

SARS-CoV-2 Antigen Test Kit (Nephelometry immunoassay Method)

— Liquid Phase —



Declaration of conformity

Basic Parameters

CE KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITÀ **CE**

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

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Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que
/Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

das Medizinprodukt
le dispositif médical
il dispositivo medico

SARS-CoV-2 Antigen Test Kit (Nephelometry immunoassay
Method)

Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl
Nom, type ou modèle, numéro de lot ou série, év. source et nombre d'exemplaires
Nome, tipo o modello, numero di lotto o di serie, ev. fonte e numero di esemplari
Name, type or model, batch or serial number, possibly source and number of being

der Klasse / de la classe / della classe
/ of class

Other IVD Devices
Nach Richtlinie 98/79/EG / selon directive 98/79/CE / secondo direttiva 98/79/CE /
according to direct. 98/79/EC

allen Anforderungen der Medizinprodukte-Richtlinie 98/79/EG entspricht, die anwendbar sind/ remplit
toutes les exigences de la directive sur les dispositifs médicaux 98/79/CE qui le concernent / soddisfa
tutte le disposizioni della direttiva 98/79/CE che lo riguardano /meets all the provisions of the directive
98/79/EC which apply to it.

Angewandte harmonisierte Normen,
nationale Normen oder andere
normative Dokumente
Normes harmonisées, normes
nationales et autres documents
normatifs appliqués
Norme armonizzate o nazionali
applicative,altri documenti normativi
applicati
Applied harmonised standards,
national standards or other
normative documents

EN ISO 15223-1:2016, EN ISO 13485:2016,
EN 13612:2002/AC:2002, EN ISO 23640:2015
EN ISO 14971:2012, EN ISO 18113-1:2011
EN ISO 18113-2:2011, EN 62366-1:2015
EN 14138:2004, EN 13975:2003
EN ISO 15193:2009, EN ISO 15194:2009
EN 13641:2002

Konformitätsbewertungsverfahren
Procédure d'évaluation de la
conformité
Procedimento di valutazione della
conformità
Conformity assessment procedure

IVDD 98/79/EC, Annex III

09-02-2021
Ort, Datum / Lieu, date / Luogo) data / Place,
date

Name und Funktion / Nom et
fonction
Nome e funzione / Name and
function

Specimen: nasopharyngeal or oropharyngeal swabs.

Test time: 6 mins

Packing: 25 Tests/Box

Box size: 14×12×7cm

Storage: 2-8°C

Shelf year: 1 year.

Accurate

- Precisely quantitative sample collection
- React in liquid phase
- High specificity and High sensitivity
- Avoid false positive and false negative

The background of the slide features several 3D rendered virus particles, likely coronaviruses, scattered across a light gray gradient. The particles are spherical with numerous spike-like protrusions on their surface. One large particle is prominent on the left side, while others are smaller and more distant.

Safe

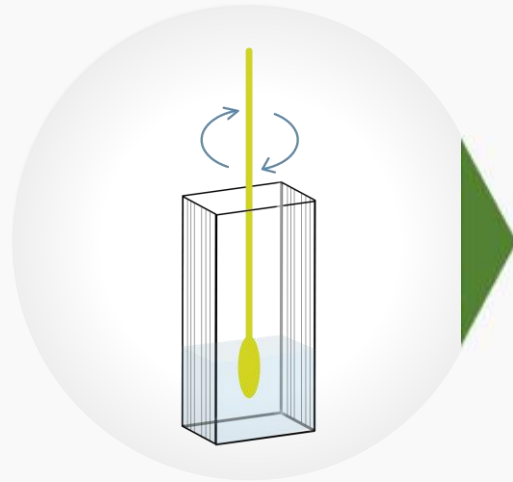
- Protect operator from contact with samples
- Works with nasopharyngeal or oropharyngeal swabs

The background features a large, detailed illustration of a virus particle with a textured, spherical surface and several protruding spikes. To the right, there is a large, textured, scale-like surface, possibly representing a biological or material structure. The overall color palette is light and monochromatic, with shades of gray and white.

Fast

- 6 minutes per test
- Results displayed in numbers

Steps



Interpretation

Positive: Test result $\geq 25\text{ng/ mL}$

Negative: Test result $< 25\text{ng/ mL}$

Clinical significance

This kit is used for in vitro qualitative diagnosis of SARS-COV-2 antigen in nasopharyngeal swabs or oropharyngeal swab samples. It is only used for early diagnosis and management of samples taken within 7 days when the suspected patient showing symptoms during the acute infection period.



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