

Quality Assessment Schemes Program

2023



MICROBIOLOGY PROGRAMS

ADENOVIRUS

ADE

2 liquid samples (minimum 0,3 mL) of human plasma.

2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Adenovirus

ASPERGILLUS FUMIGATUS

ASF

2 liquid samples (minimum 0,3 mL) of simulated bronchoalveolar lavage (BAL) fluid or serum.

2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG, IgM and total antibodies against Aspergillus fumigatus

ASPERGILLUS GALACTOMANNAN ANTIGEN

ASPAG

2 liquid samples (minimum 0,5 mL) of simulated bronchoalveolar lavage (BAL) fluid or serum.

2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Aspergillus Antigen (Galactomannan)

BACTERIOLOGY

BAC-C, BAC-E

4 lyophilized samples (pure strains and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST guidelines (BAC-E) or according to CLSI guidelines (BAC-C)
4 surveys per year. (Simulated) clinical information about the sample type is provided.

Analytical parameters:

Identification (genus and species)
Antibiotic susceptibility testing (according to EUCAST or CLSI guidelines)

BORRELIA

BOR

2 liquid samples (minimum 0.3 mL) of human plasma.

2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Borrelia burgdorferi

BORRELIA IgG-ANTIBODY INDEX (AI)**BOR-G-AI**

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.

2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Borrelia IgG-antibody index (AI), qualitative and quantitative

BORRELIA IgM-ANTIBODY INDEX (AI)**BOR-M-AI**

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.

2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Borrelia IgM-antibody index (AI), qualitative and quantitative

BRUCELLA**BRU**

2 liquid samples (minimum 0,3 mL) of human plasma.

2 surveys per year.

Analytical parameters:

IgA, IgG and IgM antibodies against Brucella

agglutinating antibodies against Brucella

CHAGAS**CHA**

2 liquid samples (minimum 0,3 mL) of human plasma.

2 surveys per year.

Analytical parameters:

IgG antibodies against Trypanosoma cruzi

CHIKUNGUNYA VIRUS**CHIKV**

2 liquid samples (minimum 0,3 mL) of human plasma.

2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Chikungunya Virus

CHLAMYDIA TRACHOMATIS

CHT

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Chlamydia trachomatis

COXSACKIEVIRUS

COX

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Coxsackievirus

DENGUE VIRUS

DENV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Dengue Virus

ECHO-VIRUS

ECH

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against ECHO-Virus

ENTEROVIRUS

ENT

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Enterovirus

EPSTEIN-BARR VIRUS

EBV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-EBV VCA IgG + total

anti-EBV EBNA-1 IgG + total

anti-EBV VCA IgM

HEPATITIS A VIRUS

HAV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HAV IgG + total

anti-HAV IgM

HEPATITIS B VIRUS

HBV

2 liquid samples (minimum 1 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HBs (qual. and quant.*)
anti-HBc IgG + total

anti-HBe
HBsAg (qual. and quant.)

HBeAg
anti-HBc IgM

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

HEPATITIS E VIRUS

HEV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HEV IgG + total

anti-HEV IgM

HIV ANTIBODIES AND ANTIGEN

HIV

2 liquid samples (minimum 0,3 mL) of human plasma.
4 surveys per year.

Analytical parameters:

anti-HIV 1/2 antibodies

HIV p24 Antigen*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

HTLV I/II**HTL**

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

anti-HTLV I/II

INFECTIOUS DISEASE COMBINATION CONTROL**INF**

2 liquid samples (minimum 0,5 mL) of human plasma. 4 surveys per year (INF4).
4 liquid samples (minimum 0,5 mL) of human plasma. 4 surveys per year (INF4x4).
2 liquid samples (minimum 0,5 mL) of human plasma. 2 surveys per year (INF2).

Analytical parameters:anti-HIV 1/2 / p24 Ag
anti-HCV

anti-HBc

HBsAg

INFLUENZA A VIRUS**INA**

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza A Virus

INFLUENZA B VIRUS**INB**

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza B Virus

LEGIONELLA PNEUMOPHILA ANTIBODIES**LPAB**

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG, IgM and total antibodies against Legionella pneumophila

New
Program

LEPTOSPIRA

LEP

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Leptospira agglutinating antibodies against Leptospira*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

MALARIA MICROSCOPY

MALM

2 slides of stained smears.
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Malaria Parasite Detection Stage Identification
Species Identification Quantification of Plasmodium falciparum

MEASLES

MEA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Measles Virus

PARAINFLUENZA VIRUS

PIN

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Parainfluenza Virus

PARVOVIRUS B19

PAR

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Parvovirus B19

RESPIRATORY SYNCYTIAL VIRUS

RSV

2 liquid samples (minimum 0,3 mL) of human plasma.

2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgG, IgM and IgA antibodies against Respiratory Syncytial Virus (RSV)

SARS-CoV-2 ANTIBODIES

COVID

4 liquid samples (minimum 0,3 mL) of human plasma.

4 surveys per year.

Analytical parameters:

IgA, IgG, IgM and antibodies total against SARS-CoV-2 (qual. and quant.)
neutralizing antibodies against SARS-CoV-2 (qual. and quant.)
anti-N IgG (qual. and quant.)
anti-S IgG (qual. and quant.)
anti-RBD IgG (qual. and quant.)
anti-N total antibodies (qual. and quant.)
anti-S total antibodies (qual. and quant.)
anti-RBD total antibodies (qual. and quant.)

SARS-CoV-2 ANTIGEN

COVAG

3 liquid or lyophilized samples (minimum 0,3 mL) simulating swab specimens (e.g. oropharyngeal, nasopharyngeal, nasal etc.).

4 surveys per year. SARS-CoV-2 antigen positive samples contain inactivated whole virus.

Analytical parameters:

SARS-CoV-2 Antigen qualitative and quantitative

SYPHILIS

SYP

2 liquid samples (1 mL) of human plasma. 4 surveys per year (SYP4) in quarterly program, 2 surveys per year (SYP2) in semi-annual program.

Analytical parameters:

anti-Treponema pallidum antibodies (qualitative)
IgG and IgM antibodies against Treponema pallidum (qualitative)*
IgG and IgM, antibodies total against Treponema pallidum (semi-quantitative)*
IgG and IgM, antibodies total against Treponema pallidum (quantitative)*
Non-treponemal Lipoid antibodies (RPR/VDRL Tests) (qualitative)
Non-treponemal Lipoid antibodies (RPR/VDRL Tests Titers) (semi-quantitative)*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

TBEV IgG-ANTIBODY INDEX (AI)**TBEV-G-AI**

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample of the Tick-borne encephalitis virus antibody index survey.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

TBEV IgG-antibody index (AI)

TBEV IgM-ANTIBODY INDEX (AI)**TBEV-M-AI**

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample of the Tick-borne encephalitis virus antibody index survey.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

TBEV IgM-antibody index (AI)

ToRCH**TORCH**

2 liquid samples (minimum 1 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-CMV IgG (qual. and quant.*)	anti-HSV 1 IgG	anti-Rubella IgM
anti-CMV IgM	anti-HSV 2 IgG	anti-Toxoplasma gondii IgG
anti-HSV 1/2 IgG (qual. and quant.*)	anti-HSV 1 IgM	(qual. and quant.*)
anti-HSV 1/2 IgM	anti-HSV 2 IgM	anti-Toxoplasma gondii IgM
	anti-Rubella IgG (qual. and quant.*)	

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

VARICELLA ZOSTER VIRUS**VZV**

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Varicella Zoster Virus (VZV), qual. and quant*

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

WEST NILE VIRUS**WNV**

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against West Nile Virus

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Zika Virus