

Instructions for use Counting chambers according DIN 12847



Scope

The instructions for use apply to all counting chambers of the basic UDI listed in the table, which are marked on the label as in vitro diagnostic products IVD and bear the reference to the Instructions for use.

Counting chamber UDI
4262367210003

Counting chambers for in vitro diagnostics according to (EU) 2017/746 are made of special optical glass and are suitable for microscopy analyses.

Indication

Counting chambers are used to determine the number of particles (e.g. leucocytes and erythrocytes in blood, bacteria in liquid cultures, etc.) in liquids. The particles are counted under a microscope. The counting can be made under the microscope after a cover slip has been placed on the counting chamber.

The relevant laboratories have trained staff, so it is not the manufacturer's duty to describe the procedure to be used for filling the chamber and counting the particles depending on the task. In addition, there are task-specific extensive literature and textbooks.

General handling

Warning



Please read all information carefully before use.



If damage or signs of glass breakage can already be seen when opening the packaging, the glasses may not be used for diagnosis.

The diagnostic use of the counting chambers and the evaluation of the preparations is carried out by a physician or personnel qualified to do so under the responsibility of a physician.

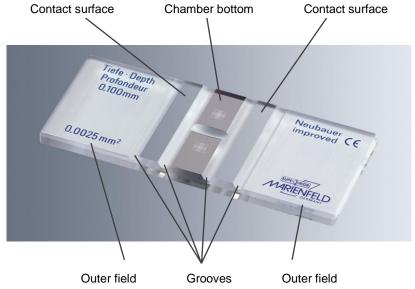
The respective national legal situation must be complied with. The accident prevention and hygiene regulations must also be complied with.



When handling potentially infectious sample material, make sure to use appropriate personal protective equipment. Compliance with indoor air quality in accordance with national regulations (e.g., Directive for Hospital Hygiene and Infection Prevention, RKI) must be ensured for safe diagnostics in the laboratory.

Application

- Counting chambers are made of glass. If handled without care, there is a risk of breakage and injury.
- Chamber bottom and contact surfaces (see illustration) are polished. Avoid mechanical damage of this surface.
- The counting grid on the chamber floor is manufactured with a tolerance of less than 2 µm. Avoid mechanical damage and temperature shocks.
- If the counting chambers are used multiple times, cleaning should be carried out in accordance with the above instructions. After cleaning with a mild disinfectant, the counting chambers can be used several times. Cleaning must be carried out with great care and caution in order to avoid injuries and damage of the counting chamber. No acidic, strong alkaline or solvent-based cleaning agents shall be used.





Message

All serious incidents that occur in connection with the product must be reported to Poly-Optik as manufacturer and to the competent authority of the Member State in which the user is established.

Manufacturer



Poly-Optik GmbH Obere Marktstraße 3 07422 Bad Blankenburg Germany

Tel.: +49 (0) 36741 2284 Fax; +49 (0) 36741 2325 E.Mail: info@poly-optik.de Internet: www.poly-optik.de

Signed

Dr. Axel Weidner, Managing Director and person in charge for regulatory compliance of Poly-Optik GmbH

Owner of the trademark MARIENFELD SUPERIOR

Paul Marienfeld GmbH & Co. KG Am Wöllerspfad 4 97922 Lauda-Königshofen Germany