# FebriDx: a new laboratory test to discriminate viral from bacterial respiratory infections in the emergency room

Published: 21-01-2021 Last updated: 08-04-2024

The primary objective of this study is to validate the accuracy of FebriDx to discriminate between viral and/or bacterial respiratory infections. Besides this, the predictive value (negative predictive value (NPV) and positive predictive value (PPV...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

# Summary

### ID

NL-OMON49476

**Source** ToetsingOnline

**Brief title** FebriDx in the Emergency Department

# Condition

• Hepatobiliary neoplasms malignant and unspecified

Synonym respiratory infection, Respiratory tract infection

Research involving

Human

### **Sponsors and support**

### Primary sponsor: Universitair Medisch Centrum Utrecht

1 - FebriDx: a new laboratory test to discriminate viral from bacterial respiratory ... 13-05-2025

Source(s) of monetary or material Support: Ministerie van OC&W, Accuramed, bedrijf

### Intervention

Keyword: Antibiotics, Emergency Department, FebriDx, RTI

### **Outcome measures**

#### **Primary outcome**

Positive predictive value, negative predictive value, sensitivity and

specificity to detect and discriminate RTI caused by viral and or bacterial

pathogens.

#### Secondary outcome

not applicable

# **Study description**

#### **Background summary**

Respiratory tract infections (RTI) are among the most important reasons for antibiotic prescriptions in the western world. At the same time, antibiotics are widely overused in RTI. Currently, it is hard to discriminate between viral and bacterial RTI\*s in the acute setting of the emergency department. Because of this, patients that in hindsight appear to have a viral infection are initially often treated with antibiotics. FebriDx was developed to encounter this problem. A couple of pilot studies showed promising results with high negative predictive values for bacterial RTI\*s. Consequently, FebriDx might be a useful tool to restrain antibiotic use and reducing bacterial resistance towards antibiotics. However, FebriDx has not been validated in a Dutch hospital setting.

### **Study objective**

The primary objective of this study is to validate the accuracy of FebriDx to discriminate between viral and/or bacterial respiratory infections. Besides this, the predictive value (negative predictive value (NPV) and positive predictive value (PPV)) of the FebriDx for bacterial and viral infections will be determined.

#### Study design

Prospective, observational diagnostic accuracy study, with FebriDx test performed at the ED via a fingerstick test.

#### Study burden and risks

The extra fingerstick blood samples will be drawn via the specific FebriDx device. The burden of this device is comparable with regular fingerstick tests and therefore negligible. Patients will not benefit from the FebriDx outcomes, since the treating physicians will be blinded for the results.

# Contacts

#### Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100 Utrecht 3584CX NL **Scientific** Universitair Medisch Centrum Utrecht

Heidelberglaan 100 Utrecht 3584CX NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- \* 18 years of age;

- Presenting to the ED of the UMCU with suspected RTI for the internal medicine department

- Febrile (temperature of >38.0 oC observed at presentation or reported fever in past 72h)

- Patients need to be treated following the \*Influenza zorgpad\* of the UMCU

# **Exclusion criteria**

No specific criteria

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	408
Туре:	Anticipated

### Medical products/devices used

Generic name:	FebriDx
Registration:	Yes - CE intended use

# **Ethics review**

4 - FebriDx: a new laboratory test to discriminate viral from bacterial respiratory ... 13-05-2025

Approved WMO
Date:
Application type:
Review commission:

21-01-2021 First submission METC NedMec

# **Study registrations**

# Followed up by the following (possibly more current) registration

No registrations found.

# Other (possibly less up-to-date) registrations in this register

No registrations found.

# In other registers

Register CCMO **ID** NL75075.041.20