# PPE COVID-19

## PRODUCT LEAFLET

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>H625-TY1-17</th>
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</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td>Collection and Transport Kit VTM, for oral sampling</td>
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<tr>
<td>UNIT OF MEASURE</td>
<td>50 pieces</td>
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<tr>
<td>DIMENSIONS</td>
<td>Not applicable</td>
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</tbody>
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### PRODUCT DESIGN

Citoswab Collection and Transport Kit provides safe and convenient collection and transport of clinical specimens. Each Collection and Transport Kit comprise a sterile peel pouch containing a sterile flocked swab used to collect the sample, a 10 ml transport tube containing 3 ml VTM medium into which the swab is placed after sampling, and a biohazard specimen bag used to place the transport tube in for transportation.

### INTENDED USE

Citoswab Collection and Transport kit is a ready to use system used for collection and transport of clinical specimens.

### INSTRUCTION FOR USE

1. Peel off the pouch and collect sample
2. Put the swab into the medium
3. Snap the stick of swab
4. Screw the tube cap tightly
5. Label the specimen
6. Put the tube into biohazard bag

### DISPOSAL

Dispose as medical waste in accordance with hospital, administrative and/or local government regulations and policies.

### REGULATORY APPROVAL

Collection swab: Approved in EU (CE) as per EU Medical Device Directive (CE Certificate as per MDD 93/42/EEC, risk class IIa)
Collection Tube and Biohazard Bag: Approved in EU (CE) as per EU Invitro Diagnostic Directive (declaration of conformity as per IVD 98/79/EC, risk class IVD Others).
Manufacturer quality management system as per ISO 13485:2016 for medical device industry.

### APPLICABLE STANDARDS

Product is complying with the following standards:
Product is as per CLSI-M40A (for quality control of Microbiology specimen Transport Device)
Product is also suitable for Preforming Molecular Biology Technique

### STORAGE

Store between 5°C to 25°C and keep in dry place

### SHELF LIFE

12 months

### PACK SIZE

- 50 tests per box
- 200 pieces per shipper carton

IDA - version 1.0