

# MIKROGEN

D I A G N O S T I K



+++ neu +++ new +++ n

MIKROGEN HIGHLIGHTS

## MIKROGEN Product Overview

Bacterial infections	Strip assay	ELISA	Luminex®	PCR
Anaplasma / Ehrlichia	✓	✓	✓	✓
Babesia	✓	✓	✓	✓
Bordetella	✓	✓	✓	✓
Borrelia + Neuroborreliosis	✓	✓	✓	✓
Brucella	✓	✓	✓	✓
Campylobacter	✓	✓	✓	✓
Chlamydia	✓	✓	✓	✓
Coxiella burnetii (Phase 1, 2)	✓	✓	✓	✓
CXCL13	✓	✓	✓	✓
Diphtheria (Corynebact. diphtheriae)	✓	✓	✓	✓
ETEC	✓	✓	✓	✓
Haemophilus influenzae	✓	✓	✓	✓
Helicobacter pylori	✓	✓	✓	✓
Klebsiella pneumoniae/oxytoca	✓	✓	✓	✓
Legionella	✓	✓	✓	✓
Leptospira	✓	✓	✓	✓
Moraxella catarrhalis	✓	✓	✓	✓
MRSA	✓	✓	✓	✓
Mycobacterium tuberculosis complex	✓	✓	✓	✓
Mycoplasma genitalium	✓	✓	✓	✓
Mycoplasma hominis	✓	✓	✓	✓
Mycoplasma pneumoniae	✓	✓	✓	✓
Neisseria gonorrhoeae	✓	✓	✓	✓
Salmonella	✓	✓	✓	✓
Shigella/EIEC	✓	✓	✓	✓
Staphylococcus aureus	✓	✓	✓	✓
Streptococcus Group B	✓	✓	✓	✓
Streptococcus pneumoniae	✓	✓	✓	✓
Tetanus (Tetanus toxoid)	✓	✓	✓	✓
Treponema pallidum	✓	✓	✓	✓
Ureaplasma	✓	✓	✓	✓
VTEC (STX1+2)	✓	✓	✓	✓
Yersinia	✓	✓	✓	✓

Viral infections	Strip assay	ELISA	Luminex®	PCR
Adenovirus	✓	✓	✓	✓
Astrovirus	✓	✓	✓	✓
Bocavirus	✓	✓	✓	✓
Chikungunya Virus	✓	✓	✓	✓
Coronavirus	✓	✓	✓	✓
Cytomegalo Virus (CMV) (Avidity)	✓	✓	✓	✓
Dengue Virus	✓	✓	✓	✓
Enterovirus	✓	✓	✓	✓
Epstein-Barr Virus (EBV) (Avidity)	✓	✓	✓	✓
Hantavirus	✓	✓	✓	✓
Hepatitis C Virus (HCV)	✓	✓	✓	✓
Hepatitis E Virus (HEV)	✓	✓	✓	✓
Herpes simplex Virus (HSV-1, -2, -1/2)	✓	✓	✓	✓
Human Immunodeficiency Virus (HIV-1, -2)	✓	✓	✓	✓
Human Papillomavirus (HPV)	✓	✓	✓	✓
Influenza Virus A, B, A H1N1	✓	✓	✓	✓
Measles Virus (Avidity)	✓	✓	✓	✓
Metapneumovirus	✓	✓	✓	✓
Mumps Virus	✓	✓	✓	✓
Norovirus	✓	✓	✓	✓
Parainfluenza Virus	✓	✓	✓	✓
Parechovirus	✓	✓	✓	✓
Parvovirus B19 (Avidity)	✓	✓	✓	✓
Respiratory Syncytialvirus (RSV)	✓	✓	✓	✓
Rotavirus	✓	✓	✓	✓
Rubella Virus (Avidity)	✓	✓	✓	✓
Sandfly fever Virus	✓	✓	✓	✓
Sapovirus	✓	✓	✓	✓
TBE Virus	✓	✓	✓	✓
Varizella Zoster Virus (VZV)	✓	✓	✓	✓
Yellow Fever Virus	✓	✓	✓	✓
Zika Virus	✓	✓	✓	✓

Autoimmune diseases	Strip assay	ELISA	Luminex®*	PCR
ANA Screen	✓			
CENP (Centromer proteins)	✓			
dsDNA (Doublestranded DNA)	✓			
Histon	✓			
Jo-1 (Aminoacyl-tRNA Synthetase)	✓			
La (SS-B)	✓			
PCNA	✓			
Rib-P (Ribosomal P)	✓			
RNP 68	✓			
RNPA	✓			
RNPC	✓			
Ro52 (SS-A) / TRIM21	✓			
Ro60 (SS-A)	✓			
Scl-70 (Topoisomerase I)	✓			
SmB	✓			
SmD	✓			

### Fungal infections

Aspergillus		✓		
Candida		✓		

### Multi parameter

HFRS / HPS**	✓			
TORCH Complex	✓			
Tropical Fever	✓			✓

\*\* HFRS = Hemorrhagic Fever Renal Syndrome, HPS = Hantavirus Pulmonary Syndrome

### Parasitic infections

Parasitic infections	Strip assay	ELISA	Luminex®*	PCR
Ascaris lumbricoides		✓		
Echinococcus		✓		
Entamoeba histolytica		✓		
Filariasis		✓		
Leishmania		✓		
Malaria		✓		
Plasmodium		✓		
Shistosoma mansoni		✓		
Strongyloides		✓		
Taenia solium		✓		
Toxocara canis		✓		
Toxoplasma gondii (Avidity)	✓	✓		
Trichinella spiralis		✓		
Trichomonas vaginalis				✓
Trypanosoma cruzi (Chagas)	✓	✓		

### Automation

Equipment solutions	✓	✓	✓	
Software solutions	✓	✓	✓	

### Molecular Diagnostics

DNA & RNA Extraction				✓
PCR Positive Controls				✓

\* Luminex® available only in the EU

Additional information:  
follow the QR-code to  
our homepage:  
[www.mikrogen.de](http://www.mikrogen.de)



## CarL

Complete automation of *recomLine* strip assays from sample preparation to result



### Key features

- ▶ **Walk-Away:** Full automation from sample to scanning
- ▶ **Safe:** Barcode identification and LIS connectivity
- ▶ **Convenient:** Integrated drying, 44 strips in one run
- ▶ **Flexible:** Combination of all assays with the same sample incubation time
- ▶ **Space saving:** Integrated camera for scanning
- ▶ **Minimised dead volume:** To save precious reagents
- ▶ **No cross-contamination:** Disposable tips for sample preparation
- ▶ **Minimal maintenance:** No daily start up routine and pump calibration by user required
- ▶ **Liquid level detection:** Pressure sensing technology for samples and reagents
- ▶ **User-friendly:** Guided operation via touch screen
- ▶ **Multi CarL Option:** Operate three CarL systems via one PC

## MIKROGEN offers a broad Lineassay Product Range

***recomLine* ANA/ENA**

***recomLine* Bordetella pertussis**

***recomLine* Borrelia**

***recomLine* Campylobacter**

***recomLine* Chlamydia**

***recomLine* CMV\***

***recomLine* EBV\***

***recomLine* HantaPlus**

***recomLine* HCV**

***recomLine* Helicobacter 2.0**

***recomLine* HEV**

***recomLine* HIV-1 & HIV-2**

***recomLine* HSV-1 & HSV-2**

***recomLine* Parvovirus B19\***

***recomLine* TORCH**

***recomLine* Toxoplasma\***

***recomLine* Treponema**

***recomLine* Tropical Fever**

***recomLine* Yersinia 2.0**

\*Avidity determination possible

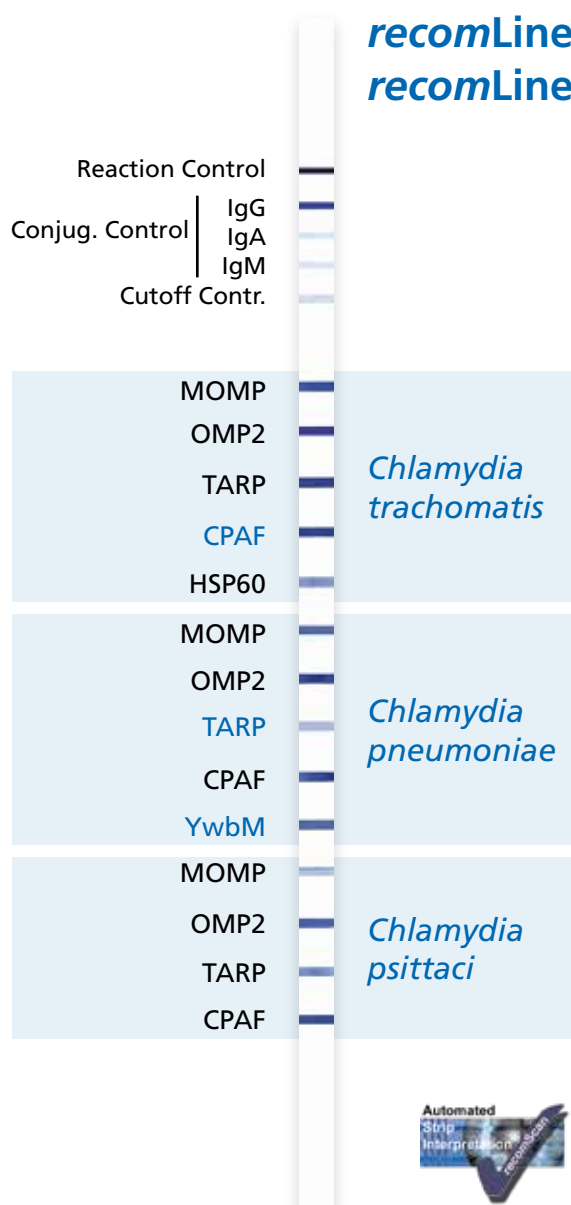


## Advantages

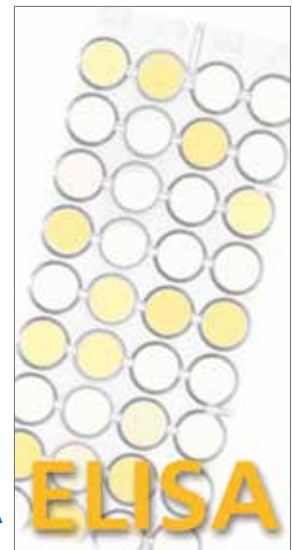
- ▶ Our Recombinant antigens offer
  - ▶ **High sensitivity and specificity**
  - ▶ **Easy and clear interpretation**
- ▶ Easy test procedure – automation possible
- ▶ Easy and objective evaluation and documentation by *recomScan* software
- ▶ Test reagents exchangeable in MIKROGEN strip tests
- ▶ Separate detection of the different antibodies
- ▶ Safe evaluation due to strip specific controls (cut-off, conjugate and incubation control)
- ▶ Mikrogen patent for avidity testing on Line Immunoassays
- ▶ Phase specific antigens indicating time of infection
- ▶ **CE label:** Our *recomLine* tests meet the high standard of the EC directive 98/79/EC on *in vitro* diagnostic medical devices

# Chlamydia

Identify Infectious Infertility and  
Reduce Invasive Imaging



- ▶ Reduced CT and CP cross-reactivities
- ▶ One-step-clarification of inconclusive Chlamydia screening results
- ▶ Diagnosis of fallopian tube infertility. Globally most frequently caused (~30%) by *Chlamydia trachomatis*



*recomWell Chlamydia trachomatis IgG, IgA*

**NEW** *recomWell Chlamydia pneumoniae IgG, IgM, IgA*

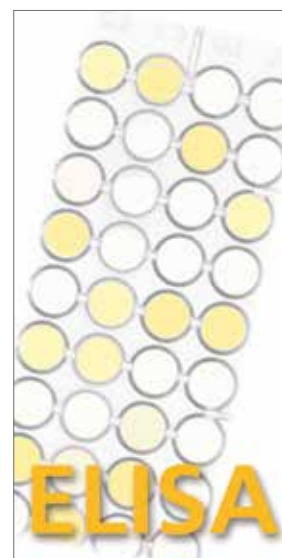
NEW

## Chlamydia pneumoniae

Enzyme immunoassay based on *Chlamydia pneumoniae* specific antigens (COMC)

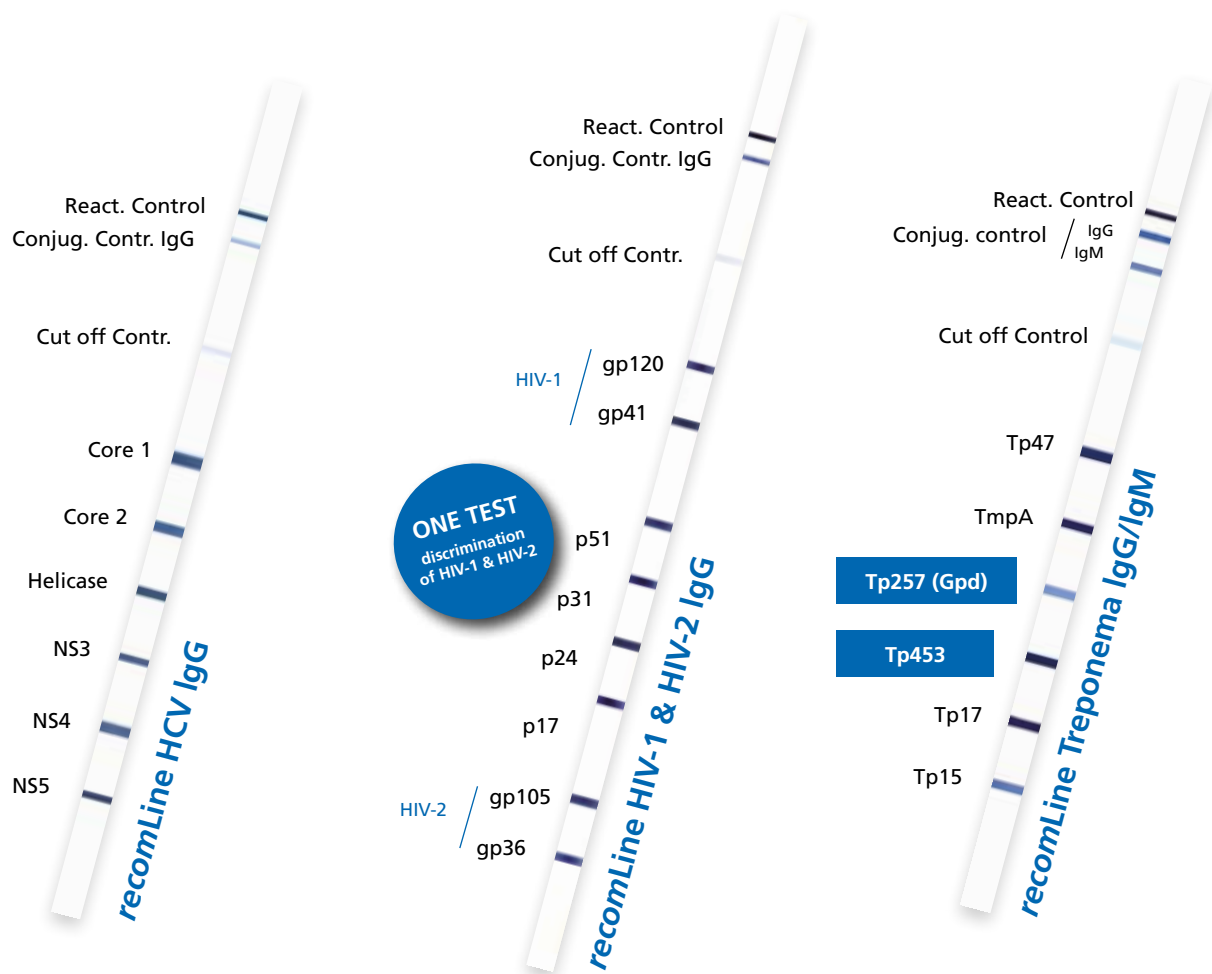
**recomWell Chlamydia pneumoniae IgG**  
**recomWell Chlamydia pneumoniae IgM**  
**recomWell Chlamydia pneumoniae IgA**

- ▶ Characterization of immune status by separate detection of IgG, IgM and IgA antibodies against *Chlamydia pneumoniae* respectively
- ▶ Serodiagnostical supplementary support of clinical and radiological examination
- ▶ Parallel proceeding of all Mikrogen *recomWell* tests possible, e.g. *recomWell Chlamydia trachomatis*, identical incubation times and washing steps
- ▶ High sensitivity – guaranteed by use of high immunogenic Chlamydia specific membrane complex COMC
- ▶ Excellent specificity – characterized by
  - ▶ minimal cross reactivity with *Chlamydia trachomatis* infections in IgA and IgM detection
  - ▶ no cross reactivity with Mycoplasma IgM positive sera in IgA and IgM detection



# HCV | HIV | Treponema

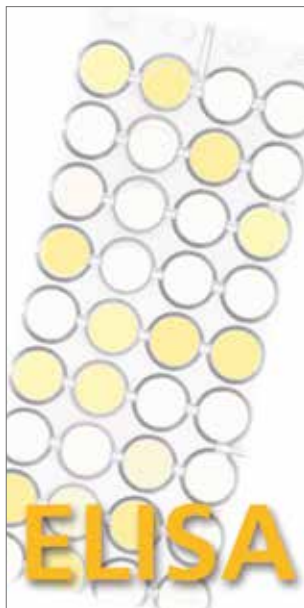
## Differentiation in one step



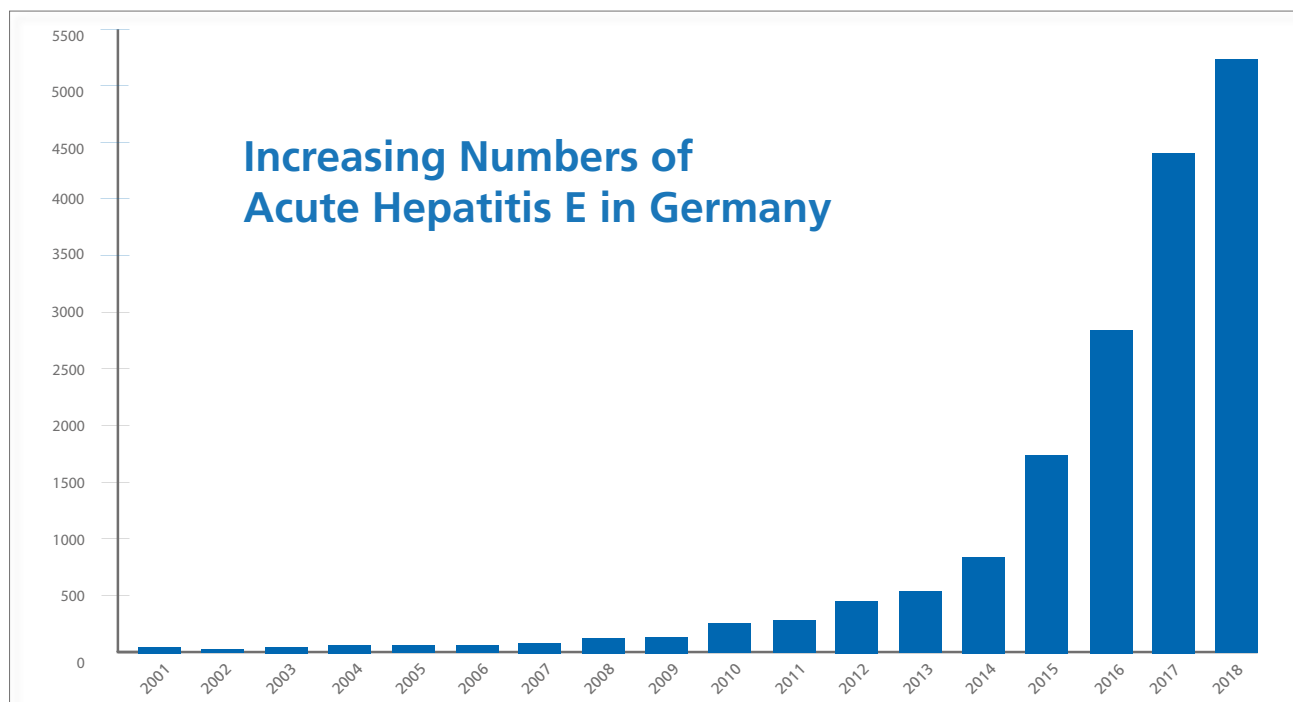
- ▶ Excellent sensitivity and specificity
- ▶ Same incubation time for all three assays
- ▶ Automated processing and interpretation
- ▶ Native, recombinant HIV / HCV / Treponema antigens

# Hepatitis E Virus

## Complete Diagnostic Portfolio



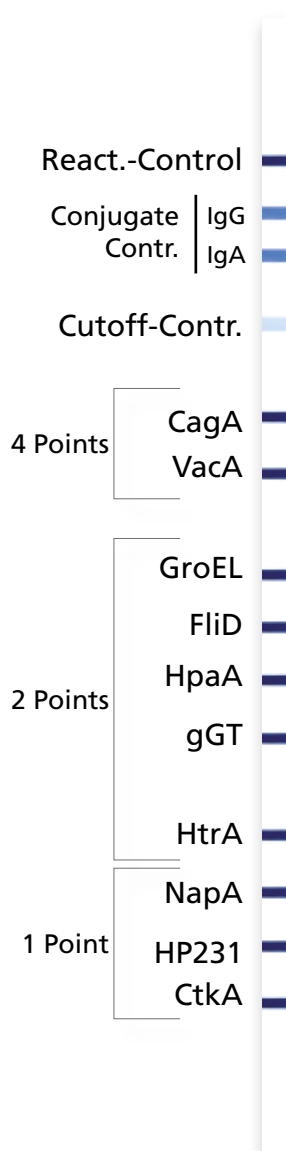
Sensitive detection of all four HEV genotypes occurring worldwide



German epidemiological data

# Helicobacter pylori 2.0

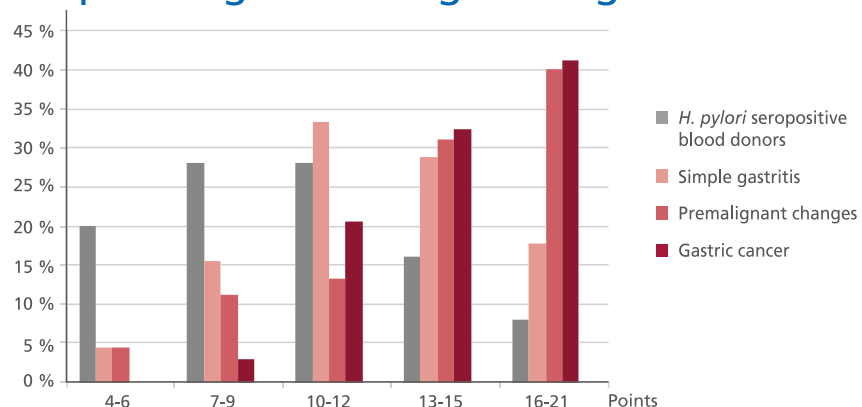
Innovative assay incorporates new serological markers and virulence factors



## recomLine Helicobacter IgG 2.0 recomLine Helicobacter IgA 2.0

- ▶ Consistently reliable test results, even in cases of low bacterial load
- ▶ CagA antibody detection guarantees identification of virulent *H.pylori* Type I strains
- ▶ Dependable diagnosis or exclusion of *H.pylori* infection

Virulence factors are associated with a higher risk for premalignant changes and gastric cancer:



recomLine Helicobacter IgG 2.0 – Distribution of score points

# Tropical Fever

## Complete Diagnostic Portfolio



### Singleplex ***ampliCube Zika Virus***

- ▶ Real-time RT-PCR for the detection of **Zika virus** (ZIKV) RNA

### Multiplex ***alphaCube Tropical Fever 1***

- ▶ Real-time RT-PCR for the detection of **Dengue, Zika, Chikungunya** and **Yellow Fever virus**



### Multiplex ***recomLine Tropical Fever***

- ▶ First and unique serological assay for simultaneous detection and differentiation of **Dengue, Chikungunya** and **Zika virus** in one test strip
- ▶ **Updated test version:** new antigens for higher sensitivity and improved differentiation



# Lyme Disease

## Screening – Confirmation – PCR

*B. burgdorferi sensu strictu, B. garnii, B. spielmanii, B. bavariensis*

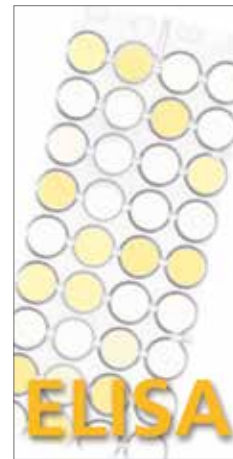
### **alphaCube Borrelia**

- ▶ Real-time PCR
- ▶ Human and tick samples



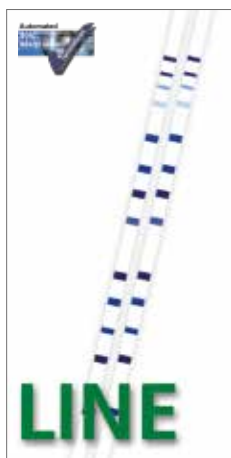
### **recomWell Borrelia IgG recomWell Borrelia IgM**

- ▶ Highly reliable screening assay



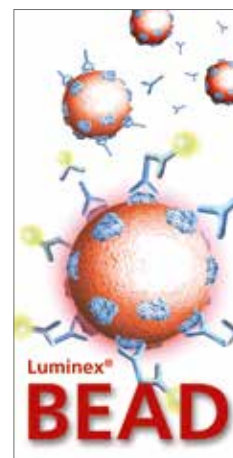
### **recomLine Borrelia IgG recomLine Borrelia IgM**

- ▶ Market leader for confirmation in Germany



### **recomBead Borrelia IgG 2.0 recomBead Borrelia IgM 2.0 recomBead CXCL13**

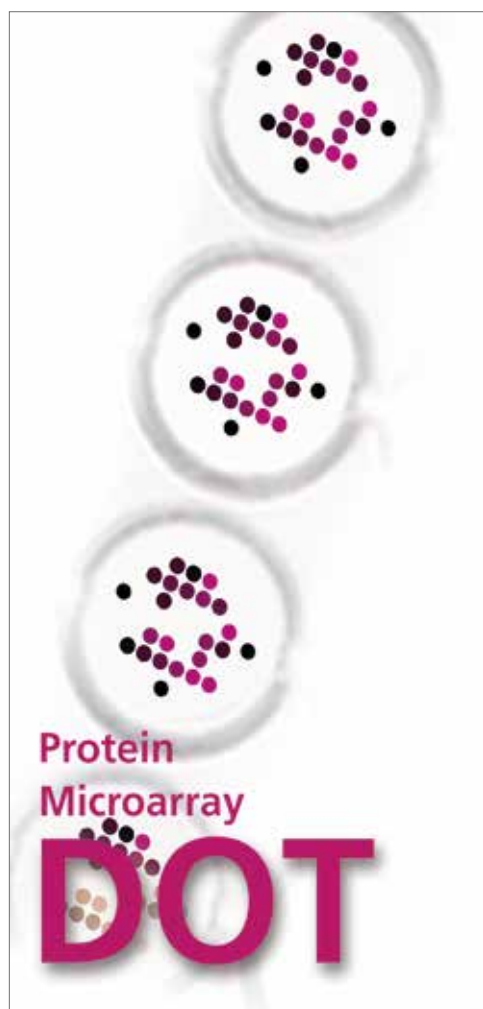
- ▶ High throughput multiplex assays



Coming  
soon

## Lyme Disease

New microarray for confirmation of suspected  
Borrelia infection



### *recomDot* Borrelia

- ▶ High throughput testing
- ▶ Easy handling
- ▶ Technical equipment for automation present in most laboratories
- ▶ Large amount of information in **one** well
- ▶ Phase specific antigens
- ▶ Species specific antigens of five different Borrelia species
- ▶ Highly purified recombinant antigens
- ▶ Reliable internal controls
- ▶ Automation and connection to LIMS

**Highly reliable diagnostics – saving time and money!**

# ELISA

## Your one-stop shop

### Bacterial infections

	IgG	IgM	IgA
Bordetella pertussis	✓	✓	✓
Bordetella pertussis toxin (PT)	IU/ml	✓	✓
Borrelia + Neuroborreliosis	✓	✓	
Brucella	✓	✓	
Campylobacter	✓		✓
Chlamydia pneumoniae	✓	✓	✓
Chlamydia trachomatis	✓	✓	✓
Coxiella burnetii (Phase 1, 2)	✓	✓	
Diphtheria (C. dipht.)	IU/ml	✓	
Helicobacter pylori	✓		✓
Legionella pneumophila	✓	✓	
Leptospira	✓	✓	
Mycoplasma	✓	✓	✓
Tetanus (Tetanustoxoid)	✓		
Treponema pallidum	✓	✓	
Yersinia	✓	✓	✓

### Fungal infections

<b>NEW</b> Aspergillus fumigatus	✓	✓	
Candida	✓	✓	✓

### Parasitic infections

Ascaris lumbricoides	✓		
Chagas (Trypanosoma cruzi)	✓		
Echinococcus	✓		
Entamoeba histolytica	✓		
<b>NEW</b> Filariasis	Antibodies		
Leishmania	✓		
<b>NEW</b> Malaria	IgG/IgM		
Schistosoma mansoni	✓		
<b>NEW</b> Strongyloides	IgG/IgM		
Taenia solium	✓		
Toxocara canis	✓		
Toxoplasma gondii*	IU/ml	✓	✓
Trichinella spiralis	✓		

### Viral infections

	IgG	IgM	IgA
Adenovirus	✓	✓	✓
Chikungunya Virus	✓	✓	
Cytomegalie Virus (CMV)*	✓	✓	
Dengue Virus	✓	✓	
Epstein-Barr Virus (EBV)	✓	✓	
Hanta Virus	✓	✓	
Hepatitis E Virus (HEV)	✓	✓	
Herpes simplex Virus (HSV-1, -2, -1/2)	✓	✓	
Influenza Virus A, B	✓	✓	✓
Measles Virus*	✓	✓	
Mumps Virus	✓	✓	
Parainfluenza Virus	✓		✓
Parvovirus B19	✓	✓	
Respiratory Syncytial Virus (RSV)	✓	✓	✓
Rubella Virus*	IU/ml	✓	✓
<b>NEW</b> TBE	✓	✓	
Varizella Zoster Virus (VZV)	✓	✓	✓
Zika Virus	✓	✓	

\*Avidity determination possible

### Antigen detection

Human Papillomavirus (HPV)

### Automation

Equipment solutions

Software solutions



Dynex DSX

**Luminex®**

Infectious Diseases

Detection of Antibodies and Biomarkers



*recomBead Borrelia IgG 2.0, IgM 2.0*

*recomBead EBV IgG 2.0, IgM 2.0*

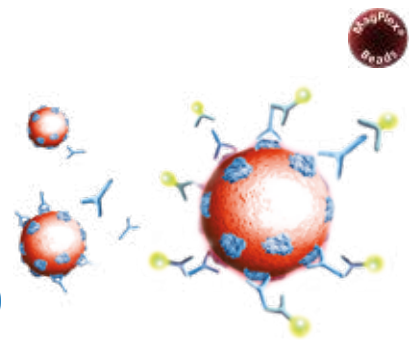
*recomBead Yersinia IgG 2.0, IgA [IgM] 2.0*

*recomBead CXCL13*

**Coming  
soon**

*recomBead Treponema IgG 2.0, IgM 2.0*

*recomBead Bordetella pertussis IgG 2.0, IgA 2.0*



Luminex® 200™



MAGPIX®

- ▶ Fast and easy test procedure
- ▶ High throughput assay
- ▶ Integrated controls ensuring highest quality standards
- ▶ High precision and reproducibility
- ▶ Low sample volume
- ▶ Large amount of information in one approach
- ▶ Automation and LIS connectivity

*only available in Europe*



## **Congenital Infections**

### **Reliable Diagnostics**

**Chlamydia**

**CMV**

**HCV**

**HIV**

**HSV**

**Parvovirus B19**

**Rubella virus**

**Syphilis**

**TORCH**

**Toxoplasmosis**

**VZV**

**Zika virus**



**ELISA | Blot | Line Assay | PCR**

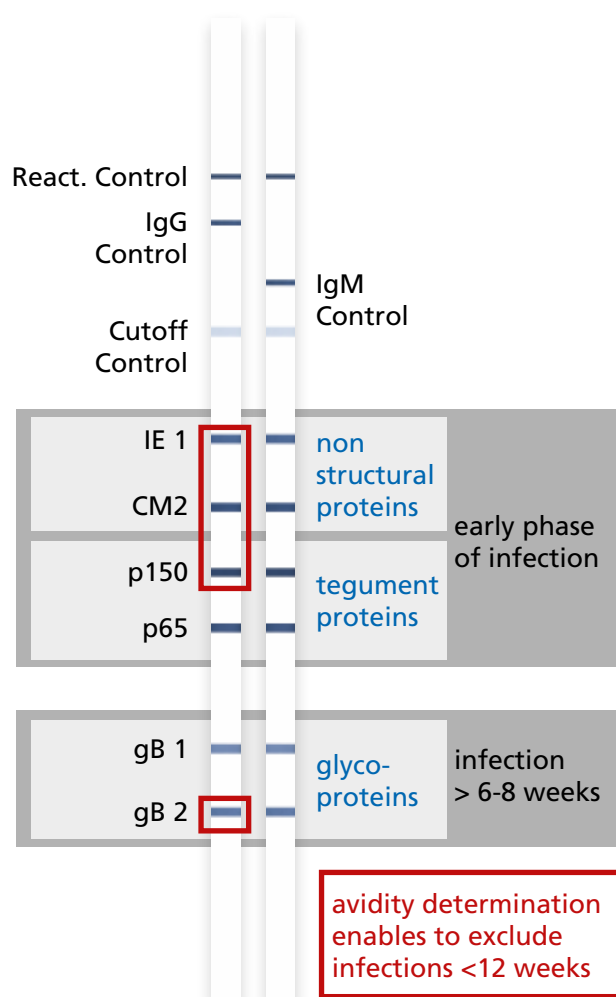
# CMV



## Pregnancy relevance and time course of infection

### recomLine CMV

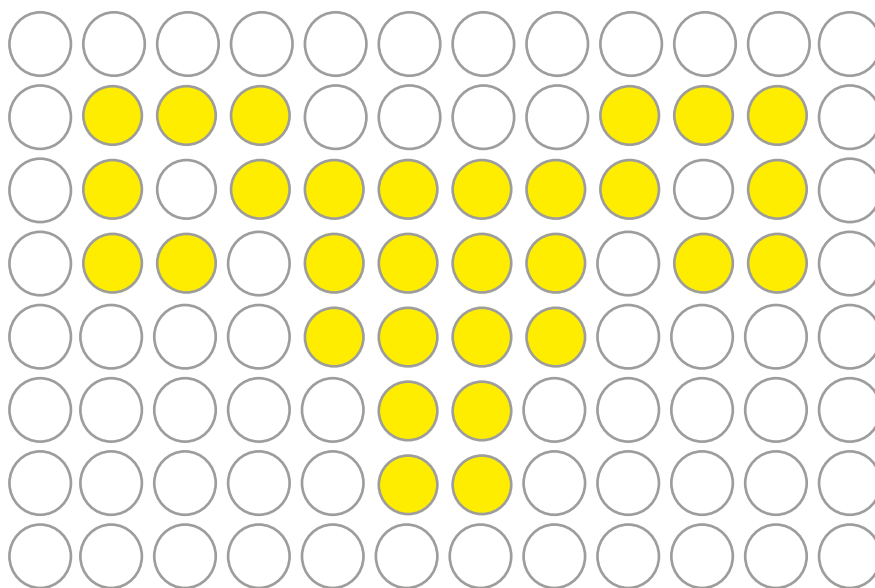
- ▶ High sensitivity and specificity ensured by the use of recombinant antigens
- ▶ Fast and easy to use due to automation and software based evaluation
- ▶ Reliable patient management assured by the use of phase-specific antigens which allow to determine the point of infection



NEW

## Human Papillomavirus | E7

Groundbreaking HPV immunoassay –  
A new era for cervical cancer diagnostics

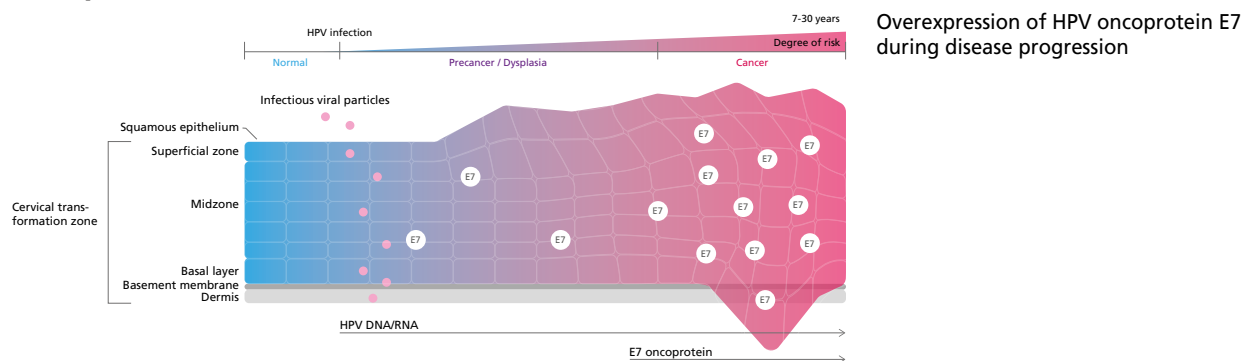


**recomWell HPV 16/18/45**

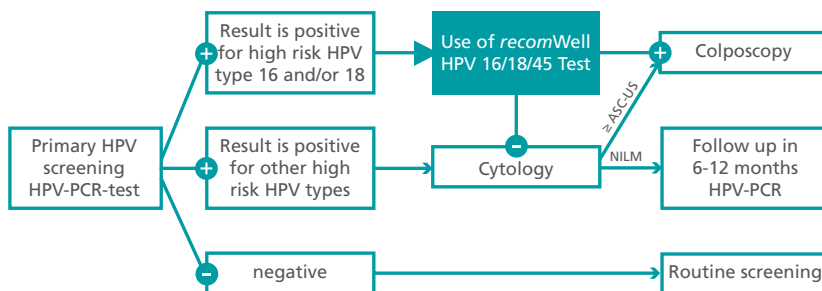
**recomWell Keratin 5/6/18**

- ▶ Detection of E7 oncoproteins
- ▶ High diagnostic significance with regard to dysplasia and cervical cancer
- ▶ Negative Predictive Value (NPV) > 97%!
- ▶ Higher Positive Predictive Value (PPV) than HPV-NAT tests
- ▶ Clinical cutoff is validated on the basis of 1574 characterized cervix specimens (CIN2+, CIN3+, CIS and CxCa)
- ▶ Secure, simple and automatable application due to ELISA format

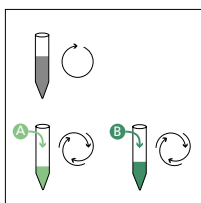
## 1. Progression to cervical carcinoma and the clinical significance of E7 oncoprotein detection



## 2. recomWell HPV 16/18/45 - possible usage in the recommended screening algorithm



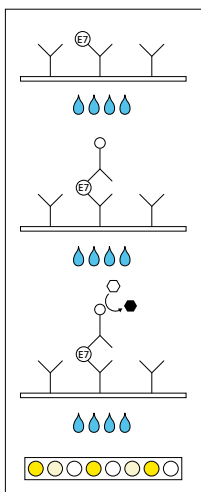
## 3. Preparation of Patient Samples & Test Principles and Procedure



**Sample preparation.**  
Before performing the *recomWell* HPV 16/18/45, the cervical smears (stored in ThinPrep® PreservCyt Solution) are processed as follows:

**Centrifugation** Transfer 15 ml sample material into a screw cap tube with conical bottom. Centrifuge for **15 minutes** at 600g. Carefully remove excess supernatant.

**Incubation** Add 500 µl lysis buffer A, vortex, and incubate for **30 minutes** at room temperature. Add 500 µl lysis buffer B and vortex.



**Indirect sandwich test.**  
Monoclonal rabbit anti-HPV 16 E7, 18 E7 and 45 E7 antibodies are fixed in the wells of a microtiter plate.

**1<sup>st</sup> Incubation** Add prepared patient sample, and incubate for **1 hour** at **room temperature**. wash 3 times

**2<sup>nd</sup> Incubation** Add ready-to-use secondary anti-HPV E7 antibody, and incubate for **1 hour** at **room temperature**. wash 3 times

**3<sup>rd</sup> Incubation** Add ready-to-use streptavidin conjugate, and incubate for **1 hour** at **room temperature**. wash 6 times

**Color reaction** Add ready-to-use TMB solution and incubate **30 minutes** at **room temperature**. Stop the substrate solution with H<sub>3</sub>PO<sub>4</sub> and measure the absorbance at 450 nm.

**Turn around time: approx. 4h**

## Molecular Diagnostics

### ► Real-time Single/Multiplex PCR



Respiratory Infections

Sexually Transmitted Diseases

Gastrointestinal Infections

Tick Borne Infections

Tropical Fever

**In Development** Antimicrobial Resistance PCR

### ► DNA & RNA Extraction

### ► PCR Positive Controls

- External run and process controls
- Monitor the complete analytical process from RNA/DNA extraction to amplification
- Complete, non-infectious microorganisms in buffer
- Can be combined with every commercial or in-house PCR assay

- 24 extractions à 200 µl can be performed
- Each PCR Positive Control is delivered with its Certificate of Analysis indicating the expected Ct value and approx. 100 copies / µl
- Size: 4.8 ml (4 x 1.2 ml)
- Storage: at  $\leq 18^{\circ}\text{C}$ , stability in use: 3 months at  $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$
- CE label

Viruses	Article no
Adenovirus PCR Control	830902
Cytomegalovirus PCR Control (RUO)	830903
Epstein Barr Virus PCR Control	830906
Enterovirus RT-PCR Control	830900
Herpes Simplex Virus Typ 1 PCR Control	830904
Herpes Simplex Virus Typ 2 PCR Control	830905
Influenza A H1 RT-PCR Control	830901
Influenza A H3 RT-PCR Control	830918
Influenza B RT-PCR Control	830917
Respiratory Syncytial Virus A RT-PCR Control	830907
Respiratory Syncytial Virus B RT-PCR Control	830908
Rotavirus RT-PCR Control	830909
TBE (Tick Borne Encephalitis Virus) RT-PCR Control	830910
Varizella Zoster Virus PCR Control	830911

Bacteria	Article no
<b>Bordetella parapertussis</b> PCR Control	830919
<b>Bordetella pertussis</b> PCR Control	830912
<b>Borrelia burgdorferi</b> PCR Control	830913
<b>Chlamydia pneumoniae</b> PCR Control (RUO)	830914
<b>Streptococcus agalactiae (GBS)</b> PCR Control	830915
<b>Mycobacterium tuberculosis complex (BCG)</b> PCR Control	830916

# Connective Tissue Diseases (CTD)



## recomLine ANA/ENA IgG

- ▶ **High sensitivity and specificity**  
ensured by the use of recombinant antigens
- ▶ **Fast and easy to use**  
due to automation and software based evaluation
- ▶ **One single approach to differentiate between the most frequent autoimmune collagenose diseases** enabled by the use of 15 different antigens
- ▶ **Highly reliable diagnostic of SLE**  
using subunits of Sm and RNP antigens and high specific SLE markers

React. Control

IgG Control

Cut-off Control

RNP68

PNPA

RNPC

SmB

SmD

Ro/SSA60

Ro/SSA52

La/SSB

Rib-P

PCNA

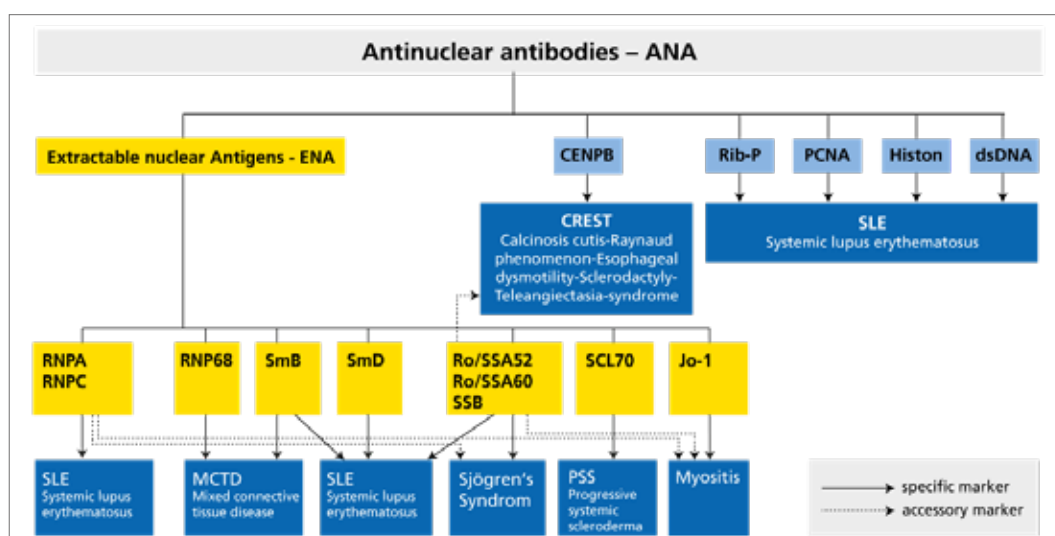
CENPB

Scl70

Jo-1

Histon

dsDNA







new +++ neu +++ new +

**MIKROGEN GmbH**  
Floriansbogen 2-4  
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