

**IVD**

Instructions for use (English)

**1 Intended purpose**

The recomCLIA Sample Diluent A is designed for diluting human serum and plasma (EDTA, heparin, citrate, CPD).

The recomCLIA Sample Diluent A can only be used with the corresponding recomCLIA test kits on the KleeYa® Instrument, STRATEC SE, by trained professional users in a suitable laboratory.

**2 Test principle**

The recomCLIA Sample Diluent A is specifically designed for use with the corresponding recomCLIA tests from MIKROGEN that require this sample diluent, as indicated in their instructions for use.

The recomCLIA Sample Diluent A enables test-specific, optimized sample dilution to achieve optimal test performance. Sample dilutions are automatically performed during test-specific assay runs on the KleeYa® Instrument.

The recomCLIA Sample Diluent A can be used batch-independently in combination with the corresponding recomCLIA tests. The same recomCLIA Sample Diluent A reagent cartridge allows parallel sample processing for multiple tests.

**3 Reagents**

**3.1 Package contents**

<b>RGT CART</b>	<b>2 reagent cartridges</b> ready-to-use
<b>DILUBUF</b>	each reagent cartridge contains: <b>4 x 10 ml recomCLIA Dilution Buffer A</b> ready-to-use contains preservative: Methylisothiazolinone (MIT) (0.01%) contains ingredient of animal origin: Bovine serum albumin (BSA) (1%)
<b>INSTRU</b>	<b>1 instructions for use</b>

The corresponding recomCLIA test specifies the number of samples that can be diluted using a single package of recomCLIA Sample Diluent A.

recomCLIA test	Number of sample dilutions
recomCLIA Borrelia IgM (article no. 74205)	2 x 200
recomCLIA HEV IgM (article no. 75005)	2 x 200

**3.2 Additionally required reagents, materials and equipment**

- Corresponding recomCLIA test kit, which requires recomCLIA Sample Diluent A
- Fully automated KleeYa® Instrument, STRATEC SE (MIKROGEN article no. 31349), with all required materials and reagents for proper operation: Refer to the instructions for use of the corresponding recomCLIA test, which requires recomCLIA Sample Diluent A.

**Optional materials:**

Refer to the instructions for use of the corresponding recomCLIA test, which requires recomCLIA Sample Diluent A.

**4 Shelf life and handling**

- Store reagents at +2 °C to +8 °C before and after use, **do not freeze**.
- Shelf life:

Shelf life of reagent cartridge	
Unopened at +2 °C to +8 °C	Until the stated expiry date
In-use stability* +2 °C to +8 °C	3 months
On-board stability +10 °C to +12 °C	28 days

\*In-use stability starts after first use of the reagent cartridge.

After the expiry date, the quality of the reagent cartridge can no longer be guaranteed.

- The component recomCLIA Dilution Buffer A must remain in the reagent cartridge and must not be removed.
- recomCLIA Sample Diluent A is required for the use of the corresponding recomCLIA test kits.
- recomCLIA Sample Diluent A must only be used by a trained and authorised professional user.

- In the event of significant changes to the product or modifications to its use by the user, the application may no longer align with the intended purpose outlined by MIKROGEN.

**5 Warnings and safety precautions**

- For *in vitro* diagnostic use only.
- All blood products must be treated as potentially infectious.
- Suitable disposable gloves must be worn throughout the entire test procedure.
- Safety notes for reagents containing hazardous substances:

RGT CART	
	Contains ingredient of animal origin
	H317: May cause an allergic skin reaction

Further information can be found in the respective safety data sheets available from MIKROGEN.

Due to space constraints, the hazard symbols of individual components cannot always be affixed to their corresponding labels. For the hazard symbols of these components, please refer to the nearest larger outer packaging or their corresponding instructions for use.

- All fluids for disposal must be collected. All collecting containers must contain suitable disinfectants for the inactivation of human pathogens. All reagents and materials contaminated with potentially infectious samples must be treated with suitable disinfectants or disposed of in accordance with applicable hygiene regulations. The concentrations and exposure times specified by the manufacturer must be strictly followed.
- All waste must be disposed of in accordance with local guidelines.
- The reagents must not be substituted or mixed with those from other manufacturers.
- The entire instructions for use document must be read before performing the test. Follow the instructions exactly as described. Any deviation from the specified test protocol may lead to incorrect results.
- Any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.
- The reagent contains the antimicrobial agent MIT (methylisothiazolinone). Avoid contact with the skin or mucous membranes.

**6 Sampling and preparation**

**Preparation of recomCLIA Dilution Buffer A**

recomCLIA Dilution Buffer A is a ready-to-use solution. No preparation of working solution is required.

**7 Test procedure**

For detailed information on the use of the recomCLIA Sample Diluent A, refer to the instructions for use of the corresponding recomCLIA test, which requires recomCLIA Sample Diluent A.

**8 Results**

For detailed information on result interpretation, refer to the instructions for use of the corresponding recomCLIA test, which requires recomCLIA Sample Diluent A.

**9 Limits of the method, restrictions**

recomCLIA Sample Diluent A is intended exclusively for use with the corresponding recomCLIA tests from MIKROGEN as specified in the instructions for use of the respective tests.

**10 Performance characteristics**

For detailed information on performance characteristics, refer to the instructions for use of the corresponding recomCLIA test, which requires recomCLIA Sample Diluent A.

### 11 Explanation of symbols

	Reagent cartridge
	recomCLIA Dilution Buffer A
	Instructions for use
	Follow the instructions for use
	<i>In vitro</i> diagnostic medical device
	Order number
	Batch/version number
	Contents, includes
	Manufacturer
	Use by Expiry date
	Store between x °C and y °C
	Do not freeze
	Contains ingredients of animal origin
	Warning

### 12 Manufacturer and version data

<b>recomCLIA Sample Diluent A</b>		Article no. <b>10120</b>
<b>Instructions for use</b> valid from		GARCSDA001EN 2025-02
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