

1. Product identifier

Articel Code ORG 311

Trade name Alegria® Negative Control

The Alegria® Test Strip Negative Control is a medical device intended for the quality control use in the Alegria® Test Strip system and the Alegria® Test Strip reagents. 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

Alegria® strips: Alegria® 8-well-test strips are equipped with antibody coated wells and a complete set of reagents.

Well C/D: Purified antibody coated onto polystyrene microwells.

Well E: Control consisting of human antibodies < 1% in phosphate buffered saline with Tween 20 as detergent, sodium azide 0.09% and ProClin 300 0.05% as preservative and bovine serum albumin (BSA) for stabilization.

Well F: Enzyme conjugate consisting of peroxidase conjugated anti-human antibodies < 0.01 % in phosphate buffered saline with 0.05% ProClin 300 as preservative and BSA for stabilization.

Well G: Sample buffer consisting of phosphate buffered saline with sodium azide 0.09% and ProClin 300 0.05% as preservative and BSA for stabilization.

Well H: Substrate solution consisting of 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.

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

System fluid: 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 system fluid 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.
During 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.

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

Alegria® strips: Alegria® strips in foil pouch.
Wash buffer: Colorless fluid 20 ml in polyethylene bottle.
System fluid: Colorless fluid 3 ml in glass 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: Introduction of 3 year period of validity according to Canadian controlled products regulation (CPR).
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.