FebriDx® Rapid Point-Of-Care Test

INTENDED USE

Rapid Point-Of-Care test | FDA 510(k) cleared (K260787)

FebriDx is a rapid, self-contained, immunoassay intended for the qualitative detection of myxovirus resistance protein A (MxA) and C-reactive protein (CRP) from fingerstick blood to aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology.

PRODUCT CONFIGURATIONS	
Contents	Integrated single-use test devices (containing lancet), instructions for use, quick reference instructions
Specimen type	Fingerstick blood
Tests per kit	25
GTIN	00850056728119
Kit dimensions	7.63” x 5.44” x 11.25”
Kit weight	1.9 lb
Case quantity	4 kits / 100 tests
Case dimensions	21” x 16” x 7”
Case weight	8.8 lbs
Pallet quantity	152 kits / 3,800 tests
Pallet dimensions	40” x 48”x 62”
Pallet weight	364.4 lbs
KEY PRODUCT CHARACTERISTICS	
Time to result	After 10 minutes
Biomarkers	MxA (viral biomarker indicating immune response to viral infection) CRP (biomarker associated with acute inflammation and infection)
Clinical performance (vs reference methods)	
NPV	99% Negative Predictive Value (NPV) to rule out bacterial infection
PPA	93.2% Positive Percent Agreement
NPA	88.4% Negative Percent Agreement
REGULATORY STATUS	
FDA clearance	FDA 510(k) cleared (K260787), CLIA-waived
Authorized use	Prescription use only
PLA code	PLA0442U
STORAGE CONDITIONS	
Shelf life	24 months
Storage	39–77°F (4–25°C); do not freeze

CLIA-waived

Instrument-free, portable and fully self-contained

Fast answers

Clear results after 10 minutes

Stewardship

Supports antimicrobial stewardship by helping reduce unnecessary antibiotic use

Differentiate

Differentiates bacterial acute respiratory infection from non-bacterial etiology

Authorized population	Setting
For patients aged 12-64 years	CLIA-waived healthcare settings

Clinical indication

For patients presenting with signs and symptoms of acute respiratory infection (ARI) who have had symptoms for less than 7 days and within three days of fever onset

ORDERING INFORMATION

Catalog number: P0211

657-233-5880 | USsales@phasesci.com
phasescientificamericas.com

FebriDx® is FDA 510(k)-cleared for prescription use only. It is intended for use in patients aged 12 to 64 presenting with signs and symptoms of acute respiratory infection, who have had symptoms for less than 7 days and within three days of fever onset. FebriDx results are to be used in conjunction with other clinical and diagnostic findings and are not intended as a stand-alone diagnostic tool. This test does not identify specific pathogens or determine infection severity. FebriDx is intended for use by healthcare professionals in CLIA-waived settings.

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