

Substrat / Substrate LINE

REF: WE200.02

SUBS RTU

Gebrauchsanweisung / Instruction For Use

NUR ZUR IN VITRO DIAGNOSTIK / FOR IN VITRO DIAGNOSTICS ONLY
Nur zur professionellen Anwendung / For professional use only

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1. INTENDED USE

SUBS	RTU	
Detection / Measurement		For use with LINE products from Virotech Diagnostics
Function		Reagent for colour development of the LINE test sample by enzyme activity.
Specific Information about	n/a	
Automated	n/a	
Type	n/a	
Specimen		Human Serum or Plasma / CSF
Testing Population	n/a	
Intended User		Specialised personnel in laboratories

2. TEST PRINCIPLE

When performing the LINE, after addition of

SUBS **RTU**

a blue dye is produced by enzyme activity (peroxidase), provided that suitable antibodies have bound to the antigen fixed on the nitrocellulose test strip.

3. PACKAGE CONTENTS

SUBS **RTU**

57ml substrate (BCIP/NBT), ready-to-use

Quality Control Certificate

Single component note

The SDS is available at: www.virotechdiagnostics.com

4. STORAGE AND STABILITY OF THE READY-TO-USE COMPONENT

SUBS **RTU**

Store at 2-8°C. The shelf life of the reagent is stated on the respective label. After opening, the reagent is stable for three months. The substrate must be stored in the dark. If the substrate develops colour, discard it.

5. PREPARATION OF THE REAGENT

Before use, bring the reagent to room temperature (20-25°C) and mix well by inverting several times. It is ready-to-use.

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6. SAMPLE DILUTION, PROCEDURE, INTERPRETATION OF RESULTS AND PERFORMANCE CHARACTERISTICS

The reagent is used according to the instructions for use of the LINE products of Virotech Diagnostics directly.

Attention: To avoid microbial contamination, the following points must be observed:

- Use only clean pipette tips, dispensers, and laboratory materials
- Do not return residual liquid to original bottle
- Do not change the lid
- Immediately reseal bottles after opening and removal
- Check reagents for contamination when used again
- Do not freeze the components of the kit and protect them from excessive heat during storage
- Do not use the reagent after the expiry date has passed
- The BCIP/ NBT substrate is light-sensitive and must be stored in the dark

The further performance and evaluation of the test is carried out according to the information in the instructions for use of the LINE product. The respective performance characteristics of the product can be found here as well.

7. QUALITY CONTROL

In accordance with Virotech Diagnostics GmbH's ISO-certified quality management system, each batch of

SUBS RTU

is tested against predetermined specifications to ensure consistent product quality.

8. LIMIT

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must not be mixed with or substituted by reagents of other manufacturers.

9. WARNINGS AND PRECAUTIONS






- In vitro diagnostic agent for professional use.
- The information, safety measures and warnings in the instructions for use must be strictly followed. In case of deviation, the user is liable for any incorrect results.
- Wearing a lab coat, disposable gloves and protective goggles is recommended during use. If contact with reagent nevertheless occurs, the relevant Safety Data Sheet (SDS) should be consulted.
- All materials of human or animal origin are to be considered potentially infectious and treated accordingly.
- Do not use after expiry date.

10. DISPOSAL CONSIDERATIONS









Information on the Reagents

Chemicals and preparations, as well as their containers, are generally hazardous waste. Their disposal is subject to national waste legislation and regulations. The competent authority provides information on the disposal of hazardous waste.

Information on Packaging Materials

 PAP 22	 Plastics HDPE 2	 PP 5	 LDPE 4	 Glass GL 72
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SYMBOL KEY

	Manufacturer
	In vitro diagnostics
	Production lot number
	Usable until
	Temperature limit
	CE marking
	Article number
 Hinweis auf eIFU	Follow the Instruction For Use http://ifudownload.virotechdiagnostics.com