EN

INSTRUCTIONS FOR USE

Anti-C, -c, -E, -e, -Kell monoclonal (IgM) CE 0123

Anti-C^{w} monoclonal (IgM) CE

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

FOR IN VITRO DIAGNOSTIC USE

Product	Clone	REF 1 x 10 ml	REF 10 x 10 ml
Anti-C monoclonal (IgM)	MS24	6752	675210
Anti-C monoclonal (IgM)	MS273	67541	675411
Anti-Cw monoclonal (IgM)	MS110	67501	///
Anti-c monoclonal (IgM)	MS33	6758	675810
Anti-c monoclonal (IgM)	c1.16C.15A	6745	674510
Anti-E monoclonal (IgM)	MS258	6756	675610
Anti-E monoclonal (IgM)	E1.16C.10F	6747	674710
Anti-e monoclonal (IgM)	MS62/69	6729	672910
Anti-e monoclonal (IgM)	MS16/21/63	6760	676010
Anti-Kell monoclonal (IgM)	K1.1.21HM.EF	6774	6775

1. Product description

Anti-C, -C^{w}, -c, -E, -e, -Kell monoclonal (IgM) are prepared from monoclonal, human IgM antibodies. The clone numbers are given on the labels of the test reagents.
Anti-C, -C^{w}, -c, -E, -e, -Kell monoclonal (IgM) are designed for use in tube test, and provides a specific, qualitative test for the detection of the corresponding antigens on human red blood cells.
For stabilization the diluent used for these reagents contains bovine albumine and macromolecular substances. The test reagents contain < 0.1% NaN_3 as preservative.
The reactivity of each lot is demonstrated with several samples positive for the corresponding antigen. The titer given on the label is determined by the tube test method with red blood cells which are positive and heterozygous for the corresponding antigen. The specificity of each lot is demonstrated by the recommended tube test method with a panel of red blood cells negative for the antigen in question.

2. Biological principle of the test

The test used with this blood grouping reagents is based on the principle of hem-agglutination. Incubation of test red cells with the monoclonal test reagents 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.

3. Storage and Shelf Life

Store the test reagents at 2...8°C. Allow the test reagents to reach room temperature (18...25°C) before use. Return reagents to 2...8°C for storage as appropriate, immediately after use. After opening the bottle the test reagents can be used until the expiry date printed on the label, if appropriate storage conditions be observed. Do not use the reagents after the expiry date printed on the label.

4. Specimen preparation

Blood samples should be collected by approved medical procedure. Blood collected without or with anticoagulant (EDTA, heparin, citrate) is suitable. Do not use haemolytic samples. Testing should be performed without delay if possible. Prolonged storage of red cells prior to testing may result in deterioration of red cell antigens and resultant weaker than expected test reactions (s. 9. Important Directions/Limitations of Procedure).

5. Additional Materials Required

Isotonic saline

Test tubes (75 x 12 mm)

Disposable Pasteur Pipettes

Centrifuge

6. Test procedure

Tube test

1. Prepare a 3 - 5% suspension of test red cells in isotonic saline.
2. Place 1 drop of test reagent and 1 drop of the prepared suspension of test red cells into a labelled test tube, mix and incubate for 5 minutes at room temperature.
3. Centrifuge for 1 minute at 150 x g (1000 rpm) or 20 seconds at 1000 x g (3000 rpm).
4. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.
5. If the reaction is weak or doubtful, incubate the tube for 30 minutes at room temperature.
6. Centrifuge for 1 minute at 150 x g (1000 rpm) or 20 seconds at 1000 x g (3000 rpm).
7. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.

Note

Do not examine tests microscopically.

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Red blood cell suspensions known to be positive (ideally heterozygous cells) and negative for the antigen, a Rh-control for monoclonal test reagents and a patient control should always be included in the test.

Use at least two different test reagents to determine the antigen. By use of two monoclonal test reagents two different clones should be used.

7. Interpretation of test results

Agglutination of test red cells with the test reagent indicates the presence of the corresponding antigen (within the accepted limitations of the test procedure).

No agglutination of test red cells with the test reagent indicates the absence of the corresponding antigen (within the accepted limitations of the test procedure).

If no agglutination occurs with the test red cells known to be positive for the antigen or if agglutination occurs with the test red cells known to be negative for the antigen or the Rh control for monoclonal test reagents or with the patient control the test results should not be interpreted.

If different test results occur with two different test reagents, repeat the determination of the antigen with an other test method and/or an other test reagent.

Pay attention to the limitations of procedure and important directions (s. 9. Important Directions/Limitation of procedure).

8. Stability of the Reaction

All test results must be interpreted immediately upon completion of the test.

9. Important directions / Limitations of Procedure

1. The test reagents are designed for in vitro diagnostic use only and should be used by properly trained, qualified staff.
2. On rare occasion, red cells coated in vivo with immunoglobulin may agglutinate spontaneously and non-specifically. In such instances similar phenomena would most likely occur in the AB0 grouping test and blood grouping tests of other blood group systems as well. Rh control for monoclonal test reagents and patient autologous serum are suitable controls. If the control test yields a positive reaction, a valid interpretation of the blood typing result cannot be made.
3. The use of unwashed test red cells suspended in plasma or serum may promote false positive reactions such as those associated with rouleaux formation, or autoantibodies. The use of well washed red cells may reduce the incidence of such false positive reactions.
4. Delays in reading tests, overvigorous resuspension of red cell buttons, and other technique variables associated with test performance may result in weaker than expected, or false negative test results.
5. The test reagents must not be used for tests with enzyme treated red cells.
6. Haemolytic samples must not be used.

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7. Furthermore, to minimize other risks for false positive reactions, the reagents must not be tested when cold. Ensure that the reagents and any test cell sample are allowed to equilibrate to ambient room temperature prior to testing.
8. False negative or unexpectedly weak reactions may occur with red cells that have been subjected to prolonged and/or inappropriate storage conditions.
9. Other variables such as improper technique, inappropriate centrifugation or incubation, improperly cleaned glassware, incorrect saline pH and/or contaminated materials and samples may cause false negative or false positive results.
10. Microbiological contamination of the test reagents must be avoided as this may reduce the life of the products and cause erroneous results. Do not use the test reagents if marked turbidity or other observable indications of product alteration occur. These signs may indicate microbiological contamination and/or product deterioration.
11. For interpretation of the test results, consider if transfusion or transplantation had happened. Take the case history of the transfusion or transplantation and also medicaments into consideration.
12. Some red cells may express quantitatively weak or Rh variants and may therefore demonstrate weaker than expected reactions with the test reagents. Further clarification and specification of the result can be carried out with **BAG**ene (BAG-SSP-Kits for the determination of Rh attributes on a molecular genetic basis).
13. Clone MS62/69 does not react with some rare e-variants. In contrast clone MS16/21/63 show a weaker but clear positive reaction with these e-variants. It is therefore recommended to use both clones for the determination of the e antigen. A negative result with clone MS62/69 and a positive result with clone MS16/21/63 points to the presence of a rare e-variant.
14. Clone MS24 and clone MS273 react with C^{w} and C^{x} and may give weaker reactions with C-antigene of an R_2R_Z individual. It has been reported that clone MS24 does not agglutinate red cells of the very rare type rG, however clone MS273 does agglutinate red cells of the type rG.
15. Clone E1.16C.10F does not react with E^{w}, E^{weak} and other unusual E-variants. Clone MS258 reacts with the E^{w} antigen. It is therefore recommended to use both clones for the determination of the E antigen. A negative result with clone E1.16C.10F and a positive result with clone MS258 points to the presence of E^{w} or other unusual E-variants.
16. The country-specific transfusion laws and/or directives (current laws or directives on transfusion medicine and blood group determination) must be taken into account.

10. Performance characteristics

Anti-C, clone MS24, and Anti-C, clone MS273

285 samples of blood donors, blood recipients and new-borns were tested in tube test with BAG-Anti-C test reagent, clone MS24, and a monoclonal Anti-C test reagent of an other manufacturer (s. table 1). All tests showed an agreement of 100% for the BAG test reagent with the comparable test reagent.

374 samples of blood donors, blood recipients and new-borns were tested in tube test with BAG-Anti-C test reagent, clone MS273, and in comparison with Anti-C test reagent, clone MS24 (s. table 1). All tests showed an agreement of 100% with the comparable test reagent.

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Clone MS24 and clone MS273 react with C^w and C^x and may give weaker reactions with C-antigene of an R_2R_Z individual. It has been reported that clone MS24 does not agglutinate red cells of the very rare type rG, however clone MS273 does agglutinate red cells of the type rG.

Anti-C^w, clone MS110

105 samples of blood donors, blood recipients and new-borns were tested in tube test with the BAG-Anti-C^w test reagent, clone MS110, and a monoclonal Anti-C^w test reagent of an other manufacturer (s. table 1). All tests showed an agreement of 100% for the BAG test reagent with the comparable test reagent.

Anti-c, clone MS33, and Anti-c, clone c1.16C.15A

304 samples of blood donors, blood recipients and new-borns were tested in tube test with both BAG-Anti-c test reagents, clone MS33 and clone c1.16C.15A, and a monoclonal Anti-c test reagent of an other manufacturer (s. table 2). All tests showed an agreement of 100% for the BAG test reagents with the comparable test reagent.

Anti-E, Klon E1.16C.10F, und Anti-E, Klon MS258

294 samples of blood donors, blood recipients and new-borns were tested in tube test with the BAG-Anti-E test reagent, clone MS258, and a monoclonal Anti-E test reagent of an other manufacturer (s. table 2). All tests showed an agreement of 100% for the BAG test reagent with the comparable test reagent.

299 samples of blood donors, blood recipients and new-borns were tested in tube test with the BAG-Anti-E test reagent, clone E1.16C.10F, and monoclonal Anti-E test reagents of other manufacturers (s. table 2). 5 samples known to be E^w, E^{weak} and E-variants reacted negative with the BAG test reagent. The comparable test reagent reacted negative with the E^{weak} erythrocytes too. With all other samples identical results were obtained with the BAG test reagent and the comparable test reagent.

Clone E1.16C.10F does not react with E^w, E^{weak} and other unusual E-variants. Clone MS258 reacts with the E^w antigen.

Anti-e, clone MS16/21/63, and Anti-e, clone MS62/69

263 samples of blood donors, blood recipients and new-borns were tested in tube test with both BAG-Anti-e test reagents, clone MS16/21/63 and clone MS62/69, and a monoclonal Anti-e test reagent of an other manufacturer (s. table 2). One sample reacted positive with both BAG test reagents and negative with the comparable test reagent. The sample was known to be positive for the e antigen, based on sooner examinations of the donor with different test reagents. With all other samples identical results were obtained with the BAG test reagents and the comparable test reagent.

Clone MS62/69 does not react with some rare e-variants. In contrast clone MS16/21/63 show a weaker but clear positive reaction with these e-variants.

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Anti-Kell, clone K1.1.21HM.EF

267 samples of blood donors, blood recipients and new-borns were tested in tube test with the BAG-Anti-Kell test reagent, clone K1.1.21HM.EF, and a monoclonal Anti-Kell test reagent of an other manufacturer (s. table 1). With all samples identical results were obtained with the BAG test reagent and the comparable test reagent.

Table 1	Anti-C		Anti-C^{w}	Anti-Kell
	MS24	MS273	MS110	K1.1.21HM.EF
Tested samples	285	374	105	267
by that:				
Positive for the corresponding antigen	208	242	5	18
Negative for the corresponding antigen	77	132	100	249
EDTA blood	76	14	20	76
Heparin blood	58	270	0	58
Citrat blood	123	79	83	102
Blood of blood group A, B and AB	123	194	57	123
Blood donors	217	302	236	199
Clinical samples	50	39	20	50
Blood from new-borns	14	22	6	18

Table 2	Anti-c		Anti-E		Anti-e	
	MS33	c1.16C.15A	MS258	E1.16C.10F	MS62/69	MS16/21/63
Tested samples	304	304	294	299	263	263
by that:						
Positive for the corresponding antigen	251	251	87	87	256	256
Negative for the corresponding antigen	53	53	207	212	7	7
EDTA blood	76	76	86	86	76	76
Heparin blood	67	67	58	58	58	58
Citrat blood	93	93	82	82	101	101
Blood of blood group A, B and AB	151	151	143	143	121	121
Blood donors	236	236	226	226	195	195
Clinical samples	50	50	50	50	50	50
Blood from new-borns	18	18	18	18	18	18

BAG test reagents in the OrthoBioVue™ system

Samples of blood donors, blood recipients and new-borns were tested in the OrthoBioVue™ system with BAG test reagents. The test reagents were pipetted in a BioVue™ Reverse Diluent cassette via AutoVue™ automat and were tested in comparison with the monoclonal test reagents in the BioVue™ Rh sub-groups/Kell cassette. The results of all tests showed an agreement of 100% for the BAG test reagents with the test reagents in the BioVue™ Rh sub-groups/Kell cassette (test reagents and number of samples s. table 3).

Furthermore 241 samples of blood donors, blood recipients and new-borns were tested in the Ortho BioVue™ system with the BAG-Anti-Kell test reagent, clone K1.1.21HM.EF by

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Ortho Clinical Diagnostics. The same samples were tested in a gel technology system of an other manufacturer. One sample reacted not clearly in the OrthoBioVue™ system with the BAG test reagent. A clear determination could not take place, because repeated testing was not possible based on lacking sample material. With all other samples identical results were obtained with the BAG test reagent in the OrthoBioVue™ system and the comparable gel technology system.

Table 3	Anti-C		Anti-c		Anti-E		Anti-e		Anti-Kell
Clone	MS 24	MS 273	MS 33	c1. 16C. 15A	E1. 16C. 10F	MS 258	MS 16 21 63	MS 62 69	K1.1. 21 HM. EF
Tested samples	135	146	135	122	135	122	135	122	135
by that:									
Positive for the corres-ponding antigen	80	104	111	99	40	34	130	117	11
Negative for the corres-ponding antigen	55	42	24	23	95	88	5	5	124
EDTA blood	135	146	135	122	135	122	135	122	135
Blood of blood group A, B and AB	56	70	56	53	56	53	56	53	56
Blood donors	106	99	106	95	106	95	106	95	106
Clinical samples	19	40	19	19	19	19	19	19	19
Blood from new-borns	10	7	10	8	10	8	10	8	10

11. Warnings and Precautions

Human source material used to produce these reagents has been tested and found negative for HBsAg and HIV and HCV antibodies. Nevertheless all used biological material must be handled as potentially infectious, because no test method can guarantee that material derived from biological sources are free from infectious agents. 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 reagents contain NaN_3 as a preservative. The reagents contain < 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 reagents are small; nevertheless when disposing of azide-containing materials, they should be flushed away with a large volume of water.

Disposal of all samples, unused reagents 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 .

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12. References

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Explanation of symbols used on Labelling	
	Storage temperature / Temperature limitation
	Use by
	Consult instructions for use
	Manufacturer
CLONE	Clone
CONT | NaN_3	Contains Natriumazide
IVD	For in vitro diagnostic use
LOT	Batch code
MONOCL | IGM	Monoclonal IgM
ORIG | HUM	Origin: human
REF	Catalogue number
TIT	Titer

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

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