

Respiratory Multiplex Array II

Rapid, simultaneous detection of 21 bacterial and viral pathogens - of the upper and lower respiratory tract



RESPIRATORY MULTIPLEX ARRAY II

Rapid, simultaneous detection of 21 bacterial and viral pathogens within the upper and lower respiratory tracts

INTRODUCTION

Respiratory tract infections (RTI) are caused by many viral and bacterial pathogens and are the second most common cause of morbidity and mortality worldwide.¹ Acute respiratory disease (ARD) accounts for more than 4 million deaths annually and are the leading cause of death in developing countries.²

Viral respiratory infections can occur in epidemics and can spread rapidly within communities across the globe.

Every year, influenza causes respiratory tract infections in 5–15% of the population and severe illness in 3–5 million people.² Upper respiratory tract infections can lead to acute asthma exacerbations, acute otitis media, and lower respiratory tract infection such as bronchitis, brochiolitis and pneumonia.³ Particularly affecting the young, elderly and the immunocompromised, RTIs can result in prolonged hospital stays and represent a significant cost burden to public health systems worldwide.

ANTIBIOTIC RESISTANCE

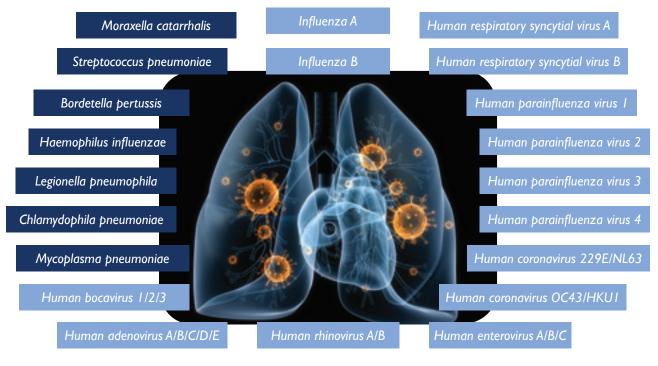
In recent years, some pathogens, such as *Streptococcus pneumoniae* have acquired resistance to antibiotics, rendering them ineffective in treating disease. This can largely be attributed to poor antibiotic stewardship. For example, antibiotics are ineffective against many respiratory tract infections, particularly viral infections, yet in the UK, RTIs account for 60% of antibiotic prescriptions in primary care.⁴ Correct identification and diagnosis of bacterial and/or viral pathogens is therefore critical to inform correct prescribing of antibiotics.

THE RESPIRATORY MULTIPLEX ARRAY

The Respiratory Multiplex Array is the most comprehensive diagnostic test for infections of both the upper and lower respiratory tracts, simultaneously detecting 21 bacterial and viral pathogens in nucleic acid extracted from a single sputum, lavage or nasopharyngeal sample.

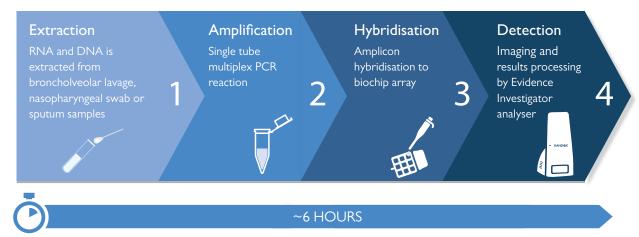
The assay is based on a combination of multiplex PCR and biochip array hybridisation. Innovative PCR priming technology permits high discrimination between multiple targets. A unique primer set is designed for each target which will hybridise to a complementary oligo-nucleotide probe spotted on a biochip discrete test region (DTR). This combination of PCR priming and spatially organised biochip array technology enables enhanced specificity of the assay. Analysis can be completed from template nucleic acid through PCR to data readout in ~6 hours. The array is CE marked for routine clinical use.

Respiratory Multiplex Array detects 21 bacterial and viral pathogens



Bacterial Viral

RESPIRATORY MULTIPLEX ARRAY PROTOCOL



BENEFITS OF THE RANDOX RESPIRATORY MULTIPLEX ARRAY II



PRODUCT FEATURES

- Rapid turnaround time of ~6 hours from extracted genomic nucleic acid to result
- Compatible with various sample matrices including sputum, lavage and nasopharyngeal samples



BENEFITS TO THE LABORATORY

- Simultaneously identifying the most prevalent pathogens, both viral and bacterial, will provide a rapid and more cost-effective diagnostic tool than current tests, which detect single pathogens
- One step RT-PCR
- Inclusion of anti-contaminant enzyme as additional control measure
- Optimised wash steps to minimise hands-on-time



BENEFITS TO THE PATIENT

- A more complete infection profile allows identification of the infective agent and detection of co-infections
- Inform correct therapeutic treatment, including the appropriate use of antibiotics, and/or physician advice to patients for optimal patient care
- Precise, rapid diagnosis allows for early therapeutic intervention
- Potentially avoids exacerbations or the need for hospitalisation
- Reduced sample requirement to perform the diagnostic test will be of particular benefit to infants, children and the elderly

CLINICAL DATA

Mass gatherings, such as the Hajj increase the likelihood of the spread of infectious diseases. The Kingdom of Saudi Arabia annually hosts over 2 million Muslim pilgrims from around 184 countries during the Hajj pilgrimage, making it one of the largest and most culturally and geographically diverse mass gatherings in the world. Respiratory tract infections (RTIs) are the most common infection transmitted between pilgrims during Hajj, and most pilgrims develop RTIs during their few weeks stay in Makkah and Madinah. The Randox Respiratory Multiplex Array was used to screen for the presence of bacterial and viral upper and lower respiratory tract infections during the 2013 Hajj:

PAPER I

Memish, Ziad. A. et al. Etiology of severe community-acquired pneumonia during the 2013 Hajj – part of the MERS-CoV surveillance program. International Journal of Infectious Diseases 25 (2014) 186-190

This study examined the presence of co-infections in patients admitted to healthcare facilities in Makkah and Madinah, Saudi Arabia, with a primary diagnosis of severe community-acquired pneumonia (CAP) during the 2013 Hajj, using the Randox Respiratory Multiplex Array. The study highlighted the frequency of co-infections in respiratory infections and the importance of using multiplex technology to detect both bacterial and viral pathogens.

- 68.4% of patients were confirmed to have co-infections
- 65.3% of co-infected patients were positive for both bacteria and viruses

Study results revealed the wide range of infections present in the patient cohort.

- The most common respiratory virus was human rhinovirus, detected in 57.7% of the positive samples, followed by influenza A virus (23.1%), and human coronaviruses (19.2%)
- The predominant bacteria detected in positive co-infected samples were Haemophilus influenza (57.7%), followed by Streptococcus pneumoniae (53.8%) and Moraxella catarrhalis (36.4%)

PAPER 2

Memish, Ziad. A. et al. Environmental sampling for respiratory pathogens in Jeddah airport during the 2013 Hajj season. American Journal of Infection Control 42 (2014) 1266-9.

This study sampled the environment in the King Abdul Aziz International (KAAI) Airport, Jeddah, during Hajj season to detect respiratory pathogens, using the Randox Respiratory Multiplex Array.

- 58 environmental samples (18 air samples and 40 surface samples) were tested for the presence of infectious pathogens, of which 8 samples were positive for at least one of the pathogens detectable by the assay.
- Air samples were negative with the exception of one (5.5%), which tested positive for influenza B virus.
- Of the 40 surface samples, 7 (17.5%) were positive for pathogens
- The most common surface contaminants of surfaces were adenovirus (3 of 7, 42.8%) and coronavirus OC43/HKU1 (3 of 7, 42.8%)
- Potentially pathogenic bacteria (e.g., *H. influenza, M. catarrhalis*) were also present on environmental surfaces

Evidence Investigator

Rapid, accurate and comprehensive molecular testing

The Evidence Investigator is a compact, semi-automated bench top platform consolidating molecular diagnostics and immunoassay on a single platform with protein and DNA biochips.

Utilising revolutionary Biochip Array Technology (BAT), the Evidence Investigator allows simultaneous detection of multiple analytes from a single sample for efficient and cost-effective testing.

The Evidence Investigator molecular package includes the following:

- I x Evidence Investigator analyser platform
- PC biochip software
- Barcode scanner
- 2 x Thermoshaker units are required to regulate biochip hybridization (60°C) and conjugation (37°C) temperatures.
- Dedicated thermal cycler.
- Biochip carrier handling tray



Biochip imaging module



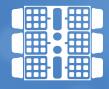
PC & imaging software



Barcode scanner







Thermoshaker

Thermal cycler

Biochip carrier handling tray

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Respiratory Multiplex Array

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ORDERING DETAILS

Description	Size	Cat. No.
Respiratory Multiplex Array II	108 Biochips	EV3947A & EV3947B
Evidence Investigator Analyser		EV3602





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