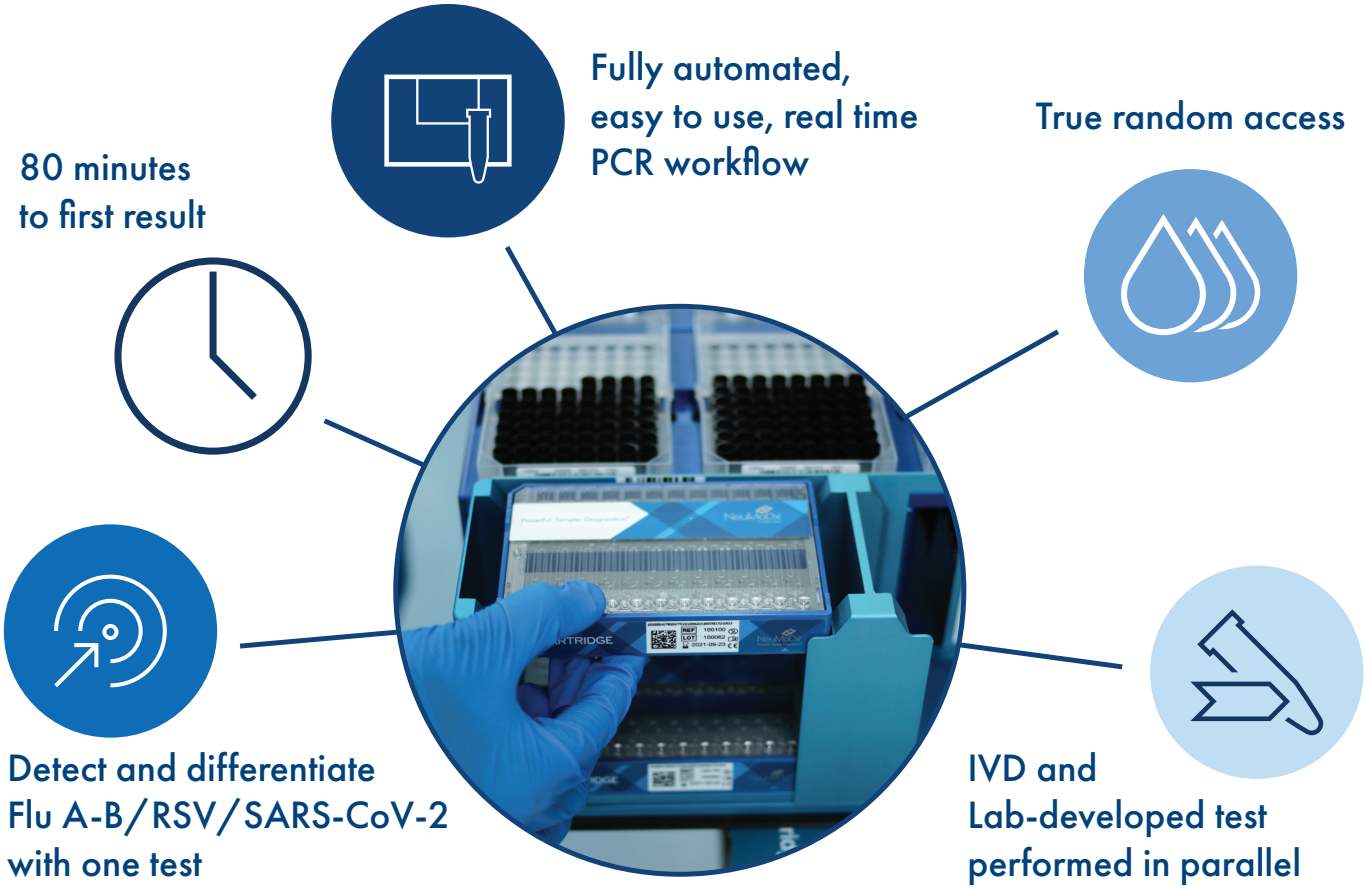
NeuMoDx™ | Molecular Diagnostics

# Four respiratory viral infections.
# One NeuMoDx test.




The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay simultaneously detects and differentiates the two most common strains of influenza (A and B), RSV and SARS-CoV-2 from individuals suspected by a health care provider of respiratory viral infection consistent with COVID-19. In around 80 minutes, you can get accurate answers to make actionable clinical decisions.

## NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay

| Parameter | Specification |
|---|---|
| Type | Qualitative |
| Targets | Flu A, Flu B, RSV: all M gene, SARS-CoV-2: Nsp2 gene |
| LOD | Flu A: 0.5 $TCID_{50}$/mL, Flu B: 0.01 $TCID_{50}$/mL, RSV: 1.0 $TCID_{50}$/mL, SARS-CoV: 250 copies/mL |
| Sample type/s | Nasopharyngeal in Universal or Viral Transport Medium |
| Time to first result | ~ 80 mins |
| Sample stability | Up to 8 hours on board, 7 days @ 2-8˚C |
| Sample volume | 550 µl |
| Minimum volume | 700 µl |
| Elution volume | 20 µl |
| Onboard stability | Up to 7 days |
| Controls period | User define positive and negative IC = SPC2 |

**Intended use:** The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Assay is a qualitative in vitro real-time RT-PCR diagnostic test for the direct detection and differentiation of influenza A, influenza B, respiratory syncytial virus and SARS-CoV-2 RNA from individuals with signs and symptoms of respiratory tract infections.

## Ordering Information

| Product | Contents | Cat. no. |
|---|---|---|
| NeuMoDx Flu A-B/RSV/ SARS-CoV-2 Vantage Test Strip | Dried RT-PCR reagents containing Flu A-B/RSV/SARS-CoV-2 specific TaqMan® probes and primers, and SPC2 specific TaqMan probe and primers. Each package contains 96 tests. | 300900 |

## QIAlab Consulting Services

At QIAGEN, we understand current challenges in the molecular diagnostics laboratory. In times of increased workloads, limited resources and financial constraints, there is a strong need for optimization. QIAlab Consulting offers an individual analysis of your processes in close collaboration with you. Together, we will identify critical steps in your workflow to improve performance and quality. We will apply optimization processes and continuous improvement techniques, based on Lean Management methods, tailored to your needs.

Take your lab to the next level. Visit for more information.

The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay is authorized under Emergency Use Authorization in the United States.

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus, influenza B virus, and/or Respiratory Syncytial Virus, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



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