

**Substrat / Substrate LINE**

**REF: WE200.02**

<b>SUBS</b>	<b>RTU</b>
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## **Instruction For Use**

**FOR IN VITRO DIAGNOSTICS ONLY**  
**For professional use only**

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## 1. INTENDED USE

<b>SUBS RTU</b>	
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	n/a
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  
Hazard information  
The Safety Data Sheet (SDS) is available at: [www.virotechdiagnostics.com](http://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. **SUBS RTU** is ready-to-use.

## 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

**SUBS** **RTU** 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 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
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## 11. 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 <a href="http://ifudownload.virotechdiagnostics.com">http://ifudownload.virotechdiagnostics.com</a>

## 12. CHANGE HISTORY

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<i>Revision</i>	<i>Section</i>	<i>Change</i>
<i>Rev 01</i>	<i>1-11</i>	<i>-</i>
<i>Rev 02</i>	<i>1-11</i>	<i>Editorial changes</i>
<i>Rev 03</i>	<i>1-12</i>	<i>Editorial changes, correction of disposal instructions, numbering of chapters added, change history created</i>