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

— Liquid Phase —

Declaration of conformity

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma / Nom et adresse de l'entreprise / Nome e indirizzo della ditta / Name and address of the firm: Shijiazhuang Hipro Biotechnology Co., Ltd, No.3 Building,Block C,Fangyi Tech. Park, No. 313Zhujiangdadao Street,Shijiazhuang,050000 China

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 / the medical device / 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 sources and number of items

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 applicate,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 14136:2004、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

Basic Parameters

Specimen: nasopharyngeal or oropharyngeal swabs.

Test time: 6 mins

Packing: 25 Tests/Box

Box size: 14×12×7cm

Storage: 2-8℃

Shelf year: 1 year.

Accurate

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

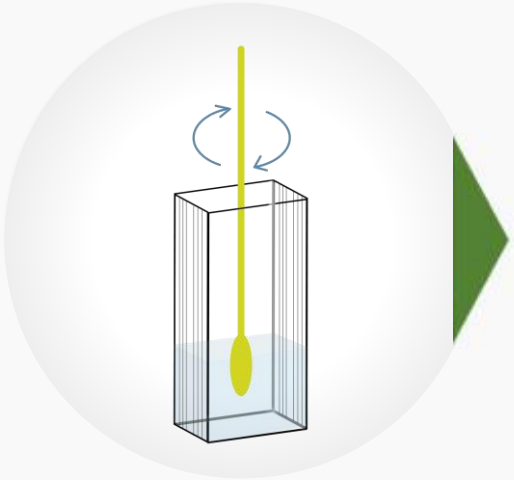
Safe

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

Fast

- 6 minutes per test
- Results displayed in numbers

Steps



Interpretation

Positive: Test result ≥25ng/ mL

Negative: Test result < 25ng/ 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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