

# **BLOT-LINE results in External Quality Assessments (EQA) Q3-Q4 2025**

# Content

## STATISTICS

Average BLOT-LINE success rate in EQA in the year 2025 .....	4
Average success rate of BLOT-LINE kits in EQA in 2025 .....	4

## INFECTIOUS DISEASES

Bordetella.....	6
Borrelia .....	7
Chlamydia.....	9
Cytomegalovirus (CMV).....	12
Epstein-Barr virus (EBV).....	14
Helicobacter .....	17
Mycoplasma.....	19
Toxoplasma .....	21
Treponema .....	22
Yersinia.....	23

## IMMUNOLOGY & AUTOIMMUNE DISEASES

Antineutrophil Cytoplasmic Antibodies (ANCA) .....	25
Antinuclear antibodies (ANA) .....	26

# Statistics

## Average BLOT-LINE success rate in EQA in the year 2025

<u>CAP</u>	<u>INSTAND</u>	<u>LABQUALITY</u>	<u>SEKK</u>	<u>SZÚ</u>
100.0%	94.9%	92.3%	100.0%	100.0%

## Average success rate of BLOT-LINE kits in EQA in 2025

### INFECTIOUS DISEASES

<u>Parameter</u>	<u>CAP</u>	<u>INSTAND</u>	<u>LABQUALITY</u>	<u>SEKK</u>	<u>SZÚ</u>
<b>Bordetella</b>		100.0%	100.0%		
<b>Borrelia</b>		100.0%	100.0%		100.0%
<b>Chlamydia</b>		100.0%	88.9%		100.0%
<b>Cytomegalovirus (CMV)</b>	100.0%	100.0%	100.0%		
<b>Epstein-Barr virus (EBV)</b>	100.0%	100.0%	100.0%		
<b>Helicobacter</b>	100.0%	100.0%	100.0%		
<b>Mycoplasma</b>	100.0%	100.0%	83.3%		
<b>Toxoplasma</b>	100.0%	100.0%			
<b>Treponema</b>					100.0%
<b>Yersinia</b>					100.0%

### IMMUNOLOGY & AUTOIMMUNE DISEASES

<u>Parameter</u>	<u>CAP</u>	<u>INSTAND</u>	<u>LABQUALITY</u>	<u>SEKK</u>	<u>SZÚ</u>
<b>Antineutrophil Cytoplasmic Antibodies (ANCA)</b>		100.0%		100.0%	
<b>Antinuclear antibodies (ANA)</b>	100.0%	100.0%		100.0%	

# Infectious Diseases

# Bordetella

## INSTAND – 11.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+
IgM	borderline, negative	negative	+
IgM	negative	negative	+
Interpretation	acute infection	acute infection	+
Interpretation	no evidence of infection	no evidence of infection	+

## LABQUALITY – 11.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+
Interpretation	infection confirmed	infection confirmed	+
Interpretation	no evidence of infection	no evidence of infection	+

# Borrelia

## LABQUALITY – 09.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	positive	positive	+
Interpretation	infection confirmed	infection confirmed	+
Interpretation	infection confirmed	infection confirmed	+

## INSTAND – 11.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgM	positive, borderline, negative	negative	+
IgM	negative	negative	+
Interpretation	late infection	late infection	+
Interpretation	no evidence of infection	no evidence of infection	+

## SZÚ – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

# Chlamydia

SZÚ – 08.2025

*Chlamydia pneumoniae*



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+
IgA	negative	negative	+
IgA	negative	negative	+
IgA	negative	negative	+
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+

*Chlamydia trachomatis*



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+
IgA	negative	negative	+
IgA	negative	negative	+
IgA	negative	negative	+
IgG	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+

## INSTAND – 11.2025

### *Chlamydia pneumoniae*



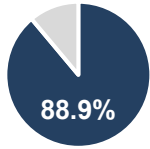
<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+
Interpretation	acute infection, late infection	acute infection	+
Interpretation	no evidence of infection	no evidence of infection	+

### *Chlamydia trachomatis*



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive, borderline, negative	negative	+
IgA	negative	negative	+
IgG	positive, borderline	positive	+
IgG	negative	negative	+
Interpretation	acute infection, late infection	late infection	+
Interpretation	no evidence of infection	no evidence of infection	+

## LABQUALITY – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	positive	negative	-
IgG	positive	positive	+
Interpretation*	the sample was not evaluated		
Interpretation*	the sample was not evaluated		
Interpretation	late infection	late infection	+

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

# Cytomegalovirus (CMV)

## INSTAND – 07.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

## LABQUALITY – 09.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	positive	positive	+
Interpretation	late infection	late infection	+
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	acute infection	acute infection	+

## CAP – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgM	negative	negative	+

# Epstein-Barr virus (EBV)

## INSTAND – 07.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA*		the sample was not evaluated	
IgA*		the sample was not evaluated	
IgG	positive	positive	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+
Interpretation	late infection	late infection	+
Interpretation	late infection	late infection	+

## LABQUALITY – 10.2025

EBV EBNA



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	negative	negative	+
IgG	positive	positive	+

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

### EBV VCA



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+

### Clinical evaluation



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	acute infection	acute infection	+
Interpretation	late infection	late infection	+

## CAP – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG*		the sample was not evaluated	
IgM*		the sample was not evaluated	

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

## INSTAND – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA*		the sample was not evaluated	
IgA*		the sample was not evaluated	
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+
Interpretation	acute infection	acute infection	+
Interpretation	late infection	late infection	+

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

# Helicobacter

## LABQUALITY – 10.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
Interpretation	infection confirmed	infection confirmed	+
Interpretation	infection confirmed	infection confirmed	+

## INSTAND – 11.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	borderline, negative	negative	+
IgA	positive, borderline, negative	negative	+
IgG	negative	negative	+
IgG	positive	positive	+
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	infection confirmed	infection confirmed	+

## CAP – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA*	the sample was not evaluated		
IgG	positive	positive	+

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

# Mycoplasma

## INSTAND – 11.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive, borderline, negative	negative	+
IgG	negative	negative	+
IgG	positive, borderline	positive	+
IgM	negative	negative	+
IgM	positive, borderline, negative	positive	+
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	acute infection, late infection	acute infection	+

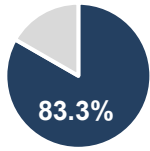
## CAP – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG*	the sample was not evaluated		
IgM*	the sample was not evaluated		

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

## LABQUALITY – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG*	the sample was not evaluated		
IgM	negative	negative	+
IgM	positive	borderline	-
Interpretation	late infection	late infection	+
Interpretation	acute infection	acute infection	+

\* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

# Toxoplasma

## LABQUALITY – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+
Interpretation	late infection	late infection	+
Interpretation	late infection	late infection	+
Interpretation	no evidence of infection	no evidence of infection	+

## CAP – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgM	negative	negative	+

# Treponema

**SZÚ – 07.2025**



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+

# Yersinia

SZÚ – 08.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+

# **Immunology & Autoimmune Diseases**

# Antineutrophil Cytoplasmic Antibodies (ANCA)

## INSTAND – 10.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
anti-GBM	negative	negative	+
anti-GBM	negative	negative	+
anti-MPO	negative	negative	+
anti-MPO	positive	positive	+
anti-PR3	positive	positive	+
anti-PR3	negative	negative	+

## SEKK – 11.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
ANCA	positive	positive	+
ANCA	negative	negative	+
GBM	positive	positive	+
GBM	negative	negative	+

# Antinuclear antibodies (ANA)

SEKK – 10.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-ds-DNA	negative	negative	+
Anti-ds-DNA	positive	positive	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/SS-A/Ro-60	positive	positive	+
Anti-ENA/SS-A/Ro-60	negative	negative	+
Anti-ENA/SS-B/La	positive	positive	+
Anti-ENA/SS-B/La	negative	negative	+

## INSTAND – 10.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
anti-DFS70	negative	negative	+
anti-DFS70	negative	negative	+
anti-dsDNA	positive	positive	+
anti-dsDNA	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/SS-A/Ro 52kD	positive	positive	+
Anti-ENA/SS-A/Ro 52kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	positive	positive	+
Anti-ENA/SS-A/Ro 60kD	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-PM/Scl	negative	negative	+
Anti-PM/Scl	negative	negative	+
Anti-Sm(D)	negative	negative	+
Anti-Sm(D)	negative	negative	+
Anti Sm(B´B)	negative	negative	+
Anti Sm(B´B)	negative	negative	+
Anti-SS-A/Ro	positive	positive	+
Anti-SS-A/Ro	negative	negative	+

## CAP – 12.2025



<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti Jo-1	negative	negative	+
Anti Scl-70	negative	negative	+