

CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test

*FOR PROFESSIONAL USE ONLY
*FOR IN VITRO DIAGNOSTIC USE ONLY

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunoassay intended for the qualitative and differential detection of SARS-CoV-2 and Influenza A and B antigens in nasal samples (from both nostrils). The multiplex test provides an efficient and accurate diagnostic solution to healthcare providers for prioritizing patients' health.

CPT code # 87804QW (Flu A)
87804QW-59 (Flu B)
87811Q (COVID-19)

NDC code # 50042-5596-35

Medicare Coverage : CCI MUE

Features and Benefits

- The **First 10-minute** test in the US for Flu A/B & COVID-19.
- No instrument needed.
- High sensitivity, specificity, and accuracy.
- Only 3 drops of sample solution needed.
- Evaluated against XBB variants.

Fast Facts:

- Patient Population: The test is designed for individuals aged 2 years and older with symptoms of COVID-19 and/or influenza A and B within the first 5 days of symptom onset.
- Production Lead Time: Varies based on volume, but 1-2 weeks in general.
- Storage: 36-86°F/2-30°C.
- Sample Type: Anterior nasal sample.

CorDx Tyfast Emergency Use Authorization (EUA) Number: EUA230055

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use in authorized settings.
- This product has been authorized only for the detection of SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens.

National Reimbursement Limit : \$70.29



Performance Specifications:

	COVID-19	Flu A	Flu B
Positive Percent Agreement(PPA)	89.1%	83.6%	90.0%
Negative Percent Agreement(NPA)	99.8%	98.8%	99.9%

*Based on multi-site clinical studies conducted in the United States.

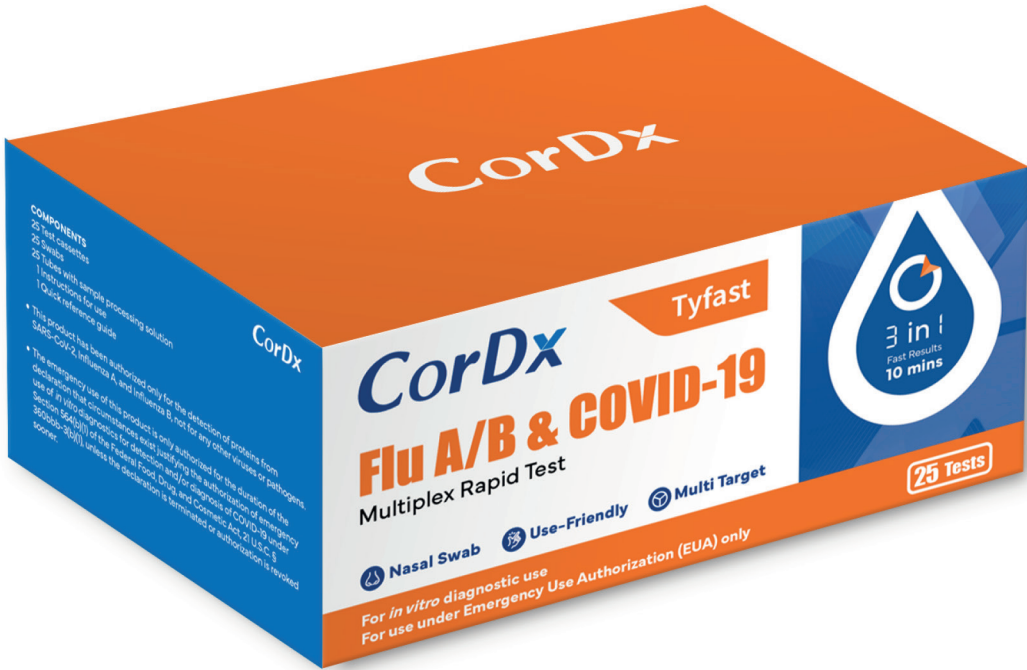
Packaging Details:

Components	25 Tests/Box
Test cassette	25
Swab	25
Tube with sample processing solution	25
Instructions for use(IFU)	1
Quick reference guide(QRG)	1

Ordering information:

Product Number	Package Configuration	Dimensions (in,L*W*H)	Weight (lb)
ACT21001-25	25Tests/Box 20Boxes/Case 500Tests/Case 45Cases/Pallet	7.4*5.1*3.3 16.1*13.4*13.6	0.7/Box 15.7/Case 738.5/Pallet

*Control swabs kit is available upon request.



CorDx
Flu A/B & COVID-19
Multiplex Rapid Test
INSTRUCTIONS FOR USE (IFU)

For use under emergency use authorization (EUA) only
For in vitro diagnostic use
For use with anterior nasal swab specimens

INTENDED USE

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A

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QUICK REFERENCE GUIDE

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PREPARING FOR THE TEST

- Read all the instructions. Failure to follow the instructions may result in inaccurate test results.
- Check the test's expiration date. **Do not use an expired test.**
- Use a flat level surface (countertop) for testing.
- Use a timer during the test.
- Make sure you have all the components before you begin.
- Bring test kit to room temperature before use.

