FebriDx® for use in the differentiation of acute viral and bacterial febrile respiratory infections

TECHNOLOGY

FebriDx® is a rapid, point of care lateral flow immunoassay developed by RPS Diagnostics. It is intended to aid the diagnosis of acute febrile respiratory infection.

The test uses a fingerstick blood sample to identify and differentiate a clinically significant immune response to suspected acute viral and/or bacterial respiratory infection. The FebriDx® test detects elevated levels of Myxovirus resistance A (MxA) and C-reactive protein (CRP).

MxA is an intracellular protein that is stimulated by interferon alpha/beta. MxA is elevated in the presence of acute viral infection, although it is not specific to any particular virus. Viral infections elevate MxA levels while only having a modest increase in CRP levels. CRP is another non-specific indicator for the presence of acute inflammation and is elevated particularly in the presence of bacterial infection. Several viruses, such as Influenza A/B and Adenovirus, may cause elevations of CRP above 20mg/L.

FebriDx® uses two lateral flow test strips in the same plastic housing. One test strip contains a control line and two result lines (MxA and low CRP). Here, the cut-off value for MxA is 40ng/mL and for low CRP is 20mg/L. The second test strip contains a control line and a single result line (high CRP). Here, the cut-off value for high CRP is 65mg/L. If the fingerstick blood sample contains elevated levels of MxA, low CRP, or high CRP, above their respective cut-off levels, the appropriate test line will appear in the result window.
The test is carried out at the point of care and takes under two minutes. Two 5 microlitre samples of blood are collected from the patient using a lancet and transferred onto a test strip via a plastic pipette. A buffer solution is then added and results are shown within 15 minutes. FebriDx® produces a multiplexed pattern of results similar to that of a pregnancy test. The test is single use and disposable.

FebriDx® received a CE mark in October 2014 and the company is in the process of introducing the technology to the NHS. The company is also in the process of establishing its European and Canadian distribution channels.

**POTENTIAL FOR IMPACT**

Acute respiratory infection is one of the most common reasons for visits to a GP and is associated with significant morbidity, mortality, and healthcare costs. Only a proportion of patients will have a bacterial infection and might therefore benefit from antibiotics. However, the overlapping signs and symptoms of both viral and bacterial infections are such that they are difficult to differentiate clinically.

The company claim that FebriDx® is the first rapid, point of care test that uses a fingerstick blood sample to identify and differentiate a clinically significant immune response to acute viral and/or bacterial respiratory infections. In isolation, neither MxA nor CRP alone is sensitive or specific enough to differentiate viral from bacterial infection. However, the company claims that by simultaneously examining levels of CRP in combination with the levels of MxA, it is possible to differentiate between viral and bacterial infections.

They state that the test will help identify and triage patients and facilitate targeted therapeutic interventions for improvement or cure.

By providing an accurate result, the company claims that FebriDx® may help guide therapeutic decisions on whether antibiotics are necessary, potentially reducing unnecessary antibiotic prescriptions and potential antibiotic resistance, adverse events and allergic reactions. Another advantage, according to the company, is that only a small amount of blood is required for a result which is quick and minimally invasive for the patients.

If clinical and cost effectiveness can be demonstrated, the FebriDx® test may offer a simple, rapid, point of care test to differentiate viral and bacterial acute respiratory infections.

This technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk):

Domain 1 Preventing people from dying prematurely;

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**

The FebriDx® is a test to help doctors find out if a patient has a respiratory infection from a virus or bacteria. Respiratory infections affect the sinuses, throat or lungs. FebriDx® uses a small blood sample that is collected through a small device called a lancet. It measures the increase of two proteins in the blood to check if a patient’s infection is caused by a bacteria or virus. Results are shown within 15 minutes. The developer says the advantage of the test is that it is quick to do and can be carried out in a doctor’s surgery. It will give doctors better information about a patient’s infection and will help them decide the best treatment option.