

Kit Information	FTD Respiratory pathogens 21	FTD FLU/HRSV	FTD SARS-CoV-2
Product numbers	FTD 2.1 SMN 10921702—32 tests SMN 10921703—64 tests	FTD 48.2 SMN 10921784—32 tests SMN 10921785—64 tests	FTD-114-96 SMN 11416284—96 tests
Sample types	Human nasopharyngeal swabs	Human nasopharyngeal swabs Human nasal swabs	Human nasopharyngeal swabs Human oropharyngeal swabs
Number of primer-probe mixes	5	1	1
Maximum number of samples per 96-well plate	17	94	94
Validated extraction methods	Nuclisens EASYMAG (bioMerieux)	Nuclisens EASYMAG (bioMerieux)	Nuclisens EASYMAG (bioMerieux)
Validated thermocyclers	Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)	Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)	Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)
Compatible thermocyclers	<ul style="list-style-type: none"> Mx3000P qPCR System (Agilent) qTOWER3 (Analytik Jena) SMARTCYCLER (Cepheid) QUANTSTUDIO 5 DX (Thermo Fisher Scientific) QUANTSTUDIO 5 (Thermo Fisher Scientific) CFX96 (Bio-Rad) LIGHTCYCLER 480 (Roche) Rotor-Gene 6000 (QIAGEN) 	<ul style="list-style-type: none"> Mx3000P qPCR System (Agilent) SMARTCYCLER (Cepheid) QUANTSTUDIO 5 DX (Thermo Fisher Scientific) QUANTSTUDIO 5 (Thermo Fisher Scientific) CFX96 (Bio-Rad) LIGHTCYCLER 480 (Roche) Rotor-Gene 6000 (QIAGEN) 	Not available***

All assays are CE-IVD.

***Compatibility testing has not been completed by FTD.

References:

1. WHO. 2020.
2. CDC. 2020.
3. Ferkol, Schraufnagel. Ann Am Thorac Soc. 2014;11(3):404-6.
4. Assay IFU.

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. All third-party trademarks listed in this brochure are the property of their respective owners.

For Fast Track Diagnostics assays, please see the compatibility list to learn more about our compatible instruments. Customer is responsible for validating the assay on instruments listed in the compatibility list.

FTD Resp 21, 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

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.^{1,2}



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 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 Resp 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 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)

Quality assays

- Designed, developed, and manufactured according to ISO 13485:2016 certified QMS.†
- Demonstrated excellent analytical and clinical performance.‡

Greater efficiency

- Provides simultaneous detection of probable pathogens with one kit using a single sample for increased testing efficiency.
- Compatible with commonly used extraction and thermal cycler platforms.§**
- Uses the same protocol, enabling operators to more easily switch during the peak season without additional training.

Better outcomes

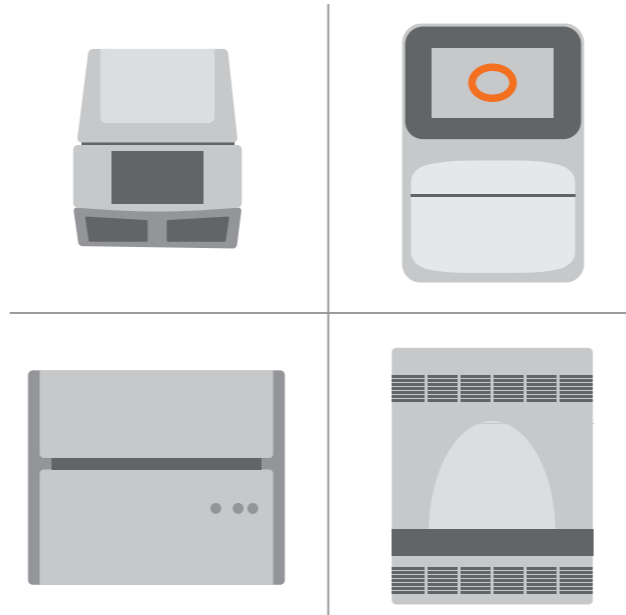
- Expands precision medicine with clinically relevant singleplex and multiplex panels.
- Supports management of respiratory infections throughout the year as well as during seasonal peaks using the same protocol and solution.
- Improves patient outcomes with clinical diagnosis that leads to an appropriate and timely treatment plan.

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.

	FTD Respiratory pathogens 21	FTD FLU/HRSV	FTD SARS-CoV-2
Overall Diagnostic Sensitivity in % (CI)††	93.94% (92.33–95.3)	98.5% (92.0–100)	100% (91.78–100)
Overall Diagnostic Specificity in % (CI)††	98.93% (98.65–99.16)	99.4% (96.6–100)	100% (93.84–100)

Simple and flexible workflow



Same PCR cycling protocol for all kits.**

†Certificate QS 076205 0014 Rev. 00.

‡Respiratory pathogens 21 IFU: Current Revision and Date 11414180_en Rev. B, 2019-12, FLUIHRSV IFU: Current Revision and Date 11414155_en Rev. B, 2020-02, SARS-CoV-2 IFU: Current Revision and Date 11416283_en Rev. A, 2020-05.

§The FTD SARS-CoV-2 Assay has been optimized on the Biomerieux EasyMag Extraction System and the Applied Biosystems 7500 Real-time PCR Thermocycler and uses the same workflow, including PCR profile, as other FTD Respiratory Disease kits from Siemens Healthineers.

**Visit fast-trackdiagnostics.com for a list of compatible instruments. Customer is responsible for validating the assay on instruments listed in the compatibility list.

††Kits Instruction for Use.

Respiratory Pathogens**

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	SARS-CoV-2 causing COVID-19 pandemic	Coronavirus disease 2019 (COVID-19).	100% detection rate on 901 SARS-CoV-2 sequences
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

**All information from Respiratory pathogens 21 Instruction for use, Pathogens, pages 3–5.

§§Instruction for use, Performance Characteristics—Inclusivity section, page 33.