EN

INSTRUCTIONS FOR USE

Rh control for monoclonal test reagents

CE 0123

Negativ control for monoclonal test reagents

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

FOR IN VITRO DIAGNOSTIC USE

REF	6748	1 x 10 ml
REF	6749	10 x 10 ml

1. Product description

The Rh control for monoclonal test reagents serves as negative control by the determination of Rh antigens with monoclonal test reagents. The test reagent contains bovine albumine and macromolecular substances. The composition of the contents is comparable to monoclonal BAG Anti-Rh test reagents and monoclonal BAG-Anti-Kell test reagents without antibodies.
The test reagent contains < 0.1% NaN_3 as preservative.
Each lot is tested by the tube test method with a panel of red blood cells positive for A, B, C, c, D, E, e, K, k, Kp^b, Js^b, M, N, S, s, Fy^a, Fy^b, Jk^a, Jk^b, Le^a, Le^b, Lu^b, P_1 and Xg^a. Other antigens will be tested if test cells are available.

2. Principle of the test

Rh control for monoclonal test reagents is used in tube test like the monoclonal BAG Anti-Rh test reagents. The test methods are based on the principle of hemagglutination. Incubation of test red cells with an Anti-Rh test reagent will result in a specific antigen-antibody reaction if the corresponding antigen is present on the test cells. Visible detection of this reaction is demonstrated by agglutination of the cells. No agglutination indicates a negative test result, and within the accepted limitations of the test procedure, indicates the absence of the corresponding antigen. The Rh control for monoclonal test reagents contains no antibodies and therefore an incubation with test red cells doesn't result in a specific antigen-antibody reaction. An agglutination with this test reagent indicates an unspecific reaction.

3. Storage and Shelf Life

Store Rh control for monoclonal test reagents at 2...8°C. Allow the test reagent to reach room temperature (18...25°C) before use. Return test reagent to 2...8°C for storage as appropriate, immediately after use. By observance of appropriate storage conditions Rh control for monoclonal test reagents can be used until the expiration date printed on the label after opening the bottle. Do not use the test reagent after the expiry date printed on the label.

4. Specimen preparation

s. Instructions for use for Anti-C, -C^w, -c, -E, -e, -Kell monoclonal (IgM)

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com

5. Additional Materials Required

s. Instructions for use for Anti-C, -C^{w}, -c, -E, -e, -Kell monoclonal (IgM)

6. Test procedure

Rh control for monoclonal test reagents should be tested parallel with the Anti-C, -C^{w}, -c, -E, -e, -Kell monoclonal (IgM) test reagents. The test procedure should be performed according to the test procedure indicated in the instructions for use for Anti-C, -C^{w}, -c, -E, -e, -Kell monoclonal (IgM).

7. Interpretation of test results

Agglutination of red blood cells with Rh control for monoclonal test reagents indicates that a positive test result with monoclonal BAG Anti-Rh test reagents is not valid. In this case additional tests should be performed (e. g. elution of cell bound antibodies or retest with washed cells).

8. Important directions / Limitations of Procedure

1. Rh control for monoclonal test reagents is designed for in vitro diagnostic use only and should be used by properly trained, qualified staff.
2. Microbiological contamination of Rh control for monoclonal test reagents must be avoid as this may reduce the life of the product and cause erroneous results. Do not use Rh control for monoclonal test reagents if marked turbidity or other observable indications of product alteration occur. These signs may indicate microbiological contamination and/or product deterioration.
3. Pay attention to all declarations in the instructions for use for Anti-C, -C^{w}, -c, -E, -e, -Kell monoclonal (IgM).

9. Performance characteristics

The Rh control for monoclonal test reagents were tested with altogether 1299 red blood cell suspensions in tube test. Tube tests were performed in accordance with the instructions for use for Anti-C, -C^{w}, -c, -E, -e, -Kell monoklonal (IgM). All red blood cell samples showed no agglutination with the Rh control for monoclonal test reagents.

Table 1	
Tested samples	1299
by that:	
EDTA blood	726
Heparin blood	187
Citrat blood	202
Blood of blood group A, B and AB	691
Blood donors	1015
Clinical samples	171
Blood from new-borns	40

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925-100
Fax: +49 (0) 6404 / 925-460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925-450
Fax: +49 (0) 6404 / 925-460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925-125
Fax: +49 (0) 6404 / 925-421
service@bag-diagnostics.com

Furthermore 135 samples of blood donors, blood recipients and new-borns were tested in the OrthoBioVue™ system with BAG Rh control for monoclonal test reagents. The test reagent was pipetted in a BioVue™ Reverse Diluent cassette via AutoVue™ automat and was tested in comparison with the Rh control in the BioVue™ Rh sub-groups/Kell cassette. The test results showed an agreement of 100% for the BAG test reagent with the test reagent in the BioVue™ Rh sub-groups/Kell cassette (s. table 2).

Table 2	
Tested samples	135
by that:	
EDTA blood	135
Blood of blood group A, B and AB	56
Blood donors	106
Clinical samples	19
Blood from new-borns	10

10. Warnings and Precautions

All used biological material must be handled as potentially infectious. When handling biological material appropriate safety precautions are recommended (Do not pipette 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).

The test reagent contains NaN_3 as a preservative. The reagent contains < 0.1% NaN_3 which is not considered to be a harmful concentration. Nevertheless avoid contact with the skin and mucous membranes. The copper and lead used in some plumbing systems can react with azides to form explosive salts. The quantities of azide used in this reagent are small; nevertheless when disposing of azide-containing materials, they should be flushed away with a large volume of water.

Disposal of all unused reagent and waste should be in accordance with country, federal, state and local regulations.

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

11. References

s. Instructions for use for Anti-C, -C^w, -c, -E, -e, -Kell monoclonal (IgM)

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925-100
Fax: +49 (0) 6404 / 925-460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925-450
Fax: +49 (0) 6404 / 925-460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925-125
Fax: +49 (0) 6404 / 925-421
service@bag-diagnostics.com

Explanation of symbols used on Labelling	
	Storage temperature / Temperature limitation
	Use by
	Consult instructions for use
	Manufacturer
CONT NaN_3	Contains Natriumazide
IVD	For in vitro diagnostic use
LOT	Batch code
REF	Catalogue number

Instructions for use	Version: 2/2019 / Issue: 2019-06

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

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com