

GenomEra[®] SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit

Fast detection and differentiation of
SARS-CoV-2, Flu A, Flu B, and RSV





Why choose our test?

The GenomEra® SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit is a new and improved version of Uniogen's GenomEra® SARS-CoV-2, Flu A/B + RSV Assay Kit. It is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), influenza A and B, and respiratory syncytial virus (RSV) from individuals with symptoms of a respiratory viral infection—now with an even faster and safer workflow.

Key benefits of version 2.0

- Improved sensitivity and specificity
- Inactivation of viruses during sample collection
- Wider usability of different sample collection media
- Quicker workflow: shorter hands-on time and reduced assay time

The RNA viruses SARS-CoV-2, influenza A, influenza B, and RSV all cause acute respiratory infections with similar clinical manifestations, ranging from asymptomatic or mild illness in most individuals to more severe and life-threatening disease. Infection management and treatment strategies, however, differ from one pathogen to another.

Key facts

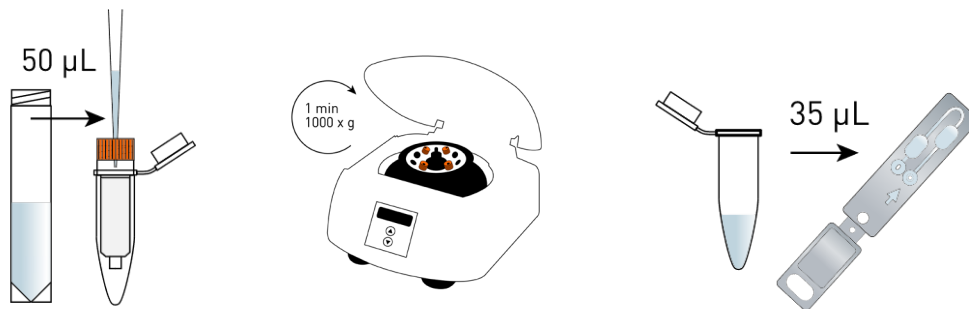
- Simultaneous detection and differentiation of SARS-CoV-2, influenza A and B, and RSV from a single respiratory specimen
- Safety guaranteed with specimen collection directly in Copan eNAT inactivating medium
- Automated and rapid RT-PCR testing—results for four samples in just 50 minutes

Assay principle

The GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit is a rapid and easy-to-use multiplex RT-PCR test for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A and B, and RSV nucleic acids from a single respiratory specimen on the GenomEra® CDX System.

Sample preparation in the GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit is simple with minimal hands-on time—only three minutes for one sample and less than five minutes for four samples.

Test procedure

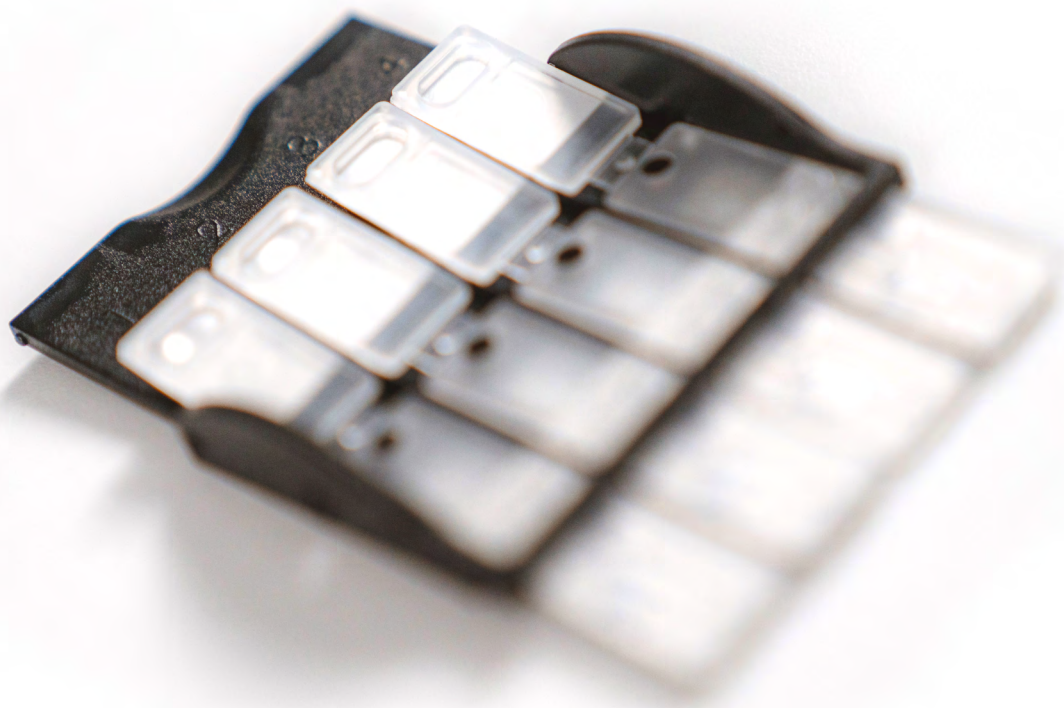


Clinical performance

The clinical performance of the GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit was evaluated at four institutions across Europe during February-April 2022 (Table 1). Study specimens consisted of fresh and frozen respiratory swab specimens collected in eSwab, UTM, PBS, or similar transport media from patients with signs and symptoms of a respiratory infection. The reference assays used were different in-house or commercial RT-PCR assays developed for SARS-CoV-2, influenza, and RSV detection.

Analyte	Sample size (n)	PPA, %	NPA, %
SARS-CoV-2	751	98.4	100
Influenza A	751	98.3	100
Influenza B	751	100	100
RSV	751	94.4	100

Table 1. The GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit shows an excellent specificity and sensitivity in clinical respiratory specimens. PPA, positive percent agreement; NPA, negative percent agreement (NPA).



Ordering information

To place an order, please contact your local distributor at uniogen.com/distributors/

Product name	Product code
GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit, 20 pcs	CDX-160-01-20
GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit, 100 pcs	CDX-160-01-100
GenomEra CDX System	CDX-10-020

Manufacturer

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Distributor



GenomEra® products carry the Finnish Key Flag Symbol,
a valued and trusted symbol of Finnish origin.

The test is CE marked in accordance with the IVD directive. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Uniogen Oy.

SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit v. 2.0, February 2023

