version 3, dated 2018-01-23 replaces vers. 2 dated 2015-01-22

Safety Data Sheet DE7780 DGP Ab IgG ELISA



1. PRODUCT IDENTIFIER

CodeDE7780NameDGP Ab IgG ELISA

DGP Ab IgG ELISA is a medical device for the quantitative detection of IgG class autoantibodies against deamidated gliadin protein epitopes (DGP) in human serum or plasma. Intended for professional in vitro diagnostic use only.

Manufacturer / Supplier

Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel, Germany Phone: +49 431 / 71922 0 Fax: +49 431 / 71922 55 info@demeditec.de www.demeditec.de

2. HAZARDS IDENTIFICATION

Product is **not classified as hazardous** according to the European Regulation 1999/45/EC or 1272/2008/EC. Human health hazards: No specific hazard.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Purified antigen coated onto polystyrene microwells.		
Calibrators/ controls: Human antibodies < 1% in phosphate buffered saline with Tween 20 as detergent,		
sodium azide 0.09% as preservative and BSA for stabilization.		
Peroxidase conjugated anti-human antibody < 0.0001% in phosphate buffered saline		
with ProClin 300 as preservative and bovine serum albumin (BSA) for stabilization.		
Phosphate buffered saline with sodium azide 0.09% as preservative and BSA for sta-		
bilization.		
Tris buffered saline with Tween 20 as detergent and sodium azide 0.09% as preserva-		
tive		
Aqueous solution of TMB (3,3`,5,5`-Tetramethylbenzidin) 0.032% with organic solvent		
2-pyrrolidone < 10%, sodium perborate, citrate, EDTA, and Kathon CG as preservative		
Aqueous solution of phosphoric acid 4.5%.		
Active substances in all mixtures do not meet the criteria for classification according to 1272/2008/EC.		

4. FIRST AID MEASURES		
Skin Contact:	In case of skin contact, immediately wash thoroughly with water and soap.	
	Remove contaminated clothing and shoes and wash before reuse.	
	If stop solution comes into contact with skin, wash thoroughly with water.	
Eye Contact:	After contact with the eyes carefully rinse the opened eye with running water for at least	
	10 minutes. Get medical attention if necessary. Remove contact lenses if this can be	
	done easily.	
Respiratory tract:	Take person to the fresh air.	
Swallowing:	Rinse the mouth and spit the fluids out. Drink 1 - 2 glasses of water immediately. Dur-	
	ing spontaneous vomiting hold the head of the casualty low with the body in a prone	
	position in order to avoid the penetration of vomit into the air tube.	

5. FIREFIGHTING MEASURES

Extinguishing Media: Use dry chemical powder, water spray, foam or carbon dioxide.

6. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Observe laboratory safety regulations.

Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth.

Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal. version 3, dated 2018-01-23 replaces vers. 2 dated 2015-01-22

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7. HANDLING AND STORAGE

Handling:Special measures are not required.Storage:Store at 2 to 8 °C. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection:Not requiredHand protection:Wear protective gloves of nitrile rubber or natural latex.Eye protection:Wear protective glasses.

9. PHYSICAL AND CHEMICAL PROPERTIES

Coated microplate:	Polystyrol microwells in foil pouch.
Calibrators:	Yellow fluid in glass bottle.
Enzyme conjugate:	Red fluid in polyethylene bottle.
Sample buffer:	Yellow fluid in polyethylene bottle.
Wash buffer:	Colorless fluid in polyethylene bottle.
Substrate solution:	Colorless fluid in polyethylene bottle.
Stop solution:	Colorless fluid in polyethylene bottle.

10. STABILITY AND REACTIVITY

Stability of components is given on the labels. Used according to intended use no dangerous reactions known.

Conditions to avoid: Substrate solution is light-sensitive. Store substrate solution in the dark.

11. TOXICOLOGICAL INFORMATION

Used according to intended use no toxicological reactions known.

12. ECOLOGICAL INFORMATION

Used according to intended use no ecological reactions known.

13. DISPOSAL CONSIDERATIONS

Waste should be disposed of in accordance with federal, state and local environmental control regulations. When disposing of conjugate solution, sample buffer or wash buffer flush drains with copious amounts of water. Disposal of packaging according to the instructions of the public authorities.

14. TRANSPORT INFORMATION

This product is not subject to official transport regulations.

15. REGULATORY INFORMATION

1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EWG and 1999/45/EG, amending 1907/2006/EG
453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

This product is not classified according to the EU regulations 1272/2008. No labeling requirement.

16. OTHER INFORMATION

Safety data for product including all components. This product is intended for professional laboratory use only.

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier assumes any liability whatsoever for the accuracy or completeness of the information contained herein. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.