ImmunoXpert™ for diagnosing bacterial and viral infections

TECHNOLOGY

The ImmunoXpert™ test is an in vitro diagnostic test developed by MeMed to distinguish between bacterial and viral infections.

The test measures three immune system biomarkers in serum: TNF-related apoptosis-inducing ligand (TRAIL), Interferon gamma-induced protein-10 (IP-10) and C-reactive protein (CRP). A computer algorithm is then used to compute a score indicating the likelihood of a bacterial versus viral (or other non-bacterial) immune response.

The test is performed by a laboratory technician, with a turn-around time of 99 minutes. The ImmunoXpert™ test can be performed on patients aged ≥3 months with a suspected acute infection such as a respiratory tract infection, symptom duration of less than seven days and a temperature of ≥38°C from the time of symptom onset.

The company state ImmunoXpert™ is not intended for use as a stand-alone diagnostic tool and should be used in conjunction with other clinical data. The company add ImmunoXpert™ is not intended to distinguish between infectious and non-infectious aetiologies.

ImmunoXpert™ was CE marked in 2014 and is in clinical use in select pilot sites in Israel and Europe. The company anticipate NHS hospital use under the MeMed ImmunoXpert™ early access program, from July 2016. ImmunoPoc™, a point-of-care, hand-held device version of the test that provides results within 15 minutes, is currently in development.

FebriDx® is another rapid, point of care lateral flow immunoassay developed by RPS diagnostics. It uses a blood sample to identify and differentiate a clinically significant immune response to suspected acute viral and/or bacterial respiratory infection. The company is in the process of introducing the technology to the NHS.
POTENTIAL FOR IMPACT

Bacterial and viral infections may be clinically indistinguishable, leading to inappropriate patient management and antibiotic misuse. Routine microbiological diagnostic tests include culture, serology and nucleic acid-based tests, which help clinicians determine the cause of the infection. However, current options present challenges for pathogen detection in cases where the infection site is not readily accessible (e.g. pneumonia), or is unknown (e.g. fever without source in children) and the patient presents with potential bacterial and viral co-infection.

ImmunoXpert™ does not directly detect the infecting pathogens. Instead it uses a host immune signature that comprises three soluble circulating proteins- TRAIL, IP-10 and CRP- which are involved in different physiological pathways and exhibit distinctive and complementary behaviours in response to infection. By assessing the host’s immune response, the type of infection need not be known or accessible.

The company claim ImmunoXpert™ demonstrated superior accuracy when compared to clinical parameters used in the differential diagnosis of bacterial or viral infections (e.g. white blood cell count, absolute neutrophil count, CRP, erythrocyte sedimentation rate and procalcitonin). According to the company ImmunoXpert™ is capable of detecting co-infection in addition to pure bacterial infections, thereby improving antibiotic treatment decisions.

The company state benefits for patients include informed treatment decisions and timely antibiotic administration, potentially curbing the rise in antibiotic resistance and the associated financial implications. The company add, through confirmation of a bacterial infection, the test offers the potential to improve patient management and satisfaction by avoiding unnecessary hospital admission, tests and procedures such as multiplex PCR and lumbar puncture. The company anticipate early detection of the infection may improve health outcomes and influence hospitalisation (admittance and discharge) decisions. The company also predict cost-savings through a reduction in prescription of unwarranted antibiotics, complications associated with incorrect or delayed diagnosis and unnecessary follow-up tests and procedures such as imaging. As a consequence of these reductions, the company also anticipate expedited triage and workflow and savings in clinician time.

If clinical and cost-effectiveness can be demonstrated, ImmunoXpert™ may offer an additional testing option for patients with infection.

This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk):
Domain 1 Preventing people from dying prematurely;
Domain 3 Helping people to recover from episodes of ill health or following injury

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


Lay summary

*ImmunoXpert™* is a blood test to check if a patient has an infection from a bacteria or a virus. After the patient provides a blood sample, the ImmunoXpert™ test makes measurements that are read by special computer software which tells the doctor if the infection is caused by a bacteria or virus. The developer says this test will help patients receive the right antibiotic treatment and more quickly.