

Rapid GenomEra® PCR tests

Molecular diagnostics made effortless, quick, and reliable





Uniogen

is a global diagnostics pioneer and a one-stop-shop for clinical diagnostics, point-of-care testing, and instrumentation for life sciences. We are based in Turku, Finland. Our products are being used in about 100 countries worldwide.

GenomEra® CDX system

is an easy to use and straightforward PCR system comprising software, instrument, and test chips. GenomEra CDX system provides simplicity, sensitivity, safety, and speed in molecular diagnostics without compromising the quality of results and reliability. This means both cost-efficiency and quicker and better care for the patients.

HSV-1/2, VZV + EV

Unique test for detecting viruses causing viral meningitis

A rapid molecular test for the simultaneous detection of the four most common causes of viral meningitis and encephalitis.

SARS-CoV-2 2.0

2nd generation COVID-19 test takes usability to a new level

The assay provides fast and reliable detection of SARS-CoV-2 using RT-PCR, the golden standard for COVID-19 diagnostics.

■ SARS-CoV-2, Flu A/B + RSV 2.0 Fast detection and differentiation of SARS-CoV-2, Flu A, Flu B, and RSV

Key benefits of version 2.0 are improved sensitivity and specificity, inactivation of viruses during sample collection, wider usability of different sample collection media and quicker workflow.

Norovirus

Cost-effective and reliable method for on-demand testing of norovirus

The fastest molecular assay for genogroup GI and GII noroviruses on the market.

C. difficile

Enabling a 1-step algorithm to reliably detect toxigenic *Clostridioides difficile*

A rapid, simple, and high-performance molecular assay to diagnose your patients directly from unformed stool samples suspected positive for toxigenic *C. difficile* in less than one hour.

MRSA/SA Multi Swab

Highly sensitive assay for ruling out MRSA/SA carriage

The test offers a rapid and simple high-performance molecular assay for the direct detection of SA and MRSA infection from clinical swab samples – nose, throat, and groins.

GenomEra Assay Kit Compatibility Sheet

At present, there are three different PCR assay protocols applied for the GenomEra Assay Kits: End-point PCR, RT qPCR and RT qPCR Rapid. Different GenomEra Assay Kits may be run simultaneously in the GenomEra CDX Instrument depending on the Assay Kits used. The assay compatibility is illustrated in the following table.

PCR Protocol			
End-point PCR (50 min)	RT qPCR* (70 min)	RT qPCR Rapid (50 min)	
C. difficile Assay Kit	Norovirus Assay Kit	SARS-CoV-2 2.0 Assay Kit	
MRSA/SA AC Assay Kit	HSV-1/2, VZV + EV Assay Kit	SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit	
MRSA/SA Multi Swab Assay Kit	SARS-CoV-2 Assay Kit		
S. pneumoniae Assay Kit	SARS-CoV-2, Flu A/B + RSV Assay Kit		
GBS Assay Kit			

^{*} Qualitative Real-Time Reverse-Transcription PCR

MRSA/SA AC

Comprehensive test for detection and differentiation of S. aureus and MRSA

A rapid and simple high-performance molecular assay enables a definitive differentiation of MRSA or SA in less than one hour from positive blood cultures, liquid cultures, or culture plates.

S. pneumoniae

Reliable way to detect S. pneumoniae from other streptococci

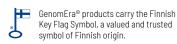
The assay enables reliable and specific detection of pneumococcus from cultured primary blood samples suspected positive for S. pneumoniae.

GBS (Group B streptococcus) Sensitive and fast detection of GBS during

pregnancy and at the time of delivery

The assay simplifies and speeds up GBS testing by providing reliable results from vaginal-rectal swab samples in less than one hour.







Rapid GenomEra® PCR tests

compromising assay reliability and quality. The current GenomEra product portfolio consists of assay kits intended to aid in the The GenomEra® CDX system provides a powerful tool for running molecular diagnostics routinely and cost-efficiently without diagnosis of CNS, critical and blood stream infections, complemented with a perinatal diagnostic assay.

n Infections Perinatal Diagnostics	Enriched	GBS (Group B Streptococcus)	
	Direct swab		
	od culture	SP S.pneumoniae	
Blood Stream Infections	Positive blood culture	SA/MRSA AC (with mecC)	
Critical Infections	Culture	SA/MR (with n	
	Direct stool	C. difficile	Norovirus (separation of Gl and GII)
	Respiratory samples	SARS-CoV-2 SARS-CoV-2 2.0	SARS-CoV-2, Flu A/B + RSV SARS-CoV-2, Flu A/B + RSV 2.0
	Skin swab	MRSA/SA Multi swab	
		-1/2 + EV	
CNS Infections	CSF	HSV-1/2 VZV + EV	
eqyt noitɔetnl	Sample type	touborq	

Tests are CE marked in accordance with the IVD directive. Product availability may vary from woll country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Uniogen 0y.

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