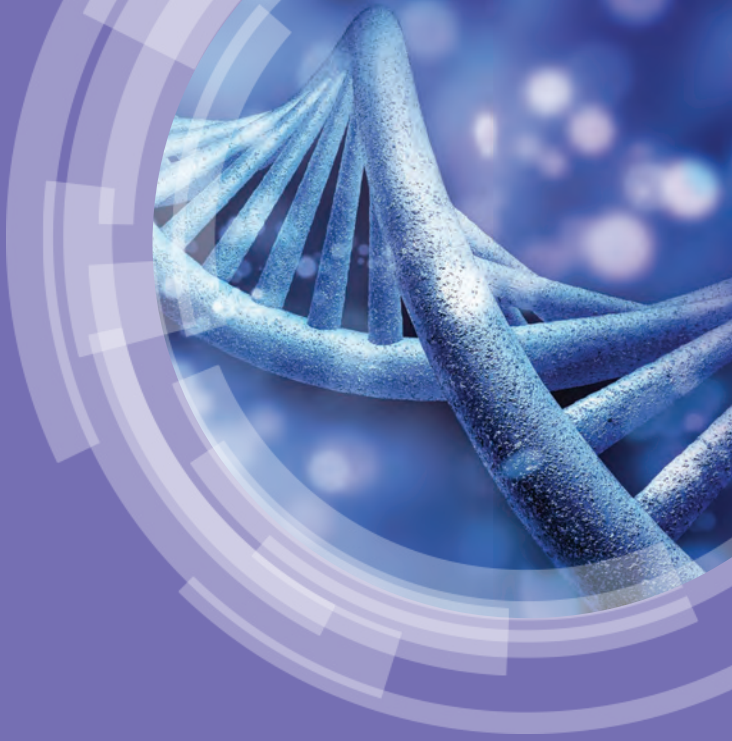
Multiplex Molecular Arrays



Precise diagnostics for targeted therapy

Randox Biosciences molecular arrays offer diagnostic, prognostic and predictive solutions across a variety of disease areas including sexually transmitted infection, respiratory tract infection, colorectal cancer, familial hypercholesterolemia (FH) and cardiovascular disease (CVD).

A wide range of assay formats are offered including SNP genotyping, pathogen detection, mutation detection and gene expression. These assays are optimised for use with the Randox Evidence Investigator semi-automated bench top biochip analyser, offering consolidation, speed and ease-of-use.

Pathogen Detection - *STI Multiplex Array and Respiratory Multiplex Array*

Pathogen detection, through nucleic acid (DNA/RNA) analysis offers rapid, sensitive, multiplex detection of viral, bacterial and protozoan pathogens. Following nucleic acid extraction from a broad range of sample types (sputum, urine, swabs etc.), target DNA/cDNA is amplified in a single reaction and subsequently hybridised to a biochip array containing multiple pathogen-specific probes. This rapid, highly sensitive and specific process enables identification of primary and co-infections simultaneously, often in asymptomatic patients and has the capacity for use with many pathogen panels.

Mutation Detection - *KRAS BRAF PIK3CA* Array and Familial Hypercholesterolemia (FH) Arrays I & II*

The assay is based on a combination of multiplex PCR and biochip array hybridisation. Innovative PCR priming technology permits high discrimination between multiple targets in a number of genes. 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 priming and spatially organised biochip array technology enables enhanced specificity of the assay.

SNP Genotyping - *Cardiovascular Risk Prediction Array*

Rapid multiplex SNP genotyping is based on innovative primer design that can discriminate DNA sequences differing only by one base. Products amplified will correspond to target portions of DNA from tissue, buccal swabs or blood. Amplified regions are then hybridised to a biochip array with spatially tethered probes complementary to target amplicons. Each position on the biochip array corresponds to a specific SNP genotype and is capable of both multiplexing and determining the zygosity of the sample.

*PIK3CA Array for research use only

Multiplex Molecular Arrays

Assay protocol & test menu

- Ready-to-use, nine biochip carrier
- Randox Biochips can support multiple assays per biochip
- Minimum batch of three biochips (one strip) which includes patient sample, positive and negative controls

Molecular testing with the Evidence Investigator is undertaken following the protocol outlined below:

Extraction

Nucleic acid is extracted from patient sample

1

Amplification

Single tube multiplex PCR reaction

2

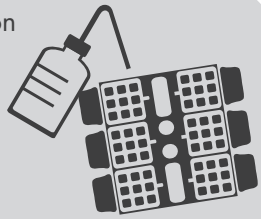
Hybridisation / conjugation

Batches of 3 to 54 biochips are placed in the thermoshaker

3

Wash step and addition of signal reagent

After washing, signal reagent is added to each biochip before imaging



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Biochip carrier loaded into Evidence Investigator

A Charged Coupled Device (CCD) camera inside the Evidence Investigator takes 2 minutes to image each biochip carrier

5

Chemiluminescence

The chemiluminescent light signal generated from each discrete test region (DTR) is simultaneously detected

6

Result reporting

Image processing software translates the light signal generated from the chemiluminescent reaction into relative light units (RLUs) and Randox QC-assigned cut-offs allow simple reporting of positive or negative results with no data interpretation or manual processing required

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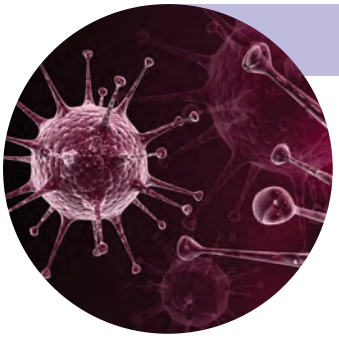


STI Multiplex Array

The Sexually Transmitted Infection (STI) Multiplex Array simultaneously detects 10 bacterial, viral and protozoan infections including primary, secondary and asymptomatic co-infections for a complete infection profile.

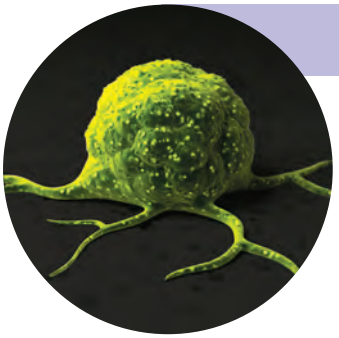
Neisseria gonorrhoea (NG)
Chlamydia trachomatis (CT)
Trichomonas vaginalis (TV)
Treponema pallidum (TP)
Herpes simplex Virus 1 (HSV-1)
Herpes simplex Virus 2 (HSV-2)
Mycoplasma genitalium (MG)
Ureaplasma urealyticum (UU)
Haemophilus ducreyi (HD)
Mycoplasma hominis (MH)

Respiratory Pathogens Array

The Respiratory Pathogens Array is the most comprehensive screening test for infections of both the upper and lower respiratory tracts, simultaneously detecting 22 viral and bacterial pathogens from a single sputum, lavage or nasopharyngeal sample.

Viral:
Human Respiratory Syncytial Virus A
Human Respiratory Syncytial Virus b
Human Parainfluenza Virus 1/2/3/4
Human Coronavirus 229E/NL63
Human Coronavirus OC43/HKU1
Human Metapneumovirus
Human Rhinovirus A/B
Human Enterovirus A/B/C
Human Adenovirus A/B/C/D/E
Human Bocavirus 1/2/3
Influenza A/B

Bacterial:
Chlamydophila pneumoniae
Mycoplasma pneumoniae
Legionella Pneumophila
Moraxella Catarrhalis
Streptococcus Pneumoniae
Staphylococcus Aureus
Haemophilus Influenza

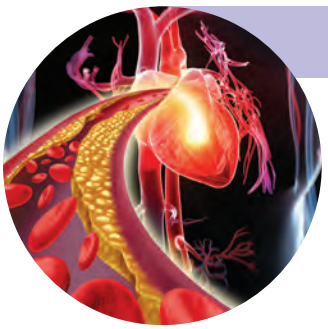


KRAS, BRAF PIK3CA* Array

The KRAS, BRAF PIK3CA Array simultaneously detects 20 point mutations within the KRAS, BRAF and PIK3CA genes. Whilst designed for colorectal cancer, the array has implications for mutation screening in other cancer types.

KRAS (codon 12, 13, 61, 146)
BRAF (codon 600)
PIK3CA* (codon 542, 545, 1047)

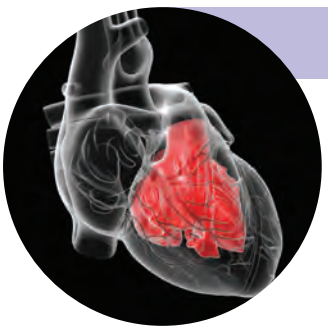
*PIK3CA Array for research use only



Familial Hypercholesterolemia (FH) Arrays I & II

The Familial Hypercholesterolemia (FH) Arrays I & II are rapid, simple and accurate diagnostic tests which enable simultaneous detection of 40 FH-causing mutations (20 mutations per array) within the LDLR, ApoB and PCSK9 genes.

LDLR - 38 mutations
APOB - 1 mutation
PCSK9 - 1 mutation



Cardiac Risk Prediction Array

The Cardiac Risk Prediction Array provides simultaneous genotyping of 20 SNPs identified from a GWAS study, for enhanced CHD risk assessment which incorporates a test to identify patients predisposed to statin-induced myopathy.