

Safety Data Sheet

ORG 600



1. Product identifier

Article No. **ORG 600**
Trade name **ANA Detect**

ANA Detect is a medical device for the qualitative screening of IgG class autoantibodies against SS-A-52, SS-A-60, SS-B, RNP/Sm, RNP-70, Sm, Scl-70, Jo-1, dsDNA, histone complex, Pm-Scl-100 and centromere B in human serum or plasma. Intended for professional in vitro diagnostic use only.

Manufacturer / Supplier

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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 microplate: Purified antigen coated onto polystyrene microwells.
Calibrators: Human antibodies < 1% in phosphate buffered saline with Tween 20 as detergent, sodium azide 0.09% as preservative and BSA for stabilization.
Enzyme conjugate: Peroxidase 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: Phosphate 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 TMB (3,3',5,5'-Tetramethylbenzidin) 0.032% with organic solvent pyrrolidone, sodium perborate, citrate, EDTA, Tween 20 as detergent and Kathon CG 0.00009% as preservative.
Stop solution: Aqueous solution of phosphoric acid 4.5%.
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.

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

According to 1907/2006/EC +
amendment 453/2010/EC
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page 2 of 2

Safety Data Sheet

ORG 600



Hand protection:	Wear protective gloves of nitril rubber or nature 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	
Revision according to 453/2010 EU.	
Safety data for product including all components. This product is intended for professional laboratory use.	

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.