

## 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 | COVID-19 | 87811QW    |
|          | Flu A    | 87804QW    |
|          | Flu B    | 87804QW-59 |

### 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 Fact:

- 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.
- Shelf life: 12 Months.

### 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.

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### Performance Specifications:

|                                  | COVID-19 | Flu A | Flu B |
|----------------------------------|----------|-------|-------|
| Positive Percent Agreement (PPA) | 89.6%    | 85%   | 87.5% |
| Negative Percent Agreement (NPA) | 99.8%    | 99.2% | 99.8% |

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

### Packaging Details

| Number of Tests/kit                  | 20 Tests/kit | 25 Tests/kit |
|--------------------------------------|--------------|--------------|
| Test Cassette                        | 20           | 25           |
| Swab                                 | 20           | 25           |
| Tube with sample processing solution | 20           | 25           |
| Instruction For Use                  | 1            | 1            |

### Ordering information:

| Product Number | Package Configuration                            | Dimensions (in, L*W*H)        | Weight (lb)                           |
|----------------|--------------------------------------------------|-------------------------------|---------------------------------------|
| CO292-20       | 20 Tests/Box<br>24 Boxes/Case<br>40 Cases/Pallet | 6.3*5.1*2.5<br>19.5*10.6*14.0 | 0.63/Box<br>15.2/Case<br>608/Pallet   |
| CO292-25       | 25 Tests/Box<br>20 Boxes/Case<br>45 Cases/Pallet | 7.5*5.1*3.3<br>15.8*13.0*14.0 | 0.76/Box<br>15.1/Case<br>679.5/Pallet |
| CUS294-10      | 10 Control Swabs (positive & negative swabs)     |                               |                                       |

\*Customized pack sizes available upon request.

\*Control swabs kit includes a positive control swab (contains influenza A, influenza B and SARS- COV-2 recombinant antigen) and a negative control swab. Control swabs kit is available upon request.