

## Safety Data Sheet

**ORG 789-08 / ORG 789-16**



### 1. Product identifier

Article No. **ORG 789-08 / ORG 789-16**

Trade name **ANCA-3-Line**

ANCA-3-Line is a medical device for the semi-quantitative determination of IgG and class autoantibodies against PR3, MPO and GBM in human serum or plasma. Intended for professional in vitro diagnostic use only.

#### Manufacturer / Supplier

ORGENTEC Diagnostika GmbH  
Carl-Zeiss-Straße 49-51  
55129 Mainz  
Germany  
Phone: +49 6131 / 9258-0  
Fax: +49 6131 / 9258-58  
orgentec@orgentec.com  
www.orgentec.com

### 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

Coated strips: Purified antigen coated onto nitrocellulose membrane strips.

Enzyme conjugate: Alkaline phosphatase conjugated anti-human antibody < 0.0001% in phosphate buffered saline with 0.05% ProClin 300 as preservative and bovine serum albumin (BSA) for stabilization.

Sample buffer: Tris buffered saline with sodium azide 0.09% as preservative and BSA for stabilization.

Wash buffer: Tris buffered saline with Tween 20 as detergent and sodium azide 0.09% as preservative.

Substrate solution: Aqueous solution of BCIP/NBT contains 1% (5-bromo-4-chloro-3-indolyl-phosphate/p-nitro blue tetrazolium chloride)

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.

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.

### 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.

### 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 required

Hand protection: Wear protective gloves of nitril rubber or natural latex.

Eye protection: Wear protective glasses.

### 9. Physical and chemical properties

Coated strips: Nitrocellulose strips in plastic bottle.

Enzyme conjugate: Red fluid in polyethylene bottle.

Sample buffer: Yellow fluid in polyethylene bottle.

Wash buffer: Colorless fluid in polyethylene bottle.

According to 1907/2006/EC +  
amendment 453/2010/EC  
Document No QM110260  
Version 1, dated 2011-08-02  
replaces ---

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Substrate 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: The calibration strip is light-sensitive. Store strips 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/EC  
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

Revision according to 453/2010 EU.  
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.*