

# BlueDiver

## Comprehensive solution for quick and accurate analysis of infectious diseases

Automatic system for immunoblot processing and evaluation



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# BlueDiver

Simple, smart and small sized device for complete automation of the immunoblot method.



## Unique Features and Advantages

### Space-saving

small sized and compact instrument without a need for extra devices

### No risk of contamination

no pumps, inlet hoses, handling with liquid reagents, “dead” volumes; disposable cartridges are ready to use

### High flexibility

it is possible to analyze up to 24 various strips at the same time - compatibility of the whole product range of D-tek and TestLine intended for automation

### Easy to use and short hands on time

simply insert the test strips, disposable reagent cartridges, patient samples and then follow the instructions on the touchscreen

### High reliability

compatibility of strips and reagents automatically checked using the integrated barcode reader

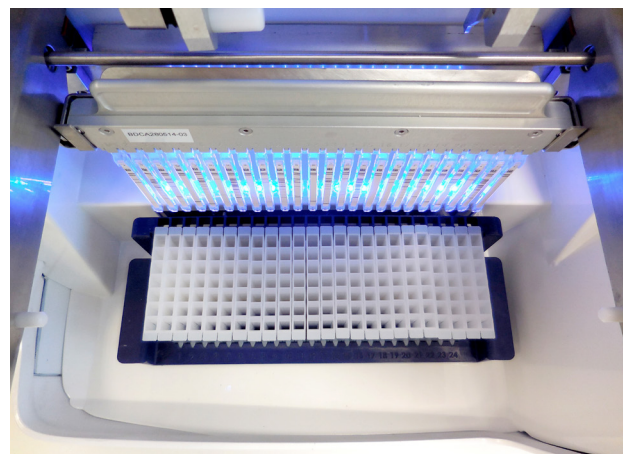
### Extremely short analysis time

through innovative patented process

## Technical Parameters

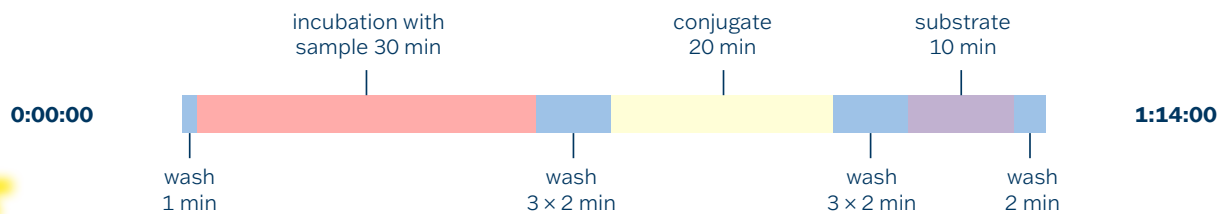
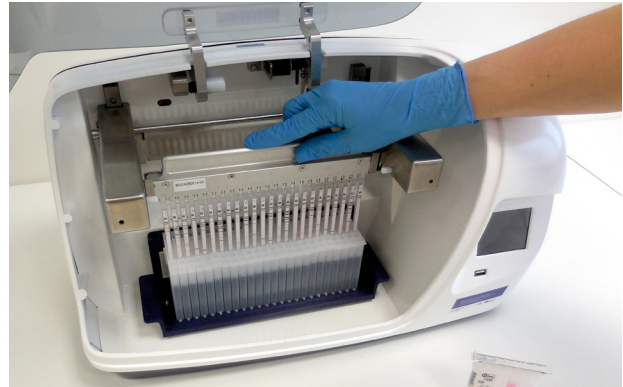
<b>Dimensions (W x H x D)</b>	51.5 x 29.8 x 28.9 cm
<b>Weight</b>	16 kg
<b>Controlling</b>	touchscreen
<b>Sample capacity</b>	1-24
<b>Input voltage</b>	24 V
<b>Power</b>	40 W
<b>Communication interface:</b>	USB 2.0 connector type A use only with USB flash drive

- Closed system - preprogramed analysis protocol
- Integrated barcode and 2D code reader



# Protocol Summary

- Inserting holders with strips and reagents into the instrument
- Automatic batch and expiry control using the integrated barcode reader
- Samples pipetting
- Automated incubation and washing
- Strips drying



# Immunoblot Software

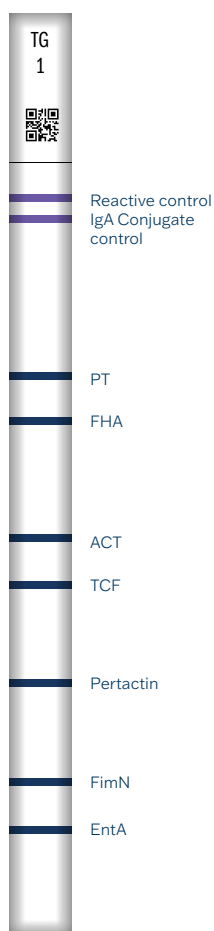
Scanner combined with intuitive and user-friendly evaluation software that allows results to be transferred to LIS.



# Recombinant IMMUNOBLOT kits for diagnostics of **pertussis** and **parapertussis**

<u>Cat. No</u>	<u>Product</u>	<u>No. of Tests</u>
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	24
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	24

## Antigens



### Diagnostic importance

#### ***B. pertussis***

PT	Pertussis toxin (45 kDa) – basic virulence factor   specific only for <i>B. pertussis</i>   the most important pertussis antigen
FHA	<i>B. pertussis</i> filamentous hemagglutinin – adhesive protein, important immunogen   selected part of the sequence with high specificity
ACT	Adenylate cyclase toxin (CyaA) – important virulence factor of <i>B. pertussis</i>   antiphagocytic factor during infection
TCF	Tracheal colonization factor – protein produced only by <i>B. pertussis</i> strain   not by <i>B. parapertussis</i>   protein adhesin, that binds to ciliated epithelial cells of respiratory tract

#### ***B. parapertussis***

Pertactin	Outer membrane protein (75 kDa) of virulent <i>B. parapertussis</i> strains
FimN Fimbriae N	Protein adhesin; it is not produced by <i>B. pertussis</i>
EntA Entericidin A	Membrane lipoprotein

- Unique parallel diagnosis of pertussis and parapertussis
- Highly advanced spectrum of antigens

**BlueBLOT-LINE**  
**Bordetella IgA**

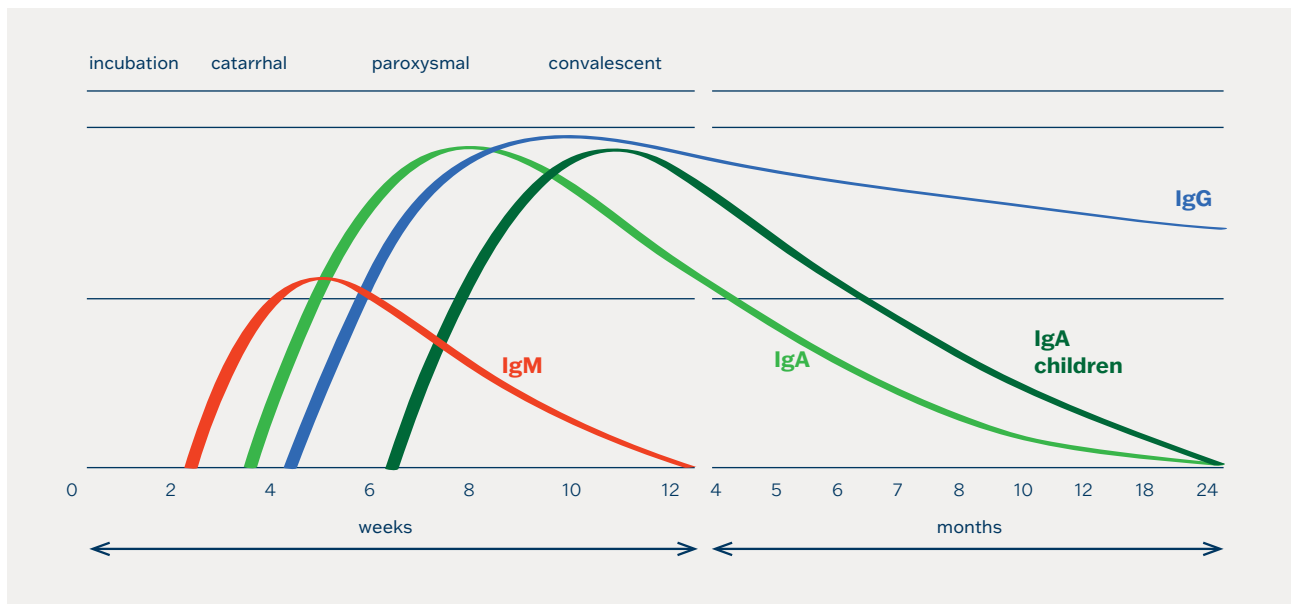
## Test Characteristics

<u>BlueBLOT-LINE</u>	<u>Diagnostic Sensitivity</u>	<u>Diagnostic Specificity</u>
Bordetella pertussis IgA	91.7%	98.8%
Bordetella pertussis IgG	92.2%	94.4%
Bordetella parapertussis IgA	92.3%	93.8%
Bordetella parapertussis IgG	99.0%	91.3%

## Interpretation of Test Results

<u>IgG</u>	<u>IgA</u>	<u>Interpretace</u>
+	+	Recent or current natural infection
-	+	Early infection stage
+	-	State after recent vaccination ( <i>B. pertussis</i> )
-	-	Seronegative (if infection is suspected test a new sample for 2-3 weeks)

## Antibody Response in Black Cough

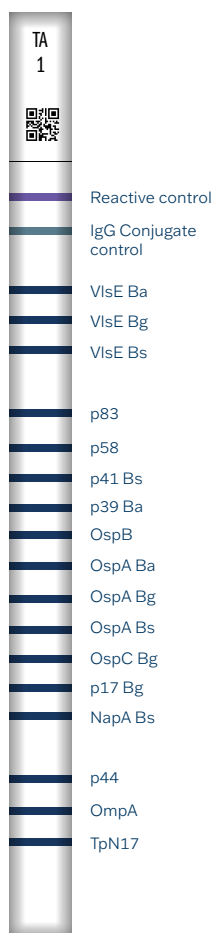




# Recombinant IMMUNOBLOT kits for diagnostics of **Lyme borreliosis** and **anaplasmosis**

<b>Cat. No</b>	<b>Product</b>	<b>No. of Tests</b>
BD-BGL024	BlueBLOT-LINE Borrelia IgG	24
BD-BML024	BlueBLOT-LINE Borrelia IgM	24

## Antigens



### BlueBLOT-LINE Borrelia IgG

#### Diagnostic importance

VlsE Ba VlsE Bg VlsE Bs	Variable major protein-like sequence, expressed   Species specific antigen   Main antigen of early and late antibody response to LB   Significantly increases test sensitivity (approx. 90% of samples of positive sera and CSF react in this antigen band)
p83	Main extracellular protein (product of p100 degradation)   Late antibody response antigen   Highly immunoreactive antigen, typical of neuroborreliosis
p58	OppA-2 (Oligopeptide permease 2)   membrane transporter   Considered a marker of disseminated stage of Lyme disease
p41	Inner part of flagellin   Highly specific antigen of early antibody response
p39	BmpA (glycosaminopeptide receptor)   Antigen of late antibody response   Significant antigen for advanced disseminated form of LB, often associated with Lyme arthritis
OspB	Outer surface protein B
OspA Ba OspA Bg OspA Bs	Outer surface protein A   Antigen of late antibody response, typical of neuroborreliosis
OspC Bg	Outer surface protein C   Antigen of early antibody response
p17 Bg	DbpA (Decorin-Binding protein A)   Antigen of early and late antibody response, typical of neuroborreliosis
NapA Bs	Neutrophil activating protein A   Strong immunogen, main marker of Lyme arthritis pathogenesis
p44	Main antigen of antibody response to HGA
OmpA	Outer membrane protein A of <i>Anaplasma phagocytophilum</i> , peptidoglycan-associated lipoprotein, significant virulence marker
TpN17	Highly specific membrane protein of <i>Treponema pallidum</i>

The test is based on highly specific recombinant *Borrelia* antigens. Nevertheless, it is sometimes possible to observe cross reactivity with other pathogens which can result in false positive results. The IgM test uses a highly specific and sensitive EBV marker (VCA-p18) to eliminate false positive *Borrelia* results, the IgG test uses the antigen TnN17 which is an important marker of syphilis infection.

# Antigens



## Diagnostic importance

VlsE Bg	Variable major protein-like sequence, expressed   Species specific antigen   Main antigen of early and late antibody response to LB   Significantly increases test sensitivity (approx. 90% of samples of positive sera and CSF react in this antigen band)
p83	Main extracellular protein (product of p100 degradation)   Late antibody response antigen   Highly immunoreactive antigen, typical of neuroborreliosis
p41	Inner part of flagellin   Highly specific antigen of early antibody response
p39	BmpA (glycosaminopeptide receptor)   Antigen of late antibody response   Significant antigen for advanced disseminated form of LB, often associated with Lyme arthritis
OspC Ba OspC Bg OspC Bs OspC Bsp	Outer surface protein C   Antigen of early antibody response
p17	DbpA (Decorin-Binding protein A)   Antigen of early and late antibody response, typical of neuroborreliosis
p44	Main antigen of antibody response to HGA
OmpA	Outer membrane protein A of <i>Anaplasma phagocytophilum</i> , peptidoglycan-associated lipoprotein, significant virulence marker
p18	Viral Capsid Antigen p18   Important marker of EBV infection

## BlueBLOT-LINE Borrelia IgM

### Test Characteristics

Immunoblot	Borrelia		Anaplasma	
	Diagnostic Sensitivity	Diagnostic Specificity	Diagnostic Sensitivity	Diagnostic Specificity
BlueBLOT-LINE Borrelia IgG	98.2%	99.0%	83.0%	99.0%
BlueBLOT-LINE Borrelia IgM	98.4%	99.0%	92.0%	96.0%

# Recombinant IMMUNOBLOT kits for diagnostics of **Epstein-Barr virus infection**

<b>Cat. No</b>	<b>Product</b>	<b>No. of Tests</b>
BD-EBGL24	BlueBLOT-LINE EBV IgG	24
BD-EBML24	BlueBLOT-LINE EBV IgM	24

## Antigens



### Diagnostic importance

EBNA-1	Epstein-Barr nuclear antigen 1   In the IgG class, an important diagnostic marker of late phase or reactivation of the infection   In IgM class detectable antibodies for 2-4 months after primary EBV infection, may also appear in reactivation
VCA-p18	Viral Capsid Antigen p18   an important marker of late phase of infection, IgG antibodies do not appear in primary infections   IgM antibodies can be detected in early phase of the infection
VCA-p23	Viral Capsid Antigen p23   antibodies to this antigen can be detected at all stages of infection in IgG and IgM class, IgG antibodies persist in the body for a long time
EA-D	Early Antigen Diffuse p54   BRF1   an additional marker of acute EBV infection, antibodies detectable in IgG and IgM class, even in the latent phase of primary infection

**BlueBLOT-LINE  
EBV IgG**



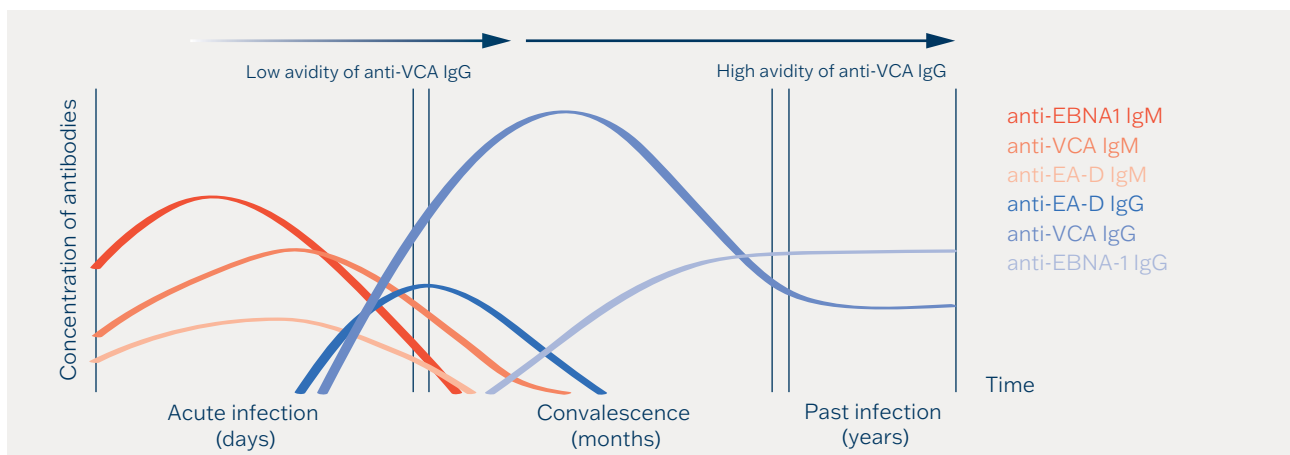
## Test Characteristics

<u>Pathogen</u>	<u>Diagnostic Sensitivity</u>	<u>Diagnostic Specificity</u>
EBNA-1 IgG	93.8%	92.3%
EBNA-1 IgM	91.3%	95.2%
VCA IgG	95.4%	93.6%
VCA IgM	92.9%	92.6%
EA-D IgG	93.6%	96.3%
EA-D IgM	93.3%	97.4%

## Interpretation of Test Results

<u>Evaluation</u>	<u>VCA</u>			<u>EA-D</u>		<u>EBNA-1</u>	
	<u>IgM</u>	<u>IgA</u>	<u>IgG</u>	<u>IgM</u>	<u>IgG</u>	<u>IgM</u>	<u>IgG</u>
Seronegativity	-	-	-	-	-	-	-
Primary infection	+	-	-	+	-	+	-
	+	+	-	+	+	(+)	-
	+	+	+	+	+	(+)	-
Postacute stage	+	(+)	+	-	(+)	-	-
	-	(+)	+	-	(+)	-	+
Previous infection	-	-	+	-	-	-	+
Reactivation	+	(+)	+	(+)	(+)	(+)	+

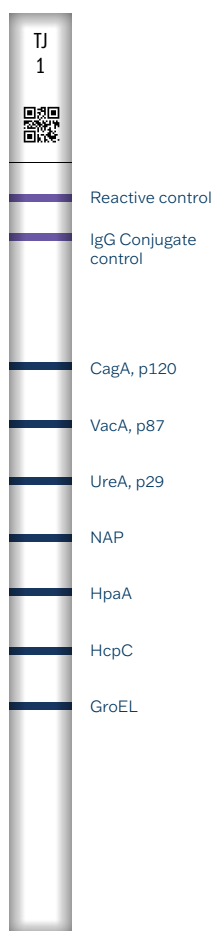
## Antibody Response



# Recombinat IMMUNOBLOT kits for diagnostics of **Helicobacter pylori**

<b>Cat. No:</b>	<b>Product</b>	<b>No. of Tests</b>
BD-HpAL24	BlueBLOT-LINE Helicobacter IgA	24
BD-HpGL24	BlueBLOT-LINE Helicobacter IgG	24

## Antigens



### Diagnostic importance

CagA, p120	Cytotoxin associated gene A, highly specific, virulence factor
VacA, p87	Vacuolating cytotoxin A, highly specific, virulence factor
UreA, p29	Light subunit of urease, specific, virulence factor
NAP	Neutrophil-activating protein, virulence factor, potential biomarker of gastritis
HpaA	Helicobacter pylori adhesin A, surface lipoprotein, potential biomarker of gastritis and gastric ulcer
HcpC	Helicobacter cystein-rich protein, virulence factor
GroEL	Chaperonin, heat shock protein (Hsp 60), virulence factor, considered as a marker of chronic infection

### Application

- Determination of presence of antibodies against specific *H. pylori* antigens
- Confirmation of positive and ambiguous results

**BlueBLOT-LINE  
Helicobacter IgG**

## Antibody Response

### IgA:

Antibodies are produced not only in the acute stage of the disease but also in chronic infection of gastric mucosa along with IgG antibodies. Increased level of IgA antibodies was also described in patients with a risk of gastric carcinoma.

### IgG:

Presence indicates contact with *H. pylori*. However, it does not provide any evidence of infection activity. Seroconversion occurs approximately 2 months after primary infection.

## Test Characteristics

<b>Pathogen</b>	<b>Diagnostic sensitivity</b>	<b>Diagnostic specificity</b>
Helicobacter pylori IgA	95.5%	96.6%
Helicobacter pylori IgG	96.2%	94.8%

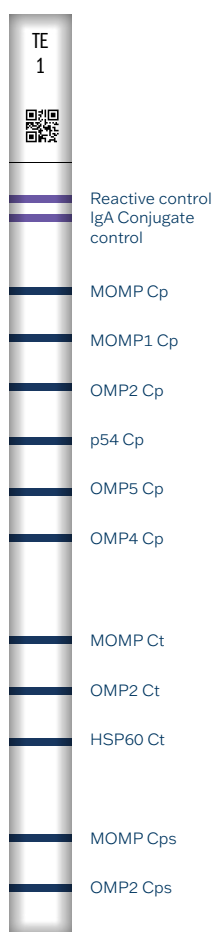
## Method Correlation

<b>BlueBLOT-LINE Helicobacter</b>	<b>Conformity in %</b>	
	<u>IgA</u>	<u>IgG</u>
EIA (TestLine)	87.6	81.7
BLOT (competition)	96.6	97.4

# Recombinant IMMUNOBLOT kits for diagnostics of **Chlamydia** infections

<b>Cat. No</b>	<b>Product</b>	<b>No. of Tests</b>
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	24
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	24

## Antigens



### Diagnostic importance

#### ***Chlamydia pneumoniae***

MOMP Cp	Dominant major outer membrane protein (species specific) – structural protein   metabolic function
MOMP1	Isoform, produced by posttranslational modification
OMP2 Cp	Outer membrane protein (species specific)   structural protein of Chlamydia outer membrane complex
OMP4	Outer membrane protein
OMP5	Outer membrane protein
P54	Immunodominant outer antigen, highly specific to <i>Ch. pneumoniae</i>   sensitive marker for diagnosis of acute infection

#### ***Chlamydia trachomatis***

MOMP Ct	Dominant major outer membrane protein (species specific) – structural protein   metabolic function
OMP2 Ct	Outer membrane protein (species specific) – structural protein of Chlamydia outer membrane complex
HSP60	Heat shock protein (GroEL)   marker of chronic infection

#### ***Chlamydia psittaci***

MOMP Cps	Dominant major outer membrane protein (species specific) – structural protein; metabolic function
OMP2 Cps	Outer membrane protein (species specific) – structural protein of Chlamydia outer membrane

**BlueBLOT-LINE**  
**Chlamydia IgA**

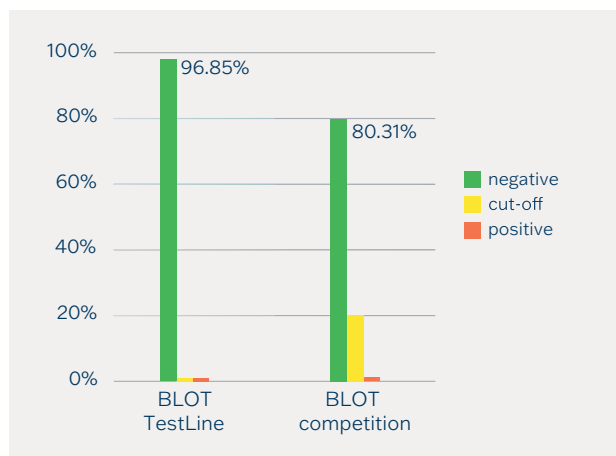
## Test Characteristics

<u>BlueBLOT-LINE</u>	<u>Diagnostic sensitivity</u>	<u>Diagnostic specificity</u>
Chlamydia pneumoniae IgA	96.3%	95.9%
Chlamydia pneumoniae IgG	95.8%	96.0%
Chlamydia trachomatis IgA	92.0%	92.0%
Chlamydia trachomatis IgG	91.3%	91.7%
Chlamydia psittaci IgA	99.0%	99.0%
Chlamydia psittaci IgG	99.0%	99.0%

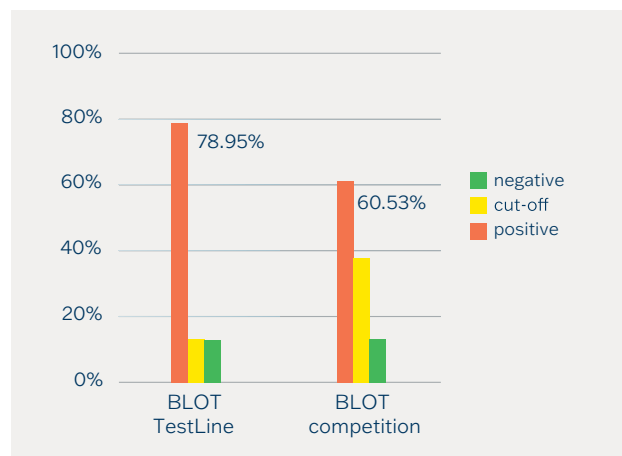
## Advantages

- Recombinant antigens provide high sensitivity and specificity of the kits
- Antigenic compositions reflect the new findings in diagnostics of Chlamydia infections
- Significant reduction of false positive results and cross-reactivity
- Possibility of simultaneous determination for all Chlamydia species

### Reactivity on panel of negative samples



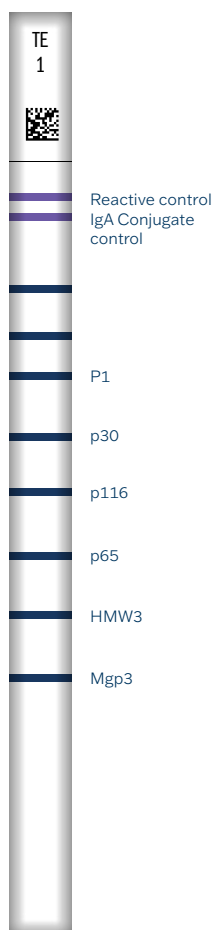
### Reactivity on panel of positive samples



# Recombinant IMMUNOBLOT kits for diagnostics of **Mycoplasma infection**

<u>Cat. No</u>	<u>Product</u>	<u>No. of Tests</u>
BD-MYAL24	BlueBLOT-LINE Mycoplasma IgA	24
BD-MYGL24	BlueBLOT-LINE Mycoplasma IgG	24
BD-MYML24	BlueBLOT-LINE Mycoplasma IgM	24

## Antigens



### Diagnostic importance

P1	Adhesin; the most important protein   a major virulence factor
p30	Cytadhesin p30; the second most important protein   a major virulence factor
p116	Adhesin, a major virulence factor
p65	Surface protein; proline-rich P65 protein
HMW3	Cytadherence high molecular weigh 3; adhesion-promoting protein
Mgp3	Adhesion-promoting protein

**BlueBLOT-LINE**  
**Mycoplasma IgA**



## Results Interpretation

<b>IgG</b>	<b>IgA</b>	<b>IgM</b>	<b>Interpretation</b>
-	-	-	No serological evidence of Mycoplasma pneumoniae infection
-	+	+	Early phase of acute infection or reinfection
-	+	-	Early phase of acute infection or reinfection
+	+	+	Acute infection
+	-	+	Acute infection (late phase)
+	+	-	Reinfection or infection without IgM production
+	-	-	Past infection or reinfection
-	-	+	Early phase of acute infection

## Test Characteristics

<b>BlueBLOT-LINE</b>	<b>Diagnostic Sensitivity</b>	<b>Diagnostic Specificity</b>
Mycoplasma IgA	96.8%	98.2%
Mycoplasma IgG	96.4%	98.2%
Mycoplasma IgM	97.8%	98.1%

## Clinical Application

- Detailed determination of the presence of antibodies against specific antigens of Mycoplasma pneumoniae
- Confirmation of ambiguous results
- Confirmation for ELISA tests

# Recombinant IMMUNOBLOT kits for diagnostics of **syphilis**

<b>Cat. No</b>	<b>Product</b>	<b>No. of Tests</b>
BD-TpGL24	BlueBLOT-LINE Treponema IgG	24
BD-TpML24	BlueBLOT-LINE Treponema IgM	24

## Antigens



### Diagnostic importance

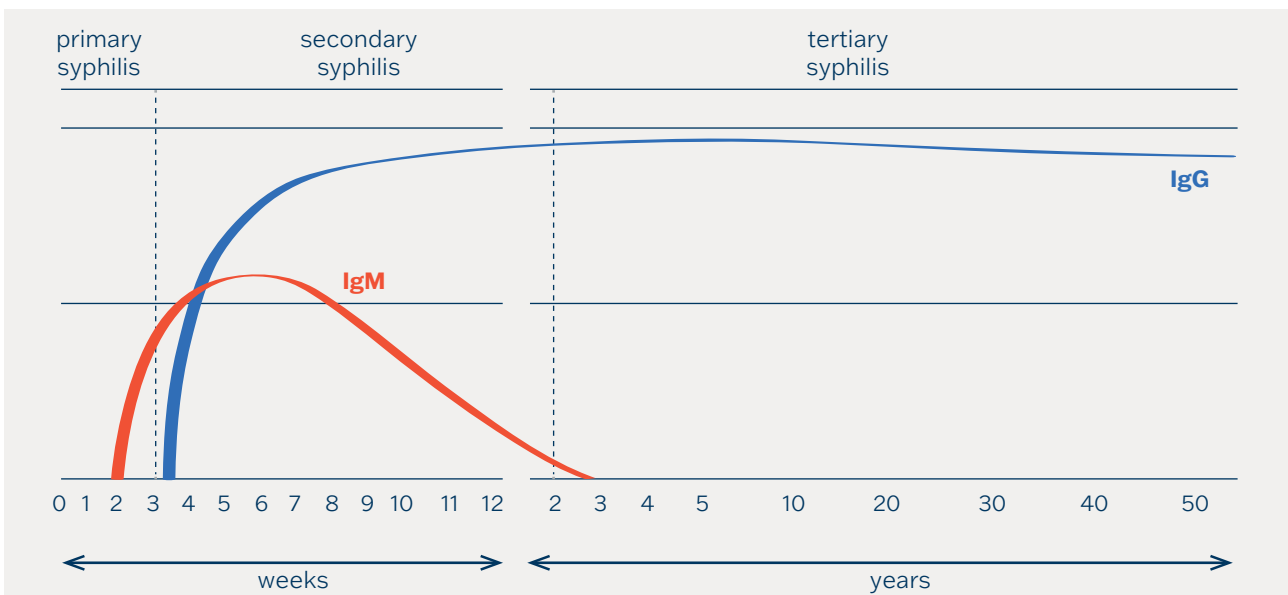
TpN47	Immunodominant antigen; highly specific marker   reacting sensitively at all stages of syphilis   IgG response characteristic of primary syphilis
p41	Outer membrane protein, among the major immunogens of <i>T. pallidum</i>
TpN17	Immunodominant antigen; highly specific marker   reacting sensitively at all stages of syphilis; uncommon in primary syphilis; IgG antibodies persist at longest in late latent syphilis
TpN15	Immunodominant antigen; highly specific marker   uncommon in primary syphilis; more common in secondary and early latent syphilis

**BlueBLOT-LINE**  
**Treponema IgG**

## Test Characteristics

<u>Pathogen</u>	<u>Diagnostic Sensitivity</u>	<u>Diagnostic Specificity</u>
Treponema pallidum IgG	98.9%	94.7%
Treponema pallidum IgM	96.2%	93.5%

## Antibody Response



## Clinical Application

- Diagnosis of individual phases of syphilis
- Confirmation of treponemal and non-treponemal tests
- Confirmation of ambiguous results

# Recombinant IMMUNOBLOT kits for diagnostics of **Yersinia infections**

<b>Cat. No.</b>	<b>Product</b>	<b>No. of Tests</b>
BD-YAL024	BlueBLOT-LINE Yersinia IgA	24
BD-YGL024	BlueBLOT-LINE Yersinia IgG	24

## Antigens



### Diagnostic importance

YopB	Yersinia outer protein, transmembrane protein
YopD	Yersinia outer protein, transmembrane protein
YopE	Yersinia outer protein
YopH	Yersinia outer protein
YopM	Yersinia outer protein
YopN	Yersinia outer protein
LcrV	Low calcium response Virulence, important for YopD a YopB secretion
Ail	Attachment-invasion locus protein early phase, involved in the adhesion and invasion process, and allows yersinia to survive outside the host cell, a significant virulence factor
Invasin	Surface adhesin that binds to $\beta 1$ integrins on the surface of target cells and is important particularly in the first stage of infection, a virulence factor
YstB	Heat-stable enterotoxin B, responsible for the virulence and pathogenicity of <i>Y. enterocolitica</i> strains, biotype 1A
YscM-Y.ent	Yop proteins translocation protein M (specific for <i>Y. enterocolitica</i> )
YscM-Y.pst	Yop proteins translocation protein M (specific for <i>Y. pseudotuberculosis</i> )

**BlueBLOT-LINE**  
**Yersinia IgG**



## Interpretation of Test Results

<b>IgG</b>	<b>IgA</b>	<b>IgM</b>	<b>Evaluation</b>
-	-	-	Negative result.
-	- / +	+	Emerging infection. Test repetition at intervals if needed.
+	-	-	Persistent IgG antibodies after the previous infection.
+	borderline / weak +	-	Previous infection. Beginning of reinfection.
+	++	-	Ongoing infection (IgM may not be present). Recurrent infection. Chronic infection (confirmation of chronicity by repeated examination after 1 and 3 months, necessary clinical signs).
+	+	+	Ongoing infection.

## Test Characteristics

<b>BlueBLOT-LINE</b>	<b>Diagnostic specificity</b>	<b>Diagnostic sensitivity</b>
Yersinia IgA	95.4%	93.8%
Yersinia IgG	96.9%	92.7%

## Clinical Application

- Determination of presence of antibodies against specific *Yersinia sp.* antigens
- Confirmation of ambiguous results
- Confirmation of ELISA test

# Ordering Information

<b>Cat. No</b>	<b>Product</b>	<b>No. of Tests</b>
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	24
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	24
BD-BGL024	BlueBLOT-LINE Borrelia IgG	24
BD-BML024	BlueBLOT-LINE Borrelia IgM	24
BD-EBGL24	BlueBLOT-LINE EBV IgG	24
BD-EBML24	BlueBLOT-LINE EBV IgM	24
BD-HpAL24	BlueBLOT-LINE Helicobacter IgA	24
BD-HpGL24	BlueBLOT-LINE Helicobacter IgG	24
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	24
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	24
BD-MYAL24	BlueBLOT-LINE Mycoplasma IgA	24
BD-MYGL24	BlueBLOT-LINE Mycoplasma IgG	24
BD-MYML24	BlueBLOT-LINE Mycoplasma IgM	24
BD-TpGL24	BlueBLOT-LINE Treponema IgG	24
BD-TpML24	BlueBLOT-LINE Treponema IgM	24
BD-YAL024	BlueBLOT-LINE Yersinia IgA	24
BD-YGL024	BlueBLOT-LINE Yersinia IgG	24

MANUFACTURER:



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