

EN INSTRUCTIONS FOR USE

RABBIT COMPLEMENT

CE₀₁₂₃

Electronic instructions for use see www.bag-diagnostics.com

FOR IN VITRO DIAGNOSTIC USE

REF 7018 Rabbit Complement, 10 x 1 ml, lyophilized

REF 7023 Rabbit Complement, 10 x 5 ml, lyophilized

Intendes use

In vitro diagnostic medical devices for use by qualified personnel.
Rabbit complement is used in the microlymphocytotoxicity test to detect HLA-antigens on the lymphocyte membrane.

Description of product

The rabbit complement is produced of a large rabbit serum pool to ensure near identical complement activity in different lots.

Test Principle

HLA-antisera react with the corresponding membrane-bound antigens on human lymphocytes. The addition of rabbit complement results in a structural change of the cell membrane which leads to a penetration of an indicator dye. Stained lymphocytes = positive reaction. In case of missing antigen-antibody reaction, the cell membrane is intact. No penetration of indicator dye takes place and the cells remain unstained = negative reaction.

Application

Dissolve lyophilized complement with 1 ml or 5 ml aqua dest. (according to package sizes). The reconstitution needs 10-15 minutes. The dissolved complement can then be used in the microlymphocytotoxicity test (microlymphocytotoxicity test: see instructions of the manufacturer of the serological HLA-typing plates).
Reconstituted complement must be stored cool (2...8°C) and used within 3 - 4 hours.
DO NOT FREEZE dissolved rabbit complement!

Performance Characteristics

5 batches of rabbit complement were tested in the microlymphocytotoxicity test using HISTO TRAY ABC 144 (5) microtesttrays (REF 7035) in comparison to a CE-marked rabbit complement. These batches were also tested against a CE-marked rabbit complement using a complement test plate (HISTO TRAY Complement ABC, REF 7003). All batches of rabbit complement were found to be well suited for use in the microlymphocytotoxicity test.

Warnings and Precautions

The **rabbit complement** is designed for in vitro diagnostic use only and should be used by properly trained personnel. Nevertheless, all used biological material should be handled as potentially infectious, because no test method can guarantee that material derived from biological sources is free from infectious agents. When handling biological material appropriate safety precautions are recommended (do not pipet by mouth; wear disposable gloves while handling biological material and performing the test; disinfect hands when finished the test).
Biological material should be inactivated before disposal (e.g. in an autoclave). Disposables should be autoclaved or incinerated after use. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a suitable standard disinfectant or 70% alcohol. Material used to clean spills, including gloves, should be inactivated before disposal (e.g. in an autoclave).
Disposal of all samples, unused reagents and waste should be in accordance with country, federal, state and local regulations. When used in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and the instructions stated in this direction, the reagent supplied should not present a hazard to health.

Do not use **rabbit complement** beyond the indicated expiration date on the label.

A declaration on Material Safety Data Sheets (MSDS) **are available to download at** www.bag-diagnostics.com .

Shelf life: lyophilized until the expiration date indicated on the label, dissolved see application

Storage: lyophilized ≤ 8°C, dissolved see application

Explanation of symbols used on Labelling			
	Use by		Consult Instructions for use
	Storage temperature / Upper limit of temperature		Manufacturer
COMPLEMENT RAB	Rabbit complement	IVD	For in vitro diagnostic use
HLA TYPING	Intended purpose: HLA-typing	LOT	Batch code
LYOPH	lyophilised	REF	Catalogue number

Instructions for use in other languages see <http://www.bag-diagnostics.com> or phone +49 (0)6404-925-125

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