

NuLexa™ System

The NULEXA™ System has set a new standard for point-of-care respiratory molecular testing by being the first to deliver RT-PCR influenza + SARS results in less than 10 minutes.*

CLIA waived.



Highly-accurate streamlined workflow

The NULEXA™ System is a breakthrough molecular diagnostic platform designed to fit seamlessly into busy point-of-care workflows.

Lab-quality performance you can trust

Proprietary thermal cycling technology allows multiple targets from a single sample.

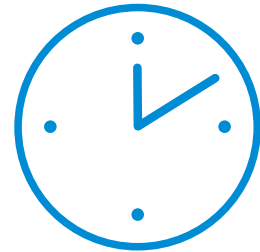
Ultra-rapid results enable fast patient care

Delivering fast and accurate results during a patient's visit helps improve the patient experience and minimizes loss to follow-up care.

Simple workflow improves operational efficiency

One-minute hands-on time saves staff time to focus on patient care.

**True RT-PCR
influenza + SARS
test results in
10 minutes or less.***



Less waiting. Faster decisions.

Providers and patients want accuracy without the wait. Molecular PCR platforms provide gold-standard results but have traditionally required specialized staffing, labor-intensive workflows and longer turnaround times.

With PCR-level specificity and CLIA-waived simplicity, the NULEXA System delivers RT-PCR results in 10 minutes or less to support faster treatment decisions.



Built for speed

The NULEXA System simplifies multiplex testing with limited hands-on steps and ultra-fast time-to-results as compared to other molecular platforms.

NULEXA System ultra-rapid RT-PCR

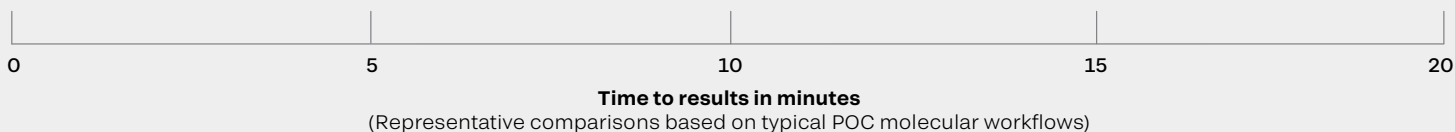
6-10 minutes **3 targets** Early-read

POC nicking enzyme amplification reaction (NEAR)

~13 minutes **1 target** Early-read

Rapid POC RT-PCR

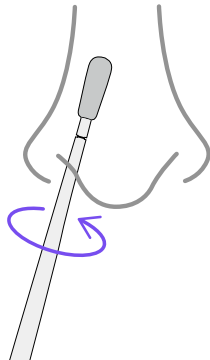
~20 minutes **3 targets** No early-read



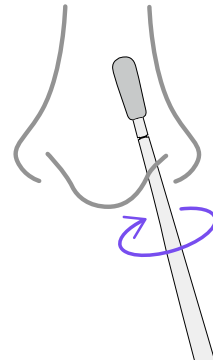
3 simple steps to results

1

Swab one nostril for 15 seconds.

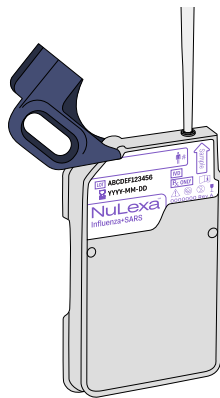


Swab other nostril with same swab.

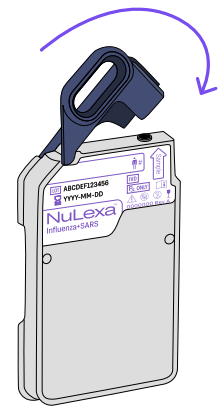


2

Break off swab in cartridge.



Close cartridge.

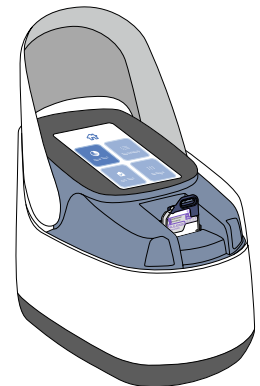


3

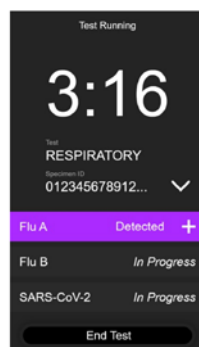
Select "New Test" and input specimen ID.



Put closed cartridge in instrument and start test.



Early-read function provides real-time results.



Full test results in 10 minutes or less.



One cartridge. Three pathogens. Results in less than 10 minutes.

With the NULEXA™ Influenza + SARS Test, you can now accurately, rapidly and simultaneously assess influenza A, influenza B and SARS-CoV-2, the most common respiratory viruses.

Prospective, paired ANS specimen results for all targets

Analyte	Positive percent agreement (PPA)			Negative percent agreement (NPA)		
	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
SARS-CoV-2	150/156 ^{a,b}	96.2	91.9 – 98.2	1507/1514	99.5	99.1 – 99.8
Influenza A	342/370 ^{a,c}	92.4	89.3 – 94.7	1295/1307 ^d	99.1	98.4 – 99.5
Influenza B	14/15 ^e	93.3	70.2 – 98.8	1646/1650	99.8	99.4 – 99.9

a Includes three (3) influenza A / SARS-CoV-2 coinfections.

b One (1) discrepant specimen tested negative on secondary reference testing.

c Two (2) discrepant specimens tested negative on secondary reference testing.

d Three (3) discrepant specimens tested positive on secondary reference testing.

e One (1) discrepant specimen tested negative on secondary reference testing.

Retrospective, paired ANS specimen results for influenza B

Analyte	Positive percent agreement (PPA)			Negative percent agreement (NPA)		
	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Influenza B	15/16	93.8	71.7 – 98.9	82/82	100	95.5 – 100

Intended use

The NULEXA Influenza + SARS Test is an automated rapid multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) test performed on the NULEXA Instrument and is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and influenza B virus nucleic acid in anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar.

The NULEXA Influenza + SARS Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A and influenza B viral nucleic acid are generally detectable in ANS specimens during the acute phase of infection.

Positive results do not rule out co-infection with other organisms. The agent(s) detected by the NULEXA Influenza + SARS Test may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.



NULEXA Instrument in detail

CLIA
WAIVED



Compact footprint 7.4 in x 11.8 in x 9.4 in • Weight: 14 lbs

NULEXA Instrument
Catalog #100002

NULEXA Influenza + SARS Test
50 Test Kit: Catalog #200003

*As of June 16, 2026, based on date of FDA clearance and time to result for RT-PCR Influenza A/B + SARS-CoV-2 diagnostic tests for point-of-care settings. See quidelortho.com/global/en/products/nulexa-system/claims-matrix-june26.



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