TMB-Substrat / Substrate ELISA REF: 151101

SUBS

Instruction For Use

FOR IN VITRO DIAGNOSTICS ONLY For professional use only

Virotech Diagnostics GmbH Waldstrasse 23 A2 63128 Dietzenbach, Germany

Tel.: +49(0)6074-23698-0 Fax.: +49(0)6074-23698-900

www.goldstandarddiagnostics.com



1. **INTENDED PURPOSE**

SUBS			
Detection/Measurement	urement 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		
Туре	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

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.

PREPARATION OF THE REAGENT 5.

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 RESULSTS 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.

QUALITY CONTROL 7.

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.

LIMIT 8.

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

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9. **WARNINGS AND PRECAUTIONS**

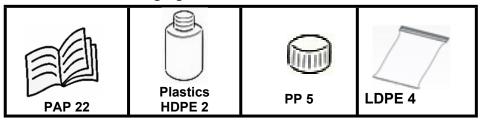
- In vitro diagnostic agent for professional use.
- The information, safety measures and warnings in the instructions for use must be strictly followed. In case of deviation, the user is liable for any incorrect results.
- Wearing a lab coat, disposable gloves and protective goggles is recommended during 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



11. SYMBOL KEY

•••	Manufacturer
IVD	In vitro diagnostics
LOT	Production lot number
\square	Usable until
1	Temperature limit
(€	CE marking
REF	Article number
Hinweis auf elFU	Follow the Instruction For Use http://ifudownload.virotechdiagnostics.com

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12. CHANGE HISTORY

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

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