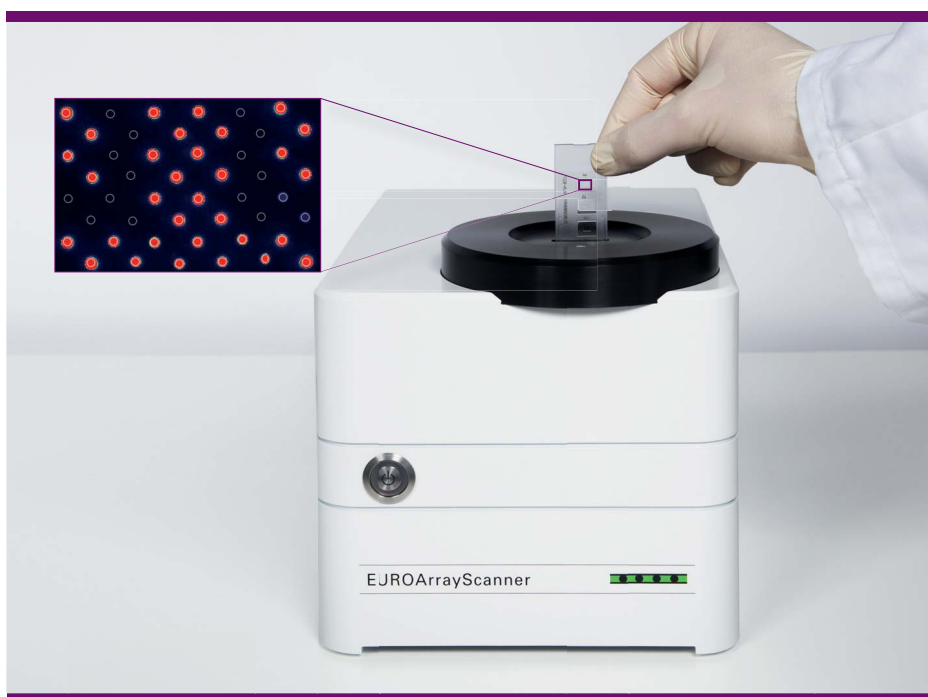




EUROArray

DNA microarray test systems for infection and genetic diagnostics (IVD)



- **Reliable multiplex test systems for the simultaneous detection of different infectious agents or disease-associated genetic features**
- **Simple test performance with ready-to-use reagents**
- **High result security due to various integrated controls**
- **EUROArray Direct: direct use of EDTA blood in genetic diagnostic tests – no separate DNA isolation required**
- **Fully automated standardised evaluation and result documentation**
- **LIMS connection available**

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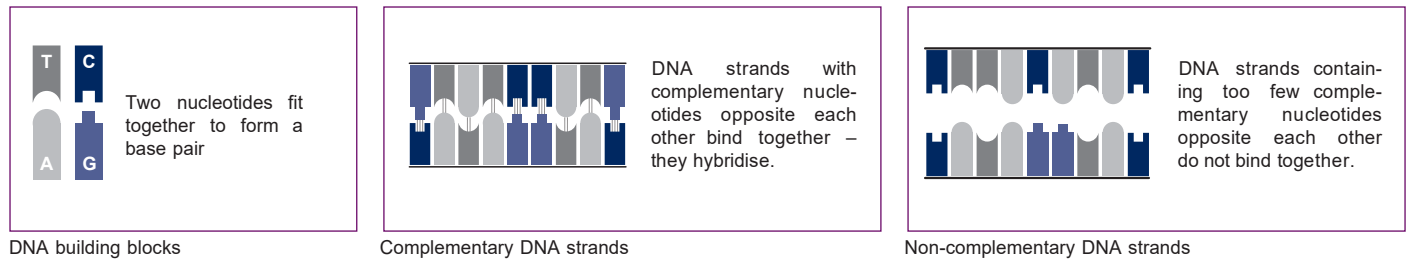
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EUROArray – EUROIMMUN’s unique microarray technology

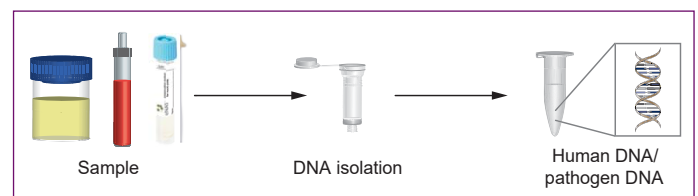
What is a microarray and how does it work?

The EUROArray technology is based on the amplification of defined gene sequences by multiplex polymerase chain reaction (PCR) and the subsequent detection of the resulting PCR products by means of a hybridisation reaction with DNA probes which are immobilised on a microarray in the form of microscopically small spots. The specificity of the reactions is achieved by the accurate binding of primers and probes to the complementary sequences of the target DNA. Tests for infection diagnostics detect specific gene sequences, based on which the respective pathogens can be directly identified and differentiated from all other organisms. In genetic diagnostic tests, particular disease-associated alleles, single-nucleotide polymorphisms or mutations in the human genome are detected. The EUROArray test systems show a very high sensitivity and specificity.



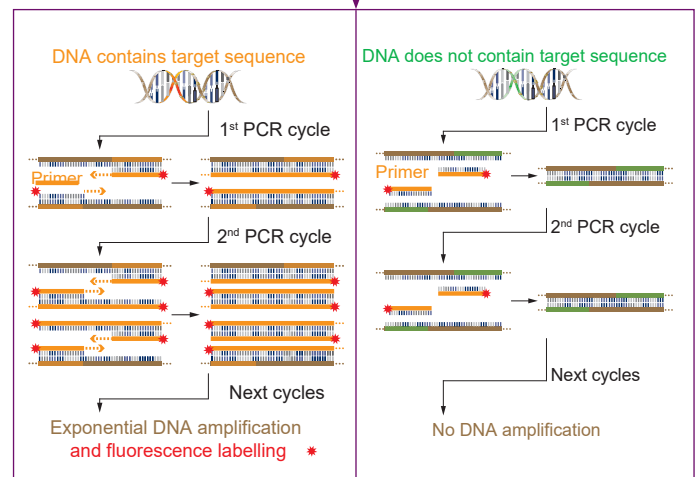
Sample preparation: DNA isolation

In order to investigate with a EUROArray whether a patient sample contains disease-associated gene sequences or pathogens, the DNA must first be isolated.



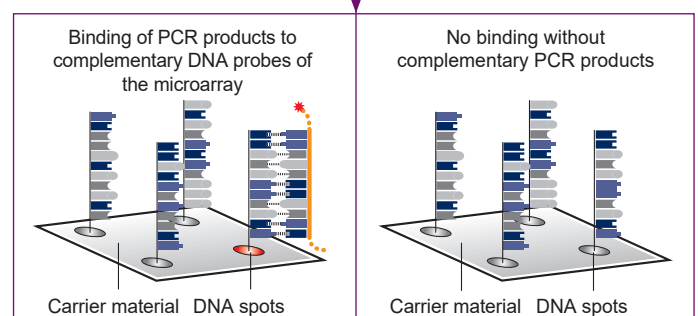
Amplification of sample DNA: polymerase chain reaction (PCR)

The sections of DNA to be investigated are amplified million-fold using the **polymerase chain reaction (PCR)**. Two starter DNA molecules (primers) define the region to be copied. If the patient DNA contains the corresponding section (target sequence), the primers bind and the target sequence is copied. This reaction is repeated many times, so that the DNA region between the primers is greatly (exponentially) amplified. The resulting PCR products are labelled with a fluorescent dye, which enables them to be detected subsequently by the microarray. If the target sequence is not present in the patient sample, the primers cannot bind and the DNA is not amplified.



Analysis of PCR products on the microarray: DNA microarray hybridisation

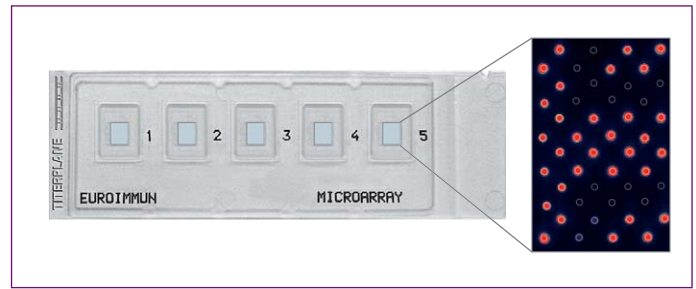
The PCR products are incubated with the microarray. They are first mixed with a hybridisation buffer, which provides optimal conditions for binding of the PCR products to the complementary probes on the microarray. This binding is measured via the fluorescence signals emitted by the spots.



Microarrays from EUROIMMUN for simple and reliable diagnostics

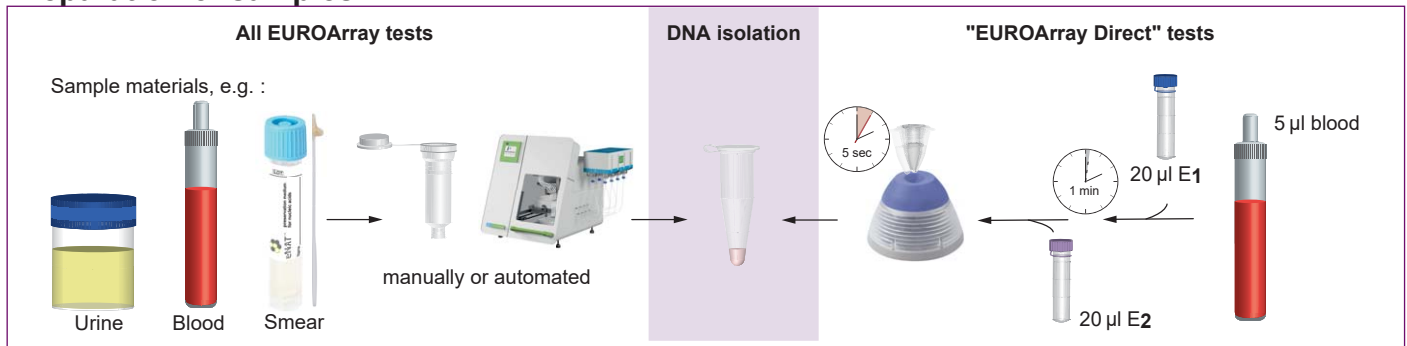
EUROArrays in IVD quality

EUROIMMUN microarrays are based on **BIOCHIP Technology** with specific DNA probes. Each BIOCHIP consists of up to 72 DNA spots and allows duplicate determinations of up to 36 different DNA sequences, including controls. One EUROArray slide consists of five test fields for parallel investigation of up to five samples. Each field can contain several BIOCHIPS in order to increase the number of detectable DNA sequences.



EUROArray slide and enlargement of a BIOCHIP

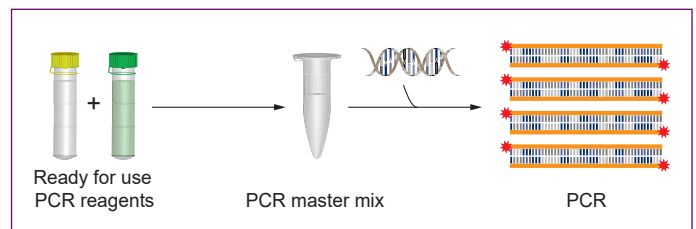
Preparation of samples:



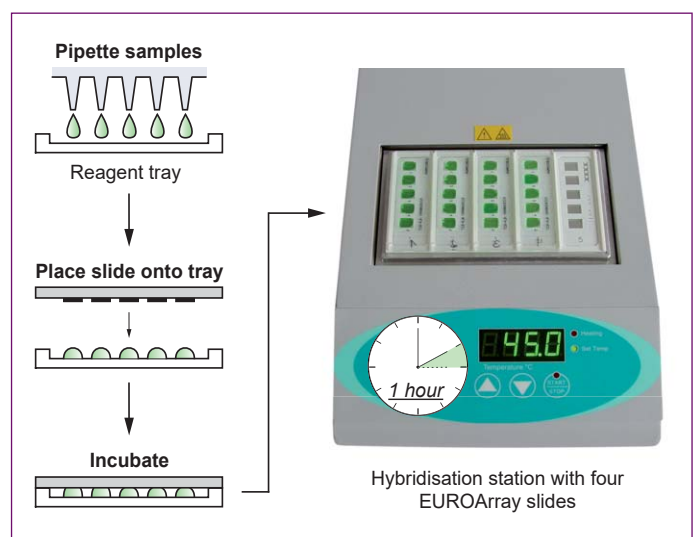
For some parameters, EUROIMMUN offers the Direct procedure which does not require prior DNA isolation. The blood is incubated with the extraction solutions included in the kit and can then be directly used in the PCR (see figure). With all other parameters, the DNA is isolated in the conventional way.

Simple, uncomplicated and effortless

All PCR reagents supplied in EUROArray kits are **ready for use**, including the DNA polymerase and the validated specific primers. The PCR works reliably with minimal effort: the pre-prepared PCR reagents are simply combined, and the DNA is then added to this master mix.

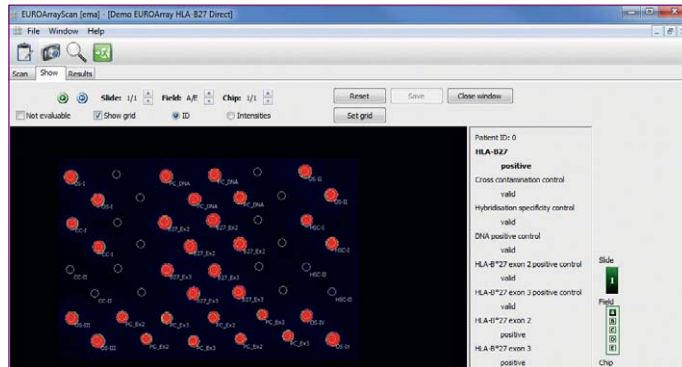


The DNA microarray hybridisation is performed under exact, standardised conditions using the proven **TITERPLANE Technique**. This procedure is simple and reliable. The samples (PCR products + hybridisation buffer) are pipetted onto the reaction fields of a reagent tray. The slides are then placed into the recesses of the reagent tray, whereby all BIOCHIPS come into contact with the liquids simultaneously. Thanks to the hydrophobic surroundings, the fluid drops remain stable on the hydrophilic reaction fields during the incubation and do not run into one another. After a one-hour incubation period in the **hybridisation station**, the EUROArray slides are washed with special buffer solutions. The **washing procedure is fast and uncomplicated**: 10 slides are processed in just 5 minutes and can then be evaluated.




Fully automated standardised evaluation delivers fast and reliable results

With the **EUROArrayScanner** and **EUROArrayScan software**, EUROArrays are evaluated easily, quickly and objectively. EUROArrayScan software can be integrated into EUROLabOffice and other laboratory information management systems (LIMS) without any difficulties. At the start of each run, the data for the samples to be examined are entered and are then transferred automatically into the working list by the software. After scanning the slides, the EUROArrayScan software fully automatically evaluates all data, produces a report and documents and archives all results. Results for a EUROArray slide (up to five samples) are obtained in less than 20 seconds!



Evaluation using EUROArrayScan (e.g. HLA-B27 Direct)

Patient ID :	0	Test :	HLA-B27 direct																	
Result from :	17.03.2015	Protocol :	Demo EUROArray HLA-B27 Direct																	
Print date :	21.09.2015 10:31:34	Patient name :	0																	
		Page :	1																	
EUROIMMUN		Medizinische Labordiagnostika AG		Automatic evaluation with the EUROArrayScan software																
<table><tr><th>Partial result</th><th>Result</th></tr><tr><td>Cross contamination control</td><td>valid</td></tr><tr><td>Hybridisation specificity control</td><td>valid</td></tr><tr><td>DNA positive control</td><td>valid</td></tr><tr><td>HLA-B*27 exon 2 positive control</td><td>valid</td></tr><tr><td>HLA-B*27 exon 3 positive control</td><td>valid</td></tr><tr><td>HLA-B*27 exon 2</td><td>positive</td></tr><tr><td>HLA-B*27 exon 3</td><td>positive</td></tr></table>		Partial result	Result	Cross contamination control	valid	Hybridisation specificity control	valid	DNA positive control	valid	HLA-B*27 exon 2 positive control	valid	HLA-B*27 exon 3 positive control	valid	HLA-B*27 exon 2	positive	HLA-B*27 exon 3	positive			
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Scanning a EUROArray slide (e.g. HLA-B27 Direct)

Reliability of analysis is ensured by many

Control	Used to check whether ...
DNA positive control	... the DNA was intact and present in sufficient quantity
PCR positive control	... PCR was successful (functioning of primers and/or PCR conditions)
Cross-contamination control	... there was any cross contamination from one test field to the other
Hybridisation specificity control	... the PCR products have bound specifically to the DNA probes
Mutation control	... non-disease-associated neighbouring mutations are present that might interfere with the analysis
Negative control (automatically included)	... the analysis was performed correctly and there are no false positives

Test systems for molecular genetic diagnostics

EUROArray test systems	Indication	Order no.	Features
APOE Direct	Alzheimer's disease	MN 5710-####-V	Detection of the APOE gene variants ε2, ε3 and ε4
FV/FII+/MTHFR Direct	Thrombosis, thrombophilia	MN 5820-####-V	Detection of or single-nucleotide poly-morphisms in the factor V gene (factor V Leiden, 1691G>A), in the factor II (prothrombin) gene (20210G>A) and/or in the MTHFR gene (677C>T and 1298A>C)
Haemochromatosis (4 SNP+) Direct Haemochromatosis (2 SNP+) Direct	Haemochromatosis	MN 5520-####-V MN 5521-####-V	Detection of H63D, C282Y, S65C and E168X Detection of H63D and C282Y
HLA-B27 Direct	Ankylosing spondylitis	MN 5110-####-V	Improved specificity: differentiation of non-disease-associated HLA-B*27 alleles
HLA-B57:01 Direct	Abacavir hypersensitivity	MN 5210-####-V	Detection of all worldwide known HLA-B*57:01 alleles
HLA-Cw6 Direct	Psoriasis	MN 5410-####	Detection of all worldwide relevant HLA-C*06 alleles
HLA-DQ2/DQ8-h Direct HLA-DQ2/DQ8 Direct	Coeliac disease	MN 5310-#### MN 5321-####-V	Detection of all alleles relevant for HLA-DQ2/DQ8
Lactose/Fructose Intolerance Direct	Lactose/fructose intolerance	MN 5350-####-V	Detection of polymorphisms -13910T > C and -22018A > G associated with primary lactose intolerance, and of mutations A149P, A174D, N334K and del4E4 associated with hereditary fructose intolerance
Dermatophytosis	Dermatophytoses	MN 2850-####	Direct detection of 50 dermatophytes as well as clear identification of 23 dermatophytes and 6 yeasts/moulds in one test
HPV	HPV detection / typing for cancer prevention	MN 2540-####	Detection and differentiation of 30 anogenitally occurring papilloma viruses for cancer prevention (cervical cancer); comprises all high- and low-risk HPV subtypes
STI	Sexually transmitted infections	MN 2830-####	Detection of up to 11 relevant sexually transmitted pathogens (bacteria, viruses, protozoa)
NEW: HSV1/2 VZV	Herpes infections	MN 2530-####-1	Detection and differentiation of HSV-1, HSV-2 and VZV

Test systems for research use*

EUROArray test systems	Order no.	Features
HLA-DRB1 Shared Epitope	MN 5150-####	Detection of all known shared-epitope alleles

Instruments and accessories

Equipment	Order no.	Features
EUROArrayScanner	YG 0602-0101	EUROArrayScanner including EUROArrayScan software
Hybridisation station (with one incubator insert) Hybridisation station (with two incubator	YG 0615-0101 YG 0615-0101-1	For EUROArray hybridisation
TITERPLANE reagent tray	ZM 9999-0105	Suited for parallel incubation of up to five EUROArray slides

* not for in vitro diagnostics in the sense of EU Directive 98/79/EC

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