus | - |
| 56 | Swab | Influenza A                 | - |
| 57 | Swab | Candida albicans            | - |
| 58 | Swab | Haemophilus influenza       | - |

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|    |      |                             |   |
|----|------|-----------------------------|---|
| 59 | Swab | Influenza A                 | - |
| 60 | Swab | Influenza A                 | - |
| 61 | Swab | Influenza A                 | - |
| 62 | Swab | Parainfluenza               | - |
| 63 | Swab | Influenza A                 | - |
| 64 | Swab | Influenza A                 | - |
| 65 | Swab | Adenovirus                  | - |
| 66 | Swab | Influenza A                 | - |
| 67 | Swab | Influenza A                 | - |
| 68 | Swab | Influenza A                 | - |
| 69 | Swab | Influenza A                 | - |
| 70 | Swab | Influenza A                 | - |
| 71 | Swab | Respiratory syncytial virus | - |
| 72 | Swab | Chlamydia pneumoniae        | - |
| 73 | Swab | Chlamydia pneumoniae        | - |
| 74 | Swab | Enterovirus                 | - |
| 75 | Swab | Chlamydia pneumoniae        | - |
| 76 | Swab | Enterovirus                 | - |
| 77 | Swab | Enterovirus                 | - |
| 78 | Swab | Influenza A                 | - |
| 79 | Swab | Bordetella pertussis        | - |
| 80 | Swab | Streptococcus pneumoniae    | - |
| 81 | Swab | Rhinovirus                  | - |
| 82 | Swab | Adenovirus                  | - |
| 83 | Swab | Influenza A                 | - |
| 84 | Swab | Streptococcus pneumoniae    | - |
| 85 | Swab | Streptococcus pneumoniae    | - |
| 86 | Swab | Influenza A                 | - |

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|     |      |                             |   |
|-----|------|-----------------------------|---|
| 87  | Swab | Mycoplasma pneumoniae       | - |
| 88  | Swab | Candida albicans            | - |
| 89  | Swab | Legionella pneumophila      | - |
| 90  | Swab | Legionella pneumophila      | - |
| 91  | Swab | Parainfluenza               | - |
| 92  | Swab | Legionella pneumophila      | - |
| 93  | Swab | Chlamydia pneumoniae        | - |
| 94  | Swab | Influenza A                 | - |
| 95  | Swab | Respiratory syncytial virus | - |
| 96  | Swab | Respiratory syncytial virus | - |
| 97  | Swab | Respiratory syncytial virus | - |
| 98  | Swab | Influenza A                 | - |
| 99  | Swab | Influenza A                 | - |
| 100 | Swab | Influenza A                 | - |
| 101 | Swab | Influenza A                 | - |
| 102 | Swab | Bordetella pertussis        | - |
| 103 | Swab | Influenza B                 | - |
| 104 | Swab | Influenza A                 | - |
| 105 | Swab | Influenza A                 | - |
| 106 | Swab | Influenza A                 | - |
| 107 | Swab | Influenza A                 | - |
| 108 | Swab | Influenza A                 | - |
| 109 | Swab | Mycoplasma pneumoniae       | - |
| 110 | Swab | Mycoplasma pneumoniae       | - |
| 111 | Swab | Mycoplasma pneumoniae       | - |
| 112 | Swab | Mycoplasma pneumoniae       | - |
| 113 | Swab | Influenza B                 | - |
| 114 | Swab | Influenza B                 | - |

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|     |      |                          |   |
|-----|------|--------------------------|---|
| 115 | Swab | Streptococcus pneumoniae | - |
| 116 | Swab | Mycoplasma pneumoniae    | - |
| 117 | Swab | Mycoplasma pneumoniae    | - |
| 118 | Swab | Enterovirus              | - |
| 119 | Swab | Mycoplasma pneumoniae    | - |
| 120 | Swab | Mycoplasma pneumoniae    | - |
| 121 | Swab | Mycoplasma pneumoniae    | - |
| 122 | Swab | Streptococcus pneumoniae | - |
| 123 | Swab | Chlamydia pneumoniae     | - |
| 124 | Swab | Chlamydia pneumoniae     | - |
| 125 | Swab | Influenza B              | - |
| 126 | Swab | Influenza B              | - |
| 127 | Swab | Mycoplasma pneumoniae    | - |
| 128 | Swab | Mycoplasma pneumoniae    | - |
| 129 | Swab | Mycoplasma pneumoniae    | - |
| 130 | Swab | Mycoplasma pneumoniae    | - |
| 131 | Swab | /                        | - |
| 132 | Swab | /                        | - |
| 133 | Swab | /                        | - |
| 134 | Swab | /                        | - |
| 135 | Swab | /                        | - |
| 136 | Swab | /                        | - |
| 137 | Swab | /                        | - |
| 138 | Swab | /                        | - |
| 139 | Swab | /                        | - |
| 140 | Swab | /                        | - |
| 141 | Swab | /                        | - |
| 142 | Swab | /                        | - |

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|     |      |   |   |
|-----|------|---|---|
| 143 | Swab | / | - |
| 144 | Swab | / | - |
| 145 | Swab | / | - |
| 146 | Swab | / | - |
| 147 | Swab | / | - |
| 148 | Swab | / | - |
| 149 | Swab | / | - |
| 150 | Swab | / | - |
| 151 | Swab | / | - |
| 152 | Swab | / | - |
| 153 | Swab | / | - |
| 154 | Swab | / | - |
| 155 | Swab | / | - |
| 156 | Swab | / | - |
| 157 | Swab | / | - |
| 158 | Swab | / | - |
| 159 | Swab | / | - |
| 160 | Swab | / | - |
| 161 | Swab | / | - |
| 162 | Swab | / | - |
| 163 | Swab | / | - |
| 164 | Swab | / | - |
| 165 | Swab | / | - |
| 166 | Swab | / | - |
| 167 | Swab | / | - |
| 168 | Swab | / | - |
| 169 | Swab | / | - |
| 170 | Swab | / | - |

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|     |      |   |   |
|-----|------|---|---|
| 171 | Swab | / | - |
| 172 | Swab | / | - |
| 173 | Swab | / | - |
| 174 | Swab | / | - |
| 175 | Swab | / | - |
| 176 | Swab | / | - |
| 177 | Swab | / | - |
| 178 | Swab | / | - |
| 179 | Swab | / | - |
| 180 | Swab | / | - |
| 181 | Swab | / | - |
| 182 | Swab | / | - |
| 183 | Swab | / | - |
| 184 | Swab | / | - |
| 185 | Swab | / | - |
| 186 | Swab | / | - |
| 187 | Swab | / | - |
| 188 | Swab | / | - |
| 189 | Swab | / | - |
| 190 | Swab | / | - |
| 191 | Swab | / | - |
| 192 | Swab | / | - |
| 193 | Swab | / | - |
| 194 | Swab | / | - |
| 195 | Swab | / | - |
| 196 | Swab | / | - |
| 197 | Swab | / | - |
| 198 | Swab | / | - |

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|     |      |   |   |
|-----|------|---|---|
| 199 | Swab | / | - |
| 200 | Swab | / | - |
| 201 | Swab | / | - |
| 202 | Swab | / | - |
| 203 | Swab | / | - |
| 204 | Swab | / | - |
| 205 | Swab | / | - |
| 206 | Swab | / | - |
| 207 | Swab | / | - |
| 208 | Swab | / | - |
| 209 | Swab | / | - |
| 210 | Swab | / | - |
| 211 | Swab | / | - |
| 212 | Swab | / | - |
| 213 | Swab | / | - |
| 214 | Swab | / | - |
| 215 | Swab | / | - |
| 216 | Swab | / | - |
| 217 | Swab | / | - |
| 218 | Swab | / | - |
| 219 | Swab | / | - |
| 220 | Swab | / | - |
| 221 | Swab | / | - |
| 222 | Swab | / | - |
| 223 | Swab | / | - |
| 224 | Swab | / | - |
| 225 | Swab | / | - |
| 226 | Swab | / | - |



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|     |      |   |   |
|-----|------|---|---|
| 227 | Swab | / | - |
| 228 | Swab | / | - |
| 229 | Swab | / | - |
| 230 | Swab | / | - |
| 231 | Swab | / | - |
| 232 | Swab | / | - |
| 233 | Swab | / | - |
| 234 | Swab | / | - |
| 235 | Swab | / | - |
| 236 | Swab | / | - |
| 237 | Swab | / | - |
| 238 | Swab | / | - |
| 239 | Swab | / | - |
| 240 | Swab | / | - |
| 241 | Swab | / | - |
| 242 | Swab | / | - |
| 243 | Swab | / | - |
| 244 | Swab | / | - |
| 245 | Swab | / | - |
| 246 | Swab | / | - |
| 247 | Swab | / | - |
| 248 | Swab | / | - |
| 249 | Swab | / | - |
| 250 | Swab | / | - |
| 251 | Swab | / | - |
| 252 | Swab | / | - |
| 253 | Swab | / | - |
| 254 | Swab | / | - |

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|     |      |   |   |
|-----|------|---|---|
| 255 | Swab | / | - |
| 256 | Swab | / | - |
| 257 | Swab | / | - |
| 258 | Swab | / | - |
| 259 | Swab | / | - |
| 260 | Swab | / | - |
| 261 | Swab | / | - |
| 262 | Swab | / | - |
| 263 | Swab | / | - |
| 264 | Swab | / | - |
| 265 | Swab | / | - |
| 266 | Swab | / | - |
| 267 | Swab | / | - |
| 268 | Swab | / | - |
| 269 | Swab | / | - |
| 270 | Swab | / | - |
| 271 | Swab | / | - |
| 272 | Swab | / | - |
| 273 | Swab | / | - |
| 274 | Swab | / | - |
| 275 | Swab | / | - |
| 276 | Swab | / | - |
| 277 | Swab | / | - |
| 278 | Swab | / | - |
| 279 | Swab | / | - |
| 280 | Swab | / | - |
| 281 | Swab | / | - |
| 282 | Swab | / | - |

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|     |      |   |   |
|-----|------|---|---|
| 283 | Swab | / | - |
| 284 | Swab | / | - |
| 285 | Swab | / | - |
| 286 | Swab | / | - |
| 287 | Swab | / | - |
| 288 | Swab | / | - |
| 289 | Swab | / | - |
| 290 | Swab | / | - |
| 291 | Swab | / | - |
| 292 | Swab | / | - |
| 293 | Swab | / | - |
| 294 | Swab | / | - |
| 295 | Swab | / | - |
| 296 | Swab | / | - |
| 297 | Swab | / | - |
| 298 | Swab | / | - |
| 299 | Swab | / | - |
| 300 | Swab | / | - |
| 301 | Swab | / | - |
| 302 | Swab | / | - |
| 303 | Swab | / | - |

\*Note: "+++" strong positive color; "++"middle positive color; "+" weak positive color; "-" negative;

### 1.4 Conclusion and report

474 clinical case samples which include 171 confirmed case samples\* and 303 confirmed excluded case samples\*, were obtained for testing, and then compared the test results between The COVID-19 Antigen Rapid Test Kit's result and the clinical diagnosis. The results of sensitivity and specificity between the two methods are show below.

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| Reagents       |          | Clinical diagnosis |          | Total |
|----------------|----------|--------------------|----------|-------|
|                |          | Positive           | Negative |       |
| Beier Reagents | Positive | 165                | 1        | 166   |
|                | Negative | 6                  | 302      | 308   |
| Total          |          | 171                | 303      | 474   |

Results analysis:

Sensitivity=96.5%(95% CI: 93.7%~99.3%)

Specificity=99.7%(95% CI: 99.0% -100%)

Positive predictive values= 99.4%(95% CI: 98.2% -100%)

Negative predictive values= 98.0%(95% CI: 96.5%-99.6%)

Total consistent: 98.5% (95%CI: 97.4%~99.6%)