

RE: Ecotest COVID-19 Antigen Saliva Test kit (COV-S23 Swab Kit)

Catalog NO: COV-S23004H

WAND: 220202-WAND-6YF9B8

To whom it may concern,

This is to confirm that the above said items shelf life has been extended by the manufacturer for their intended purpose for 36 months from the date of manufacture printed on the product.

This extension has been based on real time stability studies conducted by the manufacturer AssureTech (Hangzhou) Co.Ltd. The design Verification report COV-S23 Rev 3.0 dated 01/06/2023 was reviewed and the following conclusion was stated:

“Acceptable performance was demonstrated for all time points for kits stored at 2-8 °C or 30 °C. These results suggest the kit is stable for 36 months at 2-30°C.”

Finally, we attest that the test protocol employed by the manufacturer for the above studies is as per described in EN ISO 23640:2013, IVD MD - evaluation of stability of in vitro diagnostic reagents.

Sincerely,



Compliance Team

16/11/2023



People



Supply



Compliance



Freight



Product