FebriDx® Rapid Point-of-Care Test

INTENDED USE

Rapid diagnostic test | FDA 510(k) cleared (K230917)

FebriDx® is a rapid, self-contained, point-of-care immunoassay intended for the qualitative detection of myxovirus resistance protein A (MxA) and C-reactive protein (CRP) from capillary whole blood samples obtained by fingerstick 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, buffer, and test strip), instructions for use
Specimen type	Capillary whole blood (fingerstick)
Tests per kit	25
Retail GTIN	00850056728102
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
PERFORMANCE	
Time to result	After 10 minutes
Clinical Performance (vs reference methods)	
Negative Predictive Value (NPV)	99% to rule out bacterial infection
Biomarkers	MxA (viral biomarker indicating immune response to viral infection) CRP (biomarker associated with acute inflammation)
REGULATORY STATUS	
FDA clearance	FDA 510(k) cleared (K230917)
Authorized use	Prescription use only
PLA code	PLA0442U
STORAGE CONDITIONS	
Shelf life	24 months
Storage	39–77°F (4–25°C); do not freeze

FebriDx is FDA 510(k) cleared for prescription use only. It is intended for use in patients aged 12–64 presenting with signs and symptoms of acute respiratory infection within seven days of symptom onset and within three days of fever onset. Results must be interpreted in conjunction with other clinical findings. FebriDx does not identify specific pathogens or determine severity of illness.

Accessible
Instrument-free, portable, and fully self-contained

Fast answers
Clear results after 10 minutes

Stewardship
Supports antimicrobial stewardship, reducing unnecessary antibiotic use

Differentiate
Differentiates bacterial acute respiratory infection from non-bacterial etiology

Authorized population	Setting
For patients aged 12-64 years	Urgent care and emergency care settings

Clinical indication

For patients presenting with signs and symptoms of acute respiratory infection (ARI) within seven days of symptom onset and within three days of fever onset

LIMITATIONS

- FebriDx is FDA 510(k) cleared for prescription use only
- Intended for patients aged 12–64 years presenting in urgent or emergency care with signs and symptoms of ARI
- Results are not intended as a stand-alone diagnostic and must be interpreted in the context of clinical findings
- FebriDx does not identify specific pathogens or determine severity of illness

ORDERING INFORMATION

Catalog number: P0211

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