

IVD

Instructions for use (English)

1 Purpose

Control sera are test-independent positive or negative controls, which can be used in combination with all respective serological MIKROGEN test systems of the product lines *recomLine*, *recomBlot*, *recomWell* and *recomBead*.

2 Intended use

Test-independent control sera are intended for use in quality assurance of analytical laboratories. Positive control sera with a positive overall result or negative control sera with a negative overall result confirm the correct processing of the respective serological MIKROGEN test. Test evaluation does not require the use of test-independent control sera.

3 Test principle

Test-independent control sera are of human origin and are used and evaluated in the test procedure the same way as patient samples. Test procedure and evaluation of results are carried out according to the instructions for use of the respective MIKROGEN test system. Positive control sera show a positive overall result, negative control sera show a negative overall result.

4 Reagents

4.1 Package content

4.1.1 Positive control serum

CONTROL +	200 µl positive control serum of human origin For specificity see label Contains preservative: MIT (0.1%) and oxyprion (0.1%)
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4.1.2 Negative control serum

CONTROL -	200 µl negative control serum of human origin For specificity see label Contains preservative: MIT (0.1%) and oxyprion (0.1%)
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4.2 Additionally required reagents, materials and equipment

This information is described in the instructions for use of the respective MIKROGEN test.

5 Shelf life and handling

- ☞ Store control sera at +2 to +8 °C before and after use, **do not freeze**.
- ☞ Bring control sera to room temperature (+18 to +25 °C) for at least 30 minutes before use. The test procedure is carried out at room temperature.
- ☞ Mix control sera well, avoid foam formation.
- ☞ Tubes have to be opened just before use and closed immediately after use.
- ☞ The tubes are marked with an expiry date. If the expiry date has been exceeded, reliable quality cannot be guaranteed.
- ☞ Test batches with control sera and the respective MIKROGEN tests have to be handled by trained and authorised staff only.
- ☞ In case of changing product or instructions for use by the user, the application may not fulfil the purpose as specified by MIKROGEN.
- ☞ Control sera are part of MIKROGEN product lines and are to be used in combination with MIKROGEN products.
- ☞ Cross-contamination of control sera, patient samples or conjugates may lead to inaccurate test results. Carefully add control sera, patient samples, test strips and conjugate solution. Assure that incubation solutions do not flow over into other wells.

6 Warnings and precautions

- ☞ Only use for *in vitro* diagnostics.
- ☞ All control sera must be treated as potentially infectious.
- ☞ To prepare the control material, blood is used from donors who have been confirmed to have no antibodies to HIV 1/2 or HCV and no HBs antigen. Because an infection cannot be reliably ruled out, however, the control material must be handled with the same care as a patient sample.
- ☞ Suitable disposable gloves must be worn throughout the entire test procedure.
- ☞ The reagents contain MIT (methylisothiazolone) and oxyprion as preservatives. Avoid contact with skin or mucosa.
- ☞ All removed liquids have to be collected. All reagents and materials contaminated with potentially infectious samples must be treated with disinfectants or discarded according to the hygiene regulations. Keep the conditions given by the manufacturer concerning concentration of reagents and incubation periods.
- ☞ Do not substitute or mix control sera with reagents from other manufacturers.
- ☞ Carefully read the instructions for use before handling control sera.

7 Test procedure

Control sera are diluted like patient samples in the test procedure. Test evaluation and interpretation have to be done according to the instructions for use of the respective test system and in consideration of possible devices used and their instructions.

8 Limitations of the method - restrictions




Control sera are used for internal quality assurance only. They are not required for the evaluation of the corresponding test. The positive control serum must show a positive overall result. The negative control serum must show a negative overall result.

9 Explanation of symbols

CONT	Contents, includes
CONTROL - IgG	Negative control serum IgG
CONTROL - IgG/IgM	Negative control serum IgG and IgM
CONTROL - IgG/IgA	Negative control serum IgG and IgA
CONTROL - IgG/MA	Negative control serum IgG, IgM and IgA
CONTROL + IgG	Positive control serum IgG
CONTROL + IgM	Positive control serum IgM
CONTROL + IgA	Positive control serum IgA
IVD	In vitro diagnostic medical device
LOT	Batch/version number
REF	Order number
	Use by Expiry date
	Store at x°C to y°C
	Manufacturer

10 Manufacturer and version information

Control sera (test-independent)	Item number
ANA/ENA IgG negative control serum	26013
ANA/ENA IgG positive control serum	26017
B. pertussis IgA positive control serum	25718
B. pertussis IgG positive control serum	25717
B. pertussis IgG/IgA negative control serum	25713
Borrelia IgG positive control serum	24227
Borrelia IgG/IgM negative control serum	24223
Borrelia IgM positive control serum	24219
Campylobacter IgA positive control serum	26219
Campylobacter IgG positive control serum	26217
Campylobacter IgG/IgA negative control serum	26213
Chlamydia IgA positive control serum (C. pneumoniae, C. trachomatis)	26119
Chlamydia IgG positive control serum (C. pneumoniae, C. trachomatis)	26117
Chlamydia IgG/IgA negative control serum	26113
CMV IgG positive control serum	25517
CMV IgG/IgM negative control serum	25513
CMV IgM positive control serum	25518
EBV IgA positive control serum	24519
EBV IgG positive control serum	24507
EBV IgG/IgM/IgA negative control serum	24513
EBV IgM positive control serum	24518
Hantavirus IgG positive control serum	27617
Hantavirus IgG/IgM negative control serum	27613
Hantavirus IgM positive control serum	27618
Helicobacter IgA positive control serum	24729
Helicobacter IgG positive control serum	24727
Helicobacter IgG/IgA negative control serum	24724
HEV IgG positive control serum	25017
HEV IgG/IgM negative control serum	25013
HEV IgM positive control serum	25018
HSV IgG negative control serum	25313
HSV IgG positive control serum	25317
Parvovirus IgG positive control serum	24417
Parvovirus IgG/IgM negative control serum	24403
Parvovirus IgM positive control serum	24418
Rubella IgG positive control serum	24917
SARS-CoV-2 IgG negative control serum	27313
SARS-CoV-2 IgG positive control serum	27317
Toxoplasma IgG positive control serum	25917
Toxoplasma IgG/IgM negative control serum	25913
Toxoplasma IgM positive control serum	25918
Treponema IgG positive control serum	25117
Treponema IgG/IgM negative control serum	25113
Treponema IgM positive control serum	25118
Yersinia IgA positive control serum	24619
Yersinia IgG positive control serum	24617
Yersinia IgG/IgM/IgA negative control serum	24613
Yersinia IgM positive control serum	24618

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	MIKROGEN GmbH Anna-Sigmund-Str. 10 82061 Neuried Germany Tel. +49 89 54801-0 Fax +49 89 54801-100 E-mail mikrogen@mikrogen.de Internet www.mikrogen.de	
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