

Konjugat/Conjugate (anti-human) ELISA **CONJ**

REF: 131101

131201

131301

131601

CONJ	IgG
CONJ	IgM
CONJ	IgA
CONJ	IgA2

Instruction For Use

FOR IN VITRO DIAGNOSTICS ONLY
For professional use only



Gold Standard Diagnostics Frankfurt GmbH

Waldstrasse 23 A6

63128 Dietzenbach, Germany

Tel.: +49 6074 23698-0

Fax: +49 6074 23698-900

Email: info.frankfurt@eu.goldstandarddiagnostics.com

Website: clinical.goldstandarddiagnostics.com



1. INTENDED PURPOSE

CONJ	
Detection/Measurement	For use with VIROTECH ELISA products
Function	Reagent contains an enzyme conjugate that binds to the immune complex of antibody and antigen fixed in the MTP
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, the CONJ binds to the complex of antibody and antigen bound in the microplate (MTP) after addition, provided that matching antibodies had bound to the antigen fixed on the microplate in the previous step.

3. PACKAGE CONTENTS

CONJ 11ml Konjugat/Conjugate (anti-human) ELISA, with protein stabilisers and preservative, ready-to-use

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 CONJ 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 CONJ must be stored in the dark. Too much CONJ removed must not be returned.

5. PREPARATION OF THE REAGENT

Before use, bring the reagent to room temperature (18-25°C) and mix well by inverting several times. CONJ 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 VIROTECH ELISA products.

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
- Remove only the amount of ready-to-use CONJ required for the preparation
- Too much CONJ must not be returned 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 manufacturer's ISO-certified quality management system, each batch of CONJ is tested against predetermined specifications to ensure consistent product quality.

8. LIMIT

CONJ 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
---	---	---	--

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>1-11</i>	<i>Veterinary conjugates removed, Editorial changes</i>
<i>Rev 04</i>	<i>1-11</i>	<i>SARS conjugates removed</i>
<i>Rev 05</i>	<i>1-12</i>	<i>Editorial changes, numbering of chapters added, change history created</i>
<i>Rev 06</i>	<i>1-12</i>	<i>Change of manufacturer and adaptation of address</i>