

## **Letter of Declaration**

To whom it may concern,

This letter serves as an official statement from CITEST DIAGNOSTICS INC. regarding the Instructions for Use (IFU) updates for our COVID-19 Antigen Rapid Test Kit (Ref: ICOV-502).

We confirm that the IFU for the above-mentioned product has been revised and expanded following its initial launch. The original version of the IFU authorized the use of nasal and nasopharyngeal swab samples only.

Subsequently, in response to ongoing clinical validation and user feedback, we have conducted additional performance evaluations. Based on the positive outcomes of these studies, we have updated the IFU to include **Oropharyngeal Swab** sampling as a validated sample collection method. This modification was implemented to improve the versatility and accessibility of the test while maintaining its high accuracy and reliability. The updated IFU now authorizes the use of the kit with nasal, nasopharyngeal, and oropharyngeal swab samples. And all needed accessories are included in the kit for nasal, nasopharyngeal, and oropharyngeal swab samples.

The change was initiated and approved by **CITEST DIAGNOSTICS INC**. We hereby confirm that the kit is now fully validated for all three swab types as stated.

Should any further information or verification be required, please do not hesitate to contact us.

Signature:

Manager: Yanping Fu

Date: September 18<sup>th</sup>, 2025

CITEST DIAGNOSTICS INC.

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