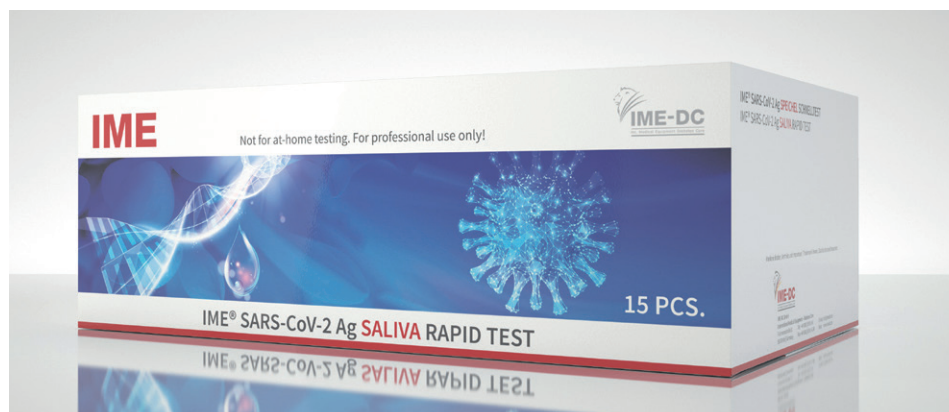


IME® SARS-CoV-2 Ag SALIVA RAPID TEST DATA SHEET



Trademark Owner, Distribution and Importer:

IME-DC GmbH
International Medical Equipment -
Diabetes Care
Fuhrmannstraße 11
95030 Hof | Germany

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Fax: +49 9281 | 85 01 6-100
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OVERVIEW

| | |
|---|--|
| Product Name | IME® SARS-CoV-2 Ag Saliva Rapid Test |
| EC Representative | Lotus NL B.V. Den Haag Netherlands |
| Commercial Licence | Exclusive Distribution by IME-DC GmbH |
| Trademark Owner, Distribution and Importer | IME-DC GmbH Hof Germany |
| Packaging Unit (PU) | 15 pcs. Single Tests |
| Master Carton | 1 Master Carton = 12 Packaging Units = 180 pcs. Single Tests |
| Sample Type | Saliva |
| Detection | Nucleocapsid protein antigen SARS-CoV-2 |
| LoD | 75.5 TCID ₅₀ /mL |
| Test Duration | approx. 15 minutes |
| Shelf Life | 24 months |
| Storage Temperature | +2 °C to +30 °C |
| Operating Environment | +15 °C to +30 °C |
| Relative Humidity | 10 % - 90 % |
| User Group | Professional Users / Laboratory |
| Product Package and Package Insert | German / English |
| PZN Listing (German Pharmaceutical Registration Number) | PZN-17179701 |
| BfArM Listing (German Listing of Antigen Tests) | Test-ID: AT524/20 |

CLINICAL PERFORMANCE

| | |
|--------------------|-----------|
| Sensitivity | 98.26 % |
| Specificity | > 99.99 % |
| Accuracy | 99.50 % |

NORMS | STANDARDS | STUDIES

| | | |
|---|-----------|-------------------------------------|
| EN ISO 13485 | fulfilled | BSI Group Amsterdam Netherlands |
| IVD Directive 98/79/EC | fulfilled | |
| Declaration of Conformity | available | |
| Safety Data Sheet | available | |
| Clinical Study Report | available | |
| Sensitivity Study Report | available | |
| Specificity Study Report | available | |
| Cross-Reactivity Study Report | available | |
| Interference Substances Study Report | available | |

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