

## ANTI**BODY** TESTING

AFIAS-6  
Automated Time Resolved  
Fluorescence Immunoassay



## ANTI**GENE** TESTING

SOFIA 2  
Sophisticated Fluorescence  
Immunoassay



# Test procedure

# ANTI**BODY** TESTING

# AFIAS

- 1 Fingertip blood
- 2 Simple operation
- 3 Data collection by network
- 4 10 min result on site



## 3 simple steps



Collect capillary blood



Place the C-tip™ in the cartridge tip hole



Press START to run the test.



# Test result

# ANTIBODY TESTING

# AFIAS

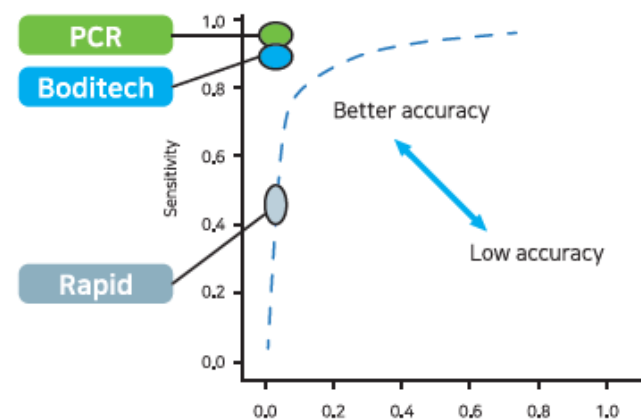
DATE: Mar-30-2020 / 14:41:06  
PATIENT ID:  
AGE:  
GENDER: N/A

COVID-19 Ab IgM  
0.47 COI  
Negative  
COVID-19 Ab IgG  
0.16 COI  
Negative

SAMPLE TYPE: Whole blood  
SAMPLE: PATIENT

INSTRUMENT S/N: FPRR0190C059  
USER ID: admin  
REAGENT LOT: WHQCA03G  
CALIBRATED\_ON:  
REFERENCE VALUE:

AFIAS COVID-19 Ab FIA Clinical Performance



|             |               | Coronavirus Disease 2019 real-time reverse transcription PCR |      |       |
|-------------|---------------|--------------------------------------------------------------|------|-------|
|             |               | Pos.                                                         | Neg. | Total |
| AFIAS       | Positive      | 46                                                           | 0    | 46    |
|             | Negative      | 0                                                            | 145  | 145   |
| COVID-19 Ab | Intermediated | 2                                                            | 5    | 7     |
|             | Total         | 48                                                           | 150  | 198   |

- Clinical sensitivity: 95.8%

- Clinical specificity: 96.7%



# Test result

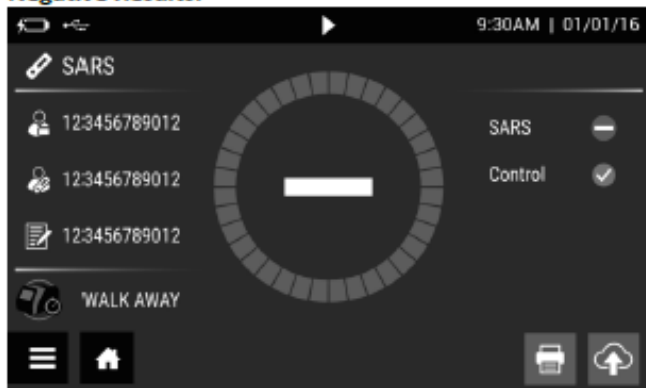
# ANTIGENE TESTING

Sofia®

## Positive Results:



## Negative Results:



## Sofia 2 SARS Antigen FIA Clinical Performance

| Nasopharyngeal<br>in VTM    | SARS-CoV-2<br>Molecular |     | Total | PPA |             | 95% CI |     |      |
|-----------------------------|-------------------------|-----|-------|-----|-------------|--------|-----|------|
|                             | POS                     | NEG |       |     |             |        |     |      |
| Sofia 2 SARS<br>Antigen FIA | POS                     | 47  | 0     | 47  | NPA         | 100%   | 96% | 100% |
|                             | NEG                     | 12  | 84    | 96  | PPV         | 100%   | 92% | 100% |
|                             | Total                   | 59  | 84    | 143 | NPV         | 88%    | 79% | 93%  |
|                             |                         |     |       |     | Prevalence  | 41%    | 34% | 49%  |
|                             |                         |     |       |     | % agreement | 92%    |     |      |

| Direct Nasal<br>Swab        | Lyra®<br>SARS-CoV-2<br>Molecular<br>EUA200016/<br>A002 |     | Total | PPA |             | 95% CI |       |        |
|-----------------------------|--------------------------------------------------------|-----|-------|-----|-------------|--------|-------|--------|
|                             | POS                                                    | NEG |       |     |             |        |       |        |
| Sofia 2 SARS<br>Antigen FIA | POS                                                    | 4   | 0     | 4   | NPA         | 100.0% | 91.8% | 100.0% |
|                             | NEG                                                    | 1   | 43    | 44  | PPV         | 100.0% | 51.0% | 100.0% |
|                             | Total                                                  | 5   | 43    | 48  | NPV         | 97.7%  | 88.2% | 99.6%  |
|                             |                                                        |     |       |     | Prevalence  | 10.4%  | 4.5%  | 22.2%  |
|                             |                                                        |     |       |     | % agreement | 97.9%  |       |        |