

Antigen Technology Lab-based and Point of Care Test

# COVID-19 Antigen Rapid Test Device

## Nasal & Nasopharyngeal Swab

The **COVID-19 Antigen Rapid Test Device** is an in vitro immunoassay intended to be used for the qualitative detection of the SARSCoV-2 viral nucleoprotein. This device will detect both viable and nonviable virus in both nasal & nasopharyngeal secretions.

### FaStep Covid-19 Antigen Rapid Test Device - Single Pack Test Kit



**NEW** - Portable and Easy to use Packaging

#### Each Box Contains

- ✓ - 1 Test Cassette
- ✓ - 1 Individually Packed Swab
- ✓ - 1 Ready to Go - Individual Extraction Buffer
- ✓ - 1 Instruction for use

### FaStep Covid-19 Antigen Rapid Test Device - 20 Pack Test Kit



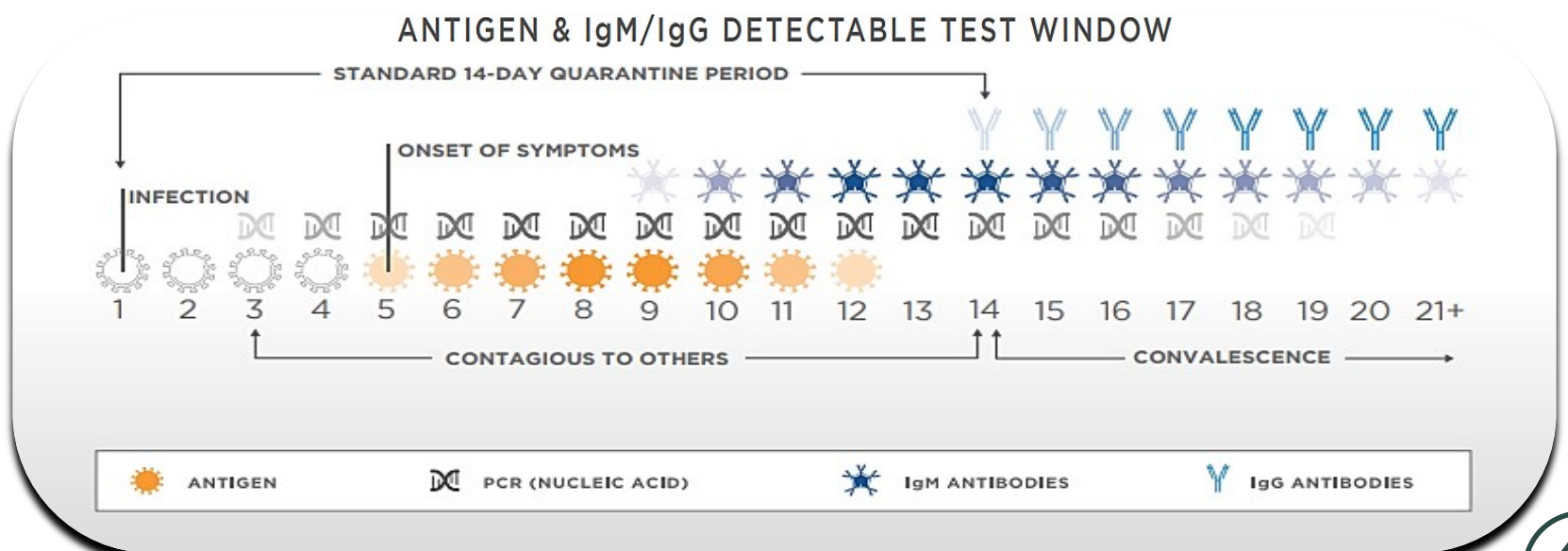
Device ID: COV-S23

#### Each Box Contains

- ✓ - 20 Test Cassette
- ✓ - 20 Individually Packed Swab
- ✓ - 20 Ready to Go - Individual Extraction Buffer
- ✓ - 1 Tube Stand
- ✓ - 1 Instruction for use

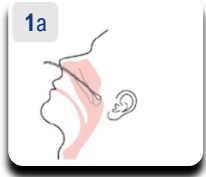


The FaStep **Covid-19 Antigen Rapid Test Device** Will Detect Antigen 5 Days After Symptoms First Appear.



## 1 Specimen Collection

### 1a. Nasopharyngeal Swab

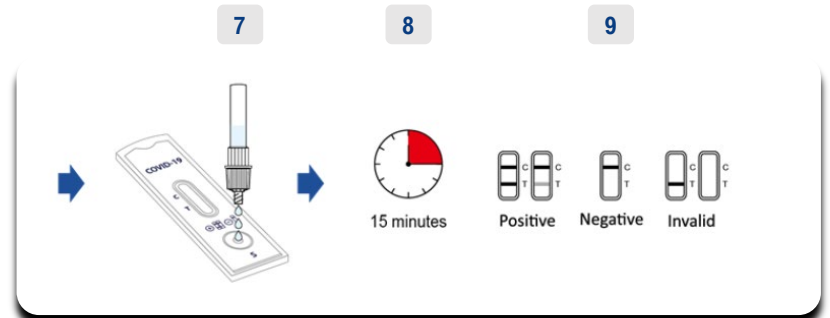
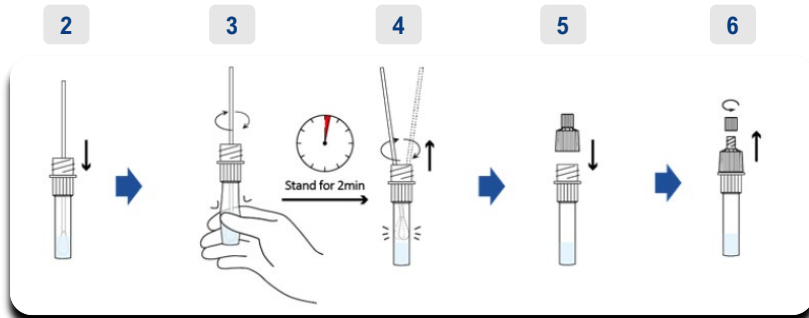


Insert the swab into the nostril parallel to the palate. Rotating against the nasal wall. (ensure swab contains cells as well as mucus)

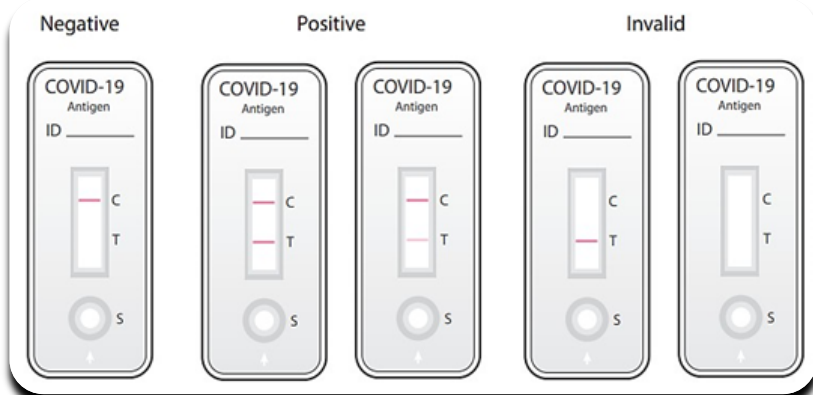
### 1b. Nasal Swab



Put the swab gently into nostril (about 1-2cm up your nose). Roll the swab firmly around the inside of the nostril, making 5 complete circles. Repeat this process for the other nostril to ensure that an adequate. Specimen is collected from both nasal cavities. (use the same swab)



## Interpretation of Test Results



### Negative:

Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

### Positive:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

### Invalid:

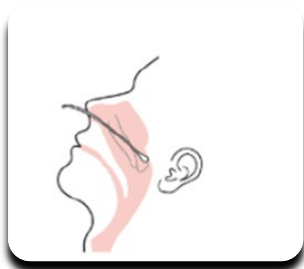
Control band fails to appear.

## Testing Information

### ✓ Clinical Performance

#### Nasopharyngeal Swab

Sensitivity = 94.3%



94.3 % (95% CI: 84.6% - 98.1%)

Assure Tech

Antigen Technology Lab-based and Point of Care Test



#### Nasal Swab

Sensitivity = 92.3%



92.3% (95% CI: 83.2% - 96.7%)

### Ordering Info

SKU   Code	Name   Description	Packaging
<b>C O V - S 2 3 - 1 T</b>	<b>COVID-19 Antigen Rapid Test Device</b> FaStep Covid-19 Antigen Rapid Test (Assure Tech) - <b>Single Pack Test/Kit</b>	<b>1 Box = 1 Tests   Kit</b> <b>1 Case = 204 Tests   Kits</b>
<b>C O V - S 2 3 - 2 0 T</b>	<b>COVID-19 Antigen Rapid Test Device</b> FaStep Covid-19 Antigen Rapid Test (Assure Tech) - <b>20 Tests/Kits</b>	<b>1 Box = 20 Tests   Kits</b> <b>1 Case = 27 Boxes (540 Tests   Kits)</b>

