

TMB-Substrat / Substrate ELISA

REF: 151101

SUBS

Instruction For Use

FOR IN VITRO DIAGNOSTICS ONLY
For professional use only

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1. INTENDED PURPOSE

SUBS	
Detection/Measurement	for use with ELISA products from Virotech Diagnostics
Function	reagent for colour development of the ELISA test sample by enzyme activity
Classification	Class A
Automation	n/a
Type	n/a
Specimen	n/a
Testing population	n/a
Intended user	Specialised personnel in laboratories

2. TEST PRINCIPLE

When performing the ELISA, a blue dye is produced by enzyme activity (peroxidase) after addition of the **SUBS**, provided that suitable antibodies have bound to the antigen fixed on the microplate.

3. PACKAGE CONTENTS

SUBS 11ml TMB-Substrat/Substrate ELISA (3,3',5,5' Tetramethylbenzidin), ready-to-use / pH 5-5,1

Quality Control Certificate

Hazard information

The Safety Data Sheet (SDS) is available at: www.virotechdiagnostics.com

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

Store **SUBS** 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 TMB substrate must be stored in the dark. If the substrate develops colour, it must be discarded.

5. PREPARATION OF THE REAGENT

Before use, bring the reagent to room temperature (18-25°C) and mix well by inverting several times. **SUBS** 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 ELISA products of Virotech Diagnostics.

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
- Take only the amount of the ready-to-use TMB Substrate required for the preparation.
- If the substrate develops colour, it must be discarded
- Too much TMB Substrate must not be recycled but discarded.

The further performance and evaluation of the test is carried out according to the information in the instructions for use of the ELISA 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** is tested against predetermined specifications to ensure consistent product quality.

8. LIMIT

SUBS 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









Reagent

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 http://ifudownload.virotechdiagnostics.com

12. CHANGE HISTORY

<i>Revision</i>	<i>Section</i>	<i>Change</i>
<i>Rev 01</i>	<i>1-11</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>