

GENOMERA® FLU A/B + RSV
-RAPID MULTIPLEXED RT-PCR TEST

FOR DIRECT DETECTION
AND DIFFERENTIATION



GENOMERA® PROVIDES THE SPEED AND PERFORMANCE NEEDED IN INFLUENZA DIAGNOSTICS



GENOMERA® FLU A/B+RSV BENEFITS

Saves work and time

- The test is performed directly from eSwab™ or UTM without RNA extraction
- Sample preparation is easy and fast
- All required materials are provided with the kit
- Results are automatically and reliably interpreted



Promotes efficiency and saves waste

- The test is very cost-efficient compared to other automated molecular test
- Waste is minimal
- Short turn-around-time and suitability for single samples allows immediate action
- Unnecessary isolation and antibiotic treatment is avoided

Streamlines laboratory workflow

- Liquid-based sample collection supports multiple testing from the same sample, so there is no need for resampling
- Customers can batch sample preparation steps to reduce workload
- Other RNA-tests can be combined in the same run
- The test's flexible capacity adapts to the needs of the flu season

Influenza (Flu) A and B together with respiratory syncytial virus (RSV) are among the main causes of respiratory infections during the winter months. It is estimated that these viruses infect 5-10 % of the world's population annually (1). Children and the elderly are particularly at risk and their infections can be severe.

Influenza and RSV cause 250 000 – 500 000 deaths every year and, for example, the economic burden of influenza due to loss of productivity in Germany and France together is estimated to be €6.4-9.8 billion. (1, 2)

As an optimal diagnostic tool to detect influenza and RSV reliably and quickly GenomEra® Flu A/B + RSV can play a major role in the prevention of epidemics, with their associated deaths and costs to society.

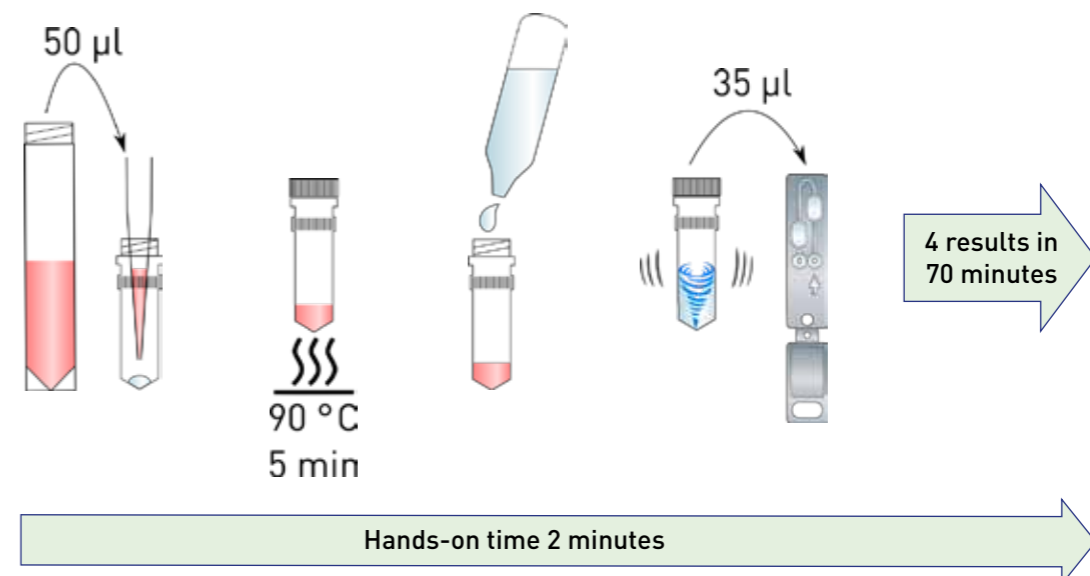
GenomEra is a simple-to-use platform without RNA-extraction to detect and differentiate influenza A, influenza B, RSV A and RSV B in a multiplexed RT-PCR assay.

RT-PCR is the most reliable method for detecting influenza and RSV and it is nowadays regarded as the golden standard. Reliable and fast results mean reduced costs through improved patient management and isolation practices.

[1.] World Health Organization Influenza (Seasonal). Fact sheet No. 211, 2009.

[2.] Keech M, Beardsworth P. The impact of influenza on working days lost: a review of the literature. Pharmacoeconomics 2008; 26:911-24

RELIABLE RESULTS WITH MINIMAL HANDS-ON-TIME



FEATURES OF GENOMERA[®]

FLU A/B + RSV

- Multiplex RT-PCR test for differentiation of influenza A/B and RSV A/B
- Reports all results separately for epidemiological surveillance
- Comprehensive up-to-date strain coverage
- Less than 80 minutes turn-around-time enables quick result reporting
- If result is negative the same stabilised sample can be used for other methods
- GenomEra CDX provides scalable capacity 1-4 samples per run and on multi-instrument settings up to 32 samples per run

EXCELLENT CLINICAL PERFORMANCE

Analyte	PPA (i.e. sensitivity)	NPA (i.e. specificity)	Accuracy
Flu A (n=1256)	97.1%	99.4%	98.6%
Flu B (n=1256)	100%	100%	100%
RSV (n=701)	98%	99.8%	98.7%

Reference methods used were CE IVD nucleic acid amplification assays for influenza A, influenza B and RSV. Samples which produced discrepant results were analysed with a third method which was a CE IVD RT-PCR assay or a well-characterized and validated in-house RT-PCR assay.

ORDERING INFORMATION

- GenomEra Flu A/B + RSV CDX-110-01-20
- GenomEra Flu A/B + RSV CDX-110-01-40
- GenomEra CDX system CDX-10-020



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