

Immunoenzymatic method for qualitative determination of total antibodies anti-SARS-CoV-2 virus in human serum, using a disposable device applied on the Chorus and Chorus TRIO instruments. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2; a serological assay help to identify individuals exposed to the virus and will be useful to decide the extent of containment measures in COVID-19 disease .

Each package contains 6 bags with 6 devices each (sufficient for the total of 36 determinations).

Each kit consists of:

DEVICE

Position 8: Space for application of bar code label

Position 7: Empty

Position 6: MICROPLATE WELL Coated with inactivated native antigen

Position 5: MICROPLATE WELL Not coated

Position 4: TMB SUBSTRATE 0.40 ml

The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulation 1907/2006, is not necessary to develop a material safety data sheet.

Contents: Tetramethylbenzidine 0.26 mg/ml and H₂O₂ 0.01% stabilized in 0.05 mol/L citrate buffer (pH 3.8)

Position 3: EMPTY WELL

Position 2: CONJUGATE 0.30 ml

The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulation 1907/2006, is not necessary to develop a material safety data sheet.

Contents: Anti-human SARS-CoV-2 antibodies labelled with horseradish peroxidase, in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.

Position 1: EMPTY WELL

In which the sample is transferred

CALIBRATOR

CALIBRATOR 0.425 ml

Contents: Protein solution containing specific antibodies capable of binding the antigen present on the microplate, and preservative Liquid, ready for use.

POSITIVE CONTROL

CONTROL + 0.425 ml

Contents: Protein solution containing specific antibodies capable of binding the antigen present on the microplate, and preservative Liquid, ready for use.

The mixtures are not classified as dangerous according to EC Regulation 1272/2008 and do not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For these mixtures, according to EC Regulation 1907/2006, is not necessary to develop a material safety data sheet.

The safety data sheet of the product is, nevertheless, reported below.



MATERIAL SAFETY DATA SHEET

CHORUS SARS-CoV-2 Screen Serum

(According to Regulation (EC) No. 1907/2006)

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIERS

Product name: CHORUS SARS-CoV-2 Screen Serum
Product code: 81406
Brand: DIESE

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCES OR MIXTURE AND USES ADVISED AGAINST

Identified use: Immunoenzymatic method For the qualitative determination of total antibodies anti-SARS-CoV-2 virus as an aid in the determination of the immune reaction to SARS-CoV-2. Professional use as laboratory reagent.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESE Diagnostica Senese S.p.A

<u>Registered office:</u> Via A. Solari 19 20144 Milan, Italy Tel: +39 02 4859121 Fax: +39 02 48008530	<u>Production plant:</u> Via delle Rose, 10 53035 Monteriggioni (SI), Italy Tel: +39 0577 587111 Fax: +39 0577 318690
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1.4 EMERGENCY TELEPHONE NUMBER

Emergency number: Centro Antiveleni, Ospedale Niguarda Ca' Granda - Milan
Tel: +39 02 66101029

Centro Antiveleni, Azienda Ospedaliera "S.G.Battista" – Molinette di Torino - Turin
Tel: +39 011 6637637

Centro Antiveleni – U.O. Tossicologia Medica, Azienda Ospedaliera Careggi – Florence
Tel: +39 055 4277238

Centro Antiveleni, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Rome
Tel: +39 06 3054343

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Naples
Tel: +39 081 7472870

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008:
The mixtures are not classified as dangerous according to Regulation 1272/2008/EC

Hazard statement: None

2.2 LABEL ELEMENTS

Pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	None

2.3 OTHER HAZARDS

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances	Not applicable
3.2 Mixtures	The product contains no mixtures and substances classified as hazardous to health and/or the environment in concentrations exceeding the limits according to Regulation 1272/2008/EC.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice:	Move the person from the exposure to open air. In case of needs consult a physician immediately and show this Material Safety Datasheet. Eyewash and shower for the treatment of emergency have to be present in the workplace.
Skin contact:	Wear off the contaminated clothes and wash with copious amounts of water (for at least 15 minutes). If irritation persists consult a physician.
Eye contact:	If present, remove immediately contact lenses. Wash with plenty of water (for at least 15 minutes), keeping eyelids opened. Consult an oculist if the irritation persists.
Inhalation:	Move the person from the exposure to open air. If irritation occurs consult a physician.
Ingestion:	Rinse mouth immediately and drink a copious amount of water. Call a physician immediately. Do not cause vomiting.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS

No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available, other than point 4.1

5. FIREFIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing	Use extinguishing measures (CO ₂ , foam, dry powder, water) that are appropriate to local
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media: circumstances and the surrounding environment.

Not Suitable

extinguishing media: None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The mixture is not flammable, however in case of fire may release irritating and/or toxic gases.

5.3 ADVICE FOR FIREFIGHTERS

Wear appropriate personal protective equipment and clothing. In case of fire, wear self-contained breathing apparatus and avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Avoid the contact with skin and eyes and evacuate the area, keeping people not involved in the intervention operations away. Ensure an adequate ventilation of the affected area.

Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the contamination of surface water, soil and the dispersion in the air. Do not let product enter into drains. Discharge into the environment must be avoided.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Contain the leakages with earth and sand. Collect the spilled material and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS

For further information see section 8 and 13.

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not inhale vapors or mists. Avoid the contact with eyes, skin and clothes. Limit repeated exposure.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the containers at 2-8°C in a cool, well-ventilated area, away from heat sources and humidity.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits: None

8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals.
Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

Appropriate engineering controls:

Ensure an adequate ventilation of the working area.

Personal Protective Equipment:

The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the

Hand protections:

Chemical-resistant gloves, compliant with EN 374

Eye protections:

Side Shields Safety Goggles compliant with EN 166

Body protections:

Work outfits

Respiratory protections:

Not required under normal work activities

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:

Do not discard residuals in the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid (Device solution, Calibrator and Positive control)
Odor:	Odorless
Odor threshold:	Not pertinent
pH:	See it at the first page
Melting point/freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point	Not applicable
Evaporation rate	Not determined
Flammability	Not flammable
Upper/lower flammability or explosive limit	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Water solubility	Soluble in water
Partition coefficient: n-octano/water	Not determined
Autoignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined
Explosive properties	Not explosive
Oxidizing properties	Not determined

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

In the normal condition, no risk of reactivity is present.

10.2 CHEMICAL STABILITY

Stable until the expire date under the recommended transport, handling and storage conditions

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

The mixture could react with the basic and/or oxidizing substances

10.4 CONDITIONS TO AVOID

Avoid the storage at temperature different from that are advised

10.5 INCOMPATIBLE MATERIALS

Strong oxidizing and reducing agents

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

No data available

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

There is no known information on toxicological effects from exposure to the mixtures. However, it's recommended to operate according to the good operational practices. Nevertheless, the mixture can cause mild health effects on sensitive people by inhalation, cutaneous absorption, contact eyes or on ingestion.

Acute toxicity	No data available
Skin irritation/corrosion	No data available
Eye lesions/severe eye irritation	No data available
Respiratory/skin sensitization	No data available
Mutagenicity for germ cells	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Toxicity for target organs (single and repeated exposures)	No data available
Hazards in case of inhalation	No data available
Additional information	No data available

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

Use according to the good working practices, avoiding the disposal in the environment.
In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

12.2 PERSISTENCE AND DEGRADABILITY

No data available

12.3 BIOACCUMULATIVE POTENTIAL

No data available

12.4 MOBILITY IN SOIL

No data available

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

No data available

12.6 OTHER ADVERSE EFFECTS

No data available

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

The samples and all the used reagents have to be handled as potentially infected.
The product and its containers should be considered special waste.
Their transport and disposal should be performed by authorized specialized companies according to the law.

14. TRANSPORT INFORMATION

Not hazardous good according to the transport regulations.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Hazard classification, labeling and packaging under Regulation 1272/2008 (EC) and its subsequent amendments.

Legislative Decree 81/2008:

The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk

Directive 96/82/EC (Seveso Directive):

Not applicable

15.2 CHEMICAL SAFETY ASSESSMENT

Not performed for the product

16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

REFERENCES:

1. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
2. Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended
3. ECHA European Chemicals Agency www.echa.europa.eu

4. The Merck Index.
5. Handling Chemical Safety
6. NIOSH - Registry of Toxic Effects of Chemical Substances
7. INRS - Fiche Toxicologique

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