Control sera (test-independent)

**IVD**

Instructions for use (English)

1 **Purpose**
Test-independent control sera are qualitative control reagents with negative or positive target value respectively. They are intended for use in serological MIKROGEN tests.

2 **Intended use**
Test-independent control sera are intended for use in quality assurance of analytical laboratories. Test evaluation does not require the use of test-independent control sera.

Positive control sera confirm the presence of specific antibodies, while negative control sera confirm the absence of specific antibodies.

3 **Test principle**
Test-independent control sera are of human origin and are used and evaluated in the test procedure the same 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 1 | 200 µl positive control serum of human origin (ready to use) For specificity see label Contains preservative: MIT (0.1%) and oxypyrion (0.1%) |

4.1.2 Negative control serum

| CONTROL 1 | 200 µl negative control serum of human origin (ready to use) For specificity see label Contains preservative: MIT (0.1%) and oxypyrion (0.1%) |

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 instruction 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. Carefully remove liquids.

6 **Warnings and precautions**
- For in vitro use only.
- All control sera must be treated as potentially infectious.
- Blood samples used for production of control sera are negative tested for antibodies against HIV 1/2, HCV and HBsAg. Nevertheless control sera must be handled with care as infection cannot be excluded with absolute certainty.
- Suitable disposable gloves must be worn throughout the entire test procedure.
- The reagents contain MIT (methylisothiazolone) and oxypyrion 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 your 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**
During the test control sera are handled same as patient samples. Test evaluation and interpretation has to be done according to the instructions for use of the respective test system.

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**

<table>
<thead>
<tr>
<th>CONT</th>
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<tbody>
<tr>
<td>CONTROL 1</td>
<td>Negative control serum IgG</td>
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<tr>
<td>CONTROL 1</td>
<td>Negative control serum IgG and IgM</td>
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<td>CONTROL 1</td>
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<td>In vitro diagnostic medical device</td>
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<td>Batch number</td>
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- Store at x°C to y°C
- Best before Expiry date
- Manufacturer

GAXXKS002EN_2013-07 1/2
## Manufacturer and version information

<table>
<thead>
<tr>
<th>Control sera (test-independent)</th>
<th>For item number, see product catalogue</th>
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</thead>
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<tr>
<td>Instructions for use</td>
<td>GAXXKS002EN</td>
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<tr>
<td>valid from</td>
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</tr>
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</table>

MIKROGEN GmbH
Floriansbogen 2-4
82061 Neuried
Germany
Tel. +49 89 54801-0
Fax +49 89 54801-100
E-mail mikrogen@mikrogen.de
Internet www.mikrogen.de

Rubella, toxoplasma, chlamydia and CMV sera

Other sera

![CE标志](GAXXKS002EN)