

Kit Information	FTD SARS-CoV-2	FTD SARS-CoV-2/ FluA/FluB/HRSV	FTD Respiratory pathogens 21	FTD FLU/HRSV
Product numbers	FTD-114-96 SMN 11416284—96 tests	FTD-127 SMN 10731383—48 tests	FTD 2.1 SMN 10921702—32 tests SMN 10921703—64 tests	FTD 48.2 SMN 10921784—32 tests SMN 10921785—64 tests
Sample types	Human nasopharyngeal swabs Human oropharyngeal swabs	Human nasopharyngeal swabs	Human nasopharyngeal swabs	Human nasopharyngeal swabs Human nasal swabs
Number of primer-probe mixes	1	2	5	1
Maximum number of samples per 96-well plate	94	45	17	94
Validated extraction methods	• VERSANT® kPCR Molecular System SP • Nuclisens EASYMAG (bioMerieux)	• VERSANT kPCR Molecular System SP	• Nuclisens EASYMAG (bioMerieux)	• Nuclisens EASYMAG (bioMerieux)
Validated thermocyclers	• VERSANT kPCR Molecular System AD • Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)	• VERSANT kPCR Molecular System AD	• Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)	• Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)

All assays are CE-IVD.

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

VERSANT and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. All third-party trademarks listed in this brochure are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

FTD Respiratory Pathogens 21, FTD SARS-CoV-2/FluA/FluB/HRSV, FTD SARS-CoV-2, and FTD FLU/HRSV assays are CE-IVD marked for diagnostic use in the EU.

Fast Track 
DIAGNOSTICS
A Siemens Healthineers Company



FTD Respiratory Assays

Syndromic Solutions:
Respiratory Infections

Syndromic testing for emerging, routine,
and seasonal outbreaks of respiratory infections
using multiplex RT-PCR



[siemens-healthineers.com/ftd-respiratory-assays](https://www.siemens-healthineers.com/ftd-respiratory-assays)

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
[siemens-healthineers.com](https://www.siemens-healthineers.com)

Legal Manufacturer
Fast Track Diagnostics
Luxembourg S.à r.l.
29, rue Henri Koch
4354 Esch-sur-Alzette
Luxembourg

for the Product
Fast Track Diagnostics Assays

Published by
Siemens Healthcare Diagnostics Inc.
Molecular Diagnostics
725 Potter Street
Berkeley, CA 94710-2722
USA
Phone: +1 510-982-4000

Challenge:

Consolidating testing for relevant pathogens and rapid diagnosis in symptomatic patients

Acute respiratory pathogen infections are common causes of acute local and systemic disease with substantial morbidity and mortality in pediatric, adult, and immunocompromised patients.

Early and accurate diagnosis of respiratory pathogens diminishes transmission and complications. More efficient laboratory testing enables the physician in determining appropriate and timely patient treatment.

Molecular laboratories are increasingly asked to do more with less in the face of laboratory staffing challenges and the need to manage multiple assays on multiple platforms and service agreements with multiple vendors.

The challenge is further compounded by the need for different PCR protocols for a wide variety of specimens across several different disease groups.

Solution:

Fast Track Diagnostics syndromic, multiplex real-time PCR Assays

- Siemens Healthineers offers solutions for the simultaneous detection of several respiratory pathogens:
- **FTD Respiratory pathogens 21 Assay*** for the detection of 20 viruses and 1 bacterium
 - **FTD SARS-CoV-2/FluA/FluB/HRSV Assay*** for the detection and differentiation of SARS-CoV-2, IAV, IBV, HRSV A/B
 - **FTD FLU/HRSV Assay*** for the detection of influenza A, influenza B, and human respiratory syncytial viruses A and B
 - **FTD SARS-CoV-2 Assay*** for the specific detection of the coronavirus causing COVID-19

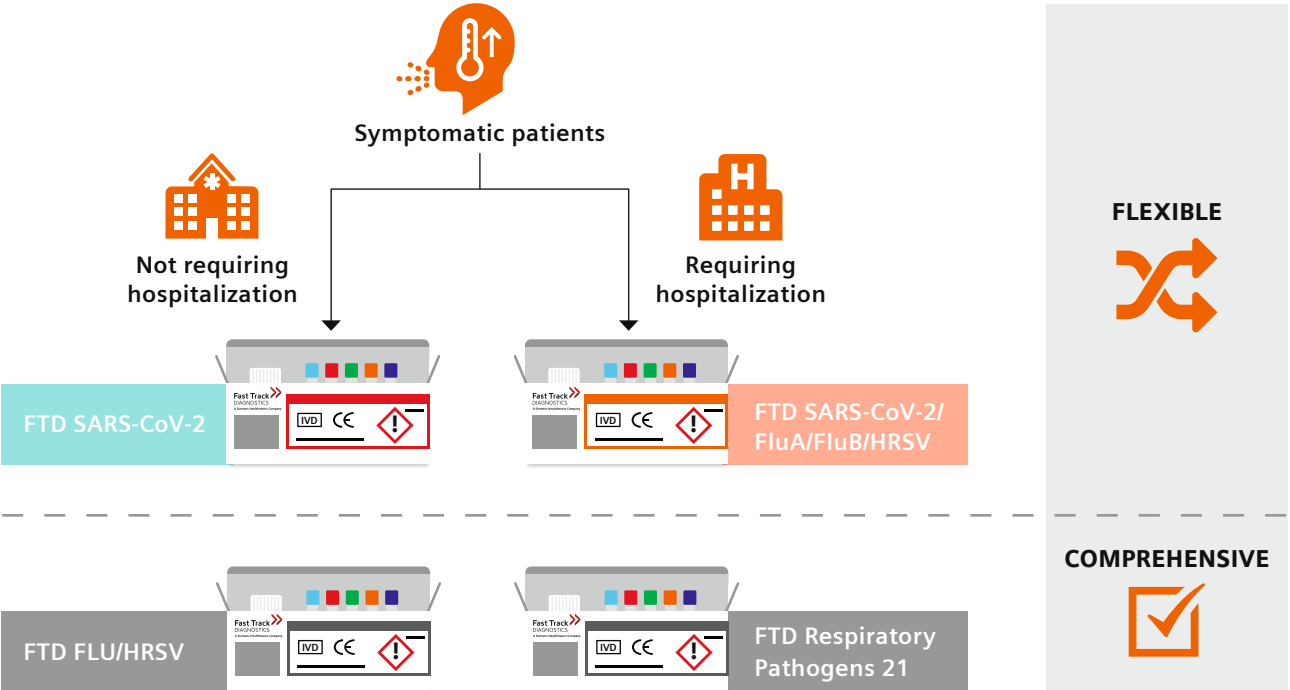
FTD Respiratory Pathogens 21: Routine detection of upper respiratory pathogens	
Human adenovirus	Influenza A
Human bocavirus	Influenza A virus H1N1 swine-lineage
Human coronavirus 229E	Influenza B
Human coronavirus HKU1	<i>Mycoplasma pneumoniae</i>
Human coronavirus NL63	Human parainfluenza virus 1
Human coronavirus OC43	Human parainfluenza virus 2
Enterovirus	Human parainfluenza virus 3
Human metapneumovirus A/B	Human parainfluenza virus 4
Human parechovirus	Human respiratory syncytial virus A/B
	Human rhinovirus

FTD SARS-CoV-2/FluA/FluB/HRSV: Targeted detection for 5 clinically relevant pathogens			
Severe acute respiratory syndrome coronavirus 2	Influenza A	Influenza B	Human respiratory syncytial virus A/B

FTD FLU/HRSV: Targeted detection of seasonal viruses		
Influenza A	Influenza B	Human respiratory syncytial virus A/B

FTD SARS-CoV-2: Targeted detection of respiratory virus SARS-CoV-2	
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	

A comprehensive and flexible respiratory testing solution



CDC testing guidance: <https://www.cdc.gov/flulprofessionals/diagnosis/testing-guidance-for-outpatient.htm>

- Quality assays**
 - Designed, developed, and manufactured according to ISO 13485:2016 certified QMS.[†]
 - Demonstrated excellent analytical and clinical performance.[‡]
- Better outcomes**
 - Expands precision medicine with clinically relevant singleplex and multiplex panels.
 - Supports management of respiratory infections throughout the year as well as during seasonal peaks using the same protocol and solution.
 - Helps improve patient outcomes by aiding in diagnosis for appropriate and timely treatment plan.
- Greater efficiency**
 - Provides simultaneous detection of probable pathogens with one kit using a single sample for increased testing efficiency.
 - Uses the same protocol, enabling operators to more easily switch during the peak season without additional training.
- Lower costs**
 - Syndromic panels enable testing of multiple pathogens at the same time, saving time and resources.
 - A single sample and test are used to determine all the probable pathogenic causes at the same time, in one run.

Pathogens detected by FTD respiratory assays[§]

Pathogen	Classification, genome	Epidemiology	Clinical manifestations	FTD assay inclusivity**
EV Enteroviruses	Family <i>Picornaviridae</i> Genus <i>Enterovirus</i> Single-stranded, positive-sense RNA	Four species (A through D). Include polioviruses, coxsackievirus, echoviruses, and other enteroviruses	Cause febrile illnesses in infants and young children. Most common cause of meningitis, myelitis, and paralysis in patients. EV is often found in respiratory secretions.	EV-A, EV-B, EV-C, EV-D
HAdV Human adenoviruses	Family <i>Adenoviridae</i> Genus <i>Mastadenovirus</i> Non-enveloped, double-stranded DNA	Seven species: HAdV-A to G Over 50 serotypes Over 70 genotypes	Cause mild infections involving the respiratory tract, gastrointestinal tract, or conjunctiva. Infections are more commonly seen in young children. The disease in immunocompromised patients causes more severe infections.	HAdV-A to G
HBoV Human bocaviruses	Family <i>Parvoviridae</i> Small, single-stranded DNA	Four subtypes. HBoV-1 causes respiratory tract infections	Mild to severe, primarily lower respiratory tract infections in children.	HBoV-1
HCoV Human coronaviruses	Family <i>Coronaviridae</i> Large, enveloped, single-stranded, positive-sense RNA	Commonly circulating HCoV: NL63, 229E, OC43, and HKU1	Common cause of infections of the respiratory tract, including bronchiolitis and pneumonia.	NL63, 229E, OC43, HKU1
SARS-CoV-2 Severe acute respiratory syndrome coronavirus 2	Family <i>Coronaviridae</i> Subgenus <i>Sarbecovirus</i> Large, enveloped, single-stranded, positive-sense RNA	Variants of concern (Alpha, Beta, Gamma, Delta, Omicron) Omicron is the most common circulating variant globally (June 2022)	Coronavirus disease 2019 (COVID-19).	100% detection rate on more than 7 million sequences (siemens-healthineers.com/ftd-sars-cov-2-assay/variants)
HMPV Human metapneumo viruses	Family <i>Pneumoviridae</i> Non-segmented, single-stranded, negative-sense RNA	Two circulating genotypes: HMPV-A and HMPV-B	Leading cause of acute respiratory infections, particularly in children, immunocompromised patients, and the elderly.	HMPV-A and HMPV-B
HPIV Human parainfluenza viruses	Family <i>Paramyxoviridae</i> Single-stranded, negative-sense RNA	Commonly circulating species: HPIV-1, HPIV-3 and HPIV-2, HPIV-4	Common community-acquired respiratory pathogens that are associated with every kind of upper and lower respiratory tract illness.	HPIV-1, HPIV-3, HPIV-2, HPIV-4
HPeV Human parechoviruses	Family <i>Picornaviridae</i> Single-stranded, positive-sense RNA	19 distinct genotypes HPeV-1 and HPeV-3 are the most frequently detected worldwide	HPeV-3 infection has been related to sepsis-like illness in young children.	HPeV-1 to 8, HPeV-10, HPeV-14 and 16–18
HRSV Human respiratory syncytial viruses	Family <i>Pneumoviridae</i> Enveloped, non-segmented, single-stranded, negative-sense RNA	Two subtypes are circulating: HRV-A, HRSV-B	Important cause of severe lower respiratory tract infections in children, immunocompromised patients, and the elderly.	HRV-A and HRSV-B
HRV Human rhinoviruses	Family <i>Picornaviridae</i> Genus <i>Enterovirus</i> Single-stranded, positive-sense RNA	Three genetically distinct species: A, B, and C More than 150 serotypes	Most frequent viral infective agents in humans and the predominant cause of the common cold, throughout the entire year. Can be associated with asthma and chronic obstructive pulmonary disease exacerbations.	HRV-A, HRV-B, HRV-C
IAV Influenza A virus	Family <i>Orthomyxoviridae</i> Encapsulated single-stranded negative-sense RNA viruses	Commonly circulating IAV subtypes: H1N1 and H3N2	Major causes of seasonal epidemics of respiratory infections in children and adults with rapid onset of fever.	Major subtypes of IAV as well as the 2009-pandemic swine-lineage influenza A virus subtype H1N1
IBV Influenza B virus	Family <i>Orthomyxoviridae</i> Encapsulated single-stranded negative-sense RNA	Circulating influenza B lineages: B/Yamagata and B/Victoria	Major causes of seasonal epidemics of respiratory infections in children and adults with rapid onset of fever.	Influenza B lineages Yamagata and Victoria
M. pneumoniae <i>Mycoplasma pneumoniae</i>	Family <i>Mycoplasmataceae</i>	Two genetic groups: subtype 1 and subtype 2	Responsible for respiratory tract infections that can range in severity from mild to life-threatening.	Subtypes 1 and 2

*CE-IVD for diagnostic use in the EU.

[†]Certificate QS 076205 0014 Rev. 00.
[‡]FTD SARS-CoV-2_CE IFU 11416283_en Rev. B, 2020-12; FTD SARS-CoV-2/FluA/FluB/HRSV IFU 10731473 Rev. B, 2022-07; FTD Respiratory pathogens 21 IFU 11414180_en Rev. C, 2021-07; FTD FLU/HRSV IFU 11414155_en Rev. C, 2021-07.

[§]All information from FTD Respiratory pathogens 21 IFU, Pathogens, pages 3–5 and FTD SARS-CoV-2 IFU, Pathogens, page 3.
^{**}Instruction for use, Performance Characteristics.