



Blood Bank Quality Assurance II (BBQA II) Testing Reagents

Reactivity Testing Reagents and Reference Red Blood Cells

For qualitatively testing reactivity of red blood cells, blood grouping and anti-human globulin serums

Summary and Principle

Good Blood Bank Quality Assurance (BBQA) includes a check of all reagents routinely employed in immunohematologic procedures on the day of use to ensure that the reagents are functioning properly and to verify techniques.^{1,2} The reactivity of certain antigens on reagent red blood cells may diminish as the erythrocytes age and/or are exposed to temperature variations. Therefore, monitoring of reagent red blood cells is recommended to ensure that acceptable levels of erythrocyte antigen reactivity are present in each vial. Similarly, good quality assurance includes a check of all blood grouping and anti-human globulin serums to ensure that acceptable levels of antibodies of the desired specificities are present in each vial. The reactivities of reagent red blood cells, blood grouping reagents and anti-human globulin serums cannot easily be measured quantitatively. Quality Assurance for qualitatively testing by using e.g. BBQA II available from Medion Diagnostics AG, is strongly recommended.

Available quantitative procedures usually involve dilution of reagents. They require more labor and reagents than qualitative procedures and are generally subject to errors of at least ± 2 fold. In addition, since the manufacturer's diluent usually contains potentiators and stabilizers which become diluted in these quantitative procedures, the results obtained may have little relevance to in-use-performance.

Reagents

Not for in vitro diagnostic use
For laboratory use only

Warning: Do not use for grouping donors or recipients. Use only in the laboratory for quality assurance of blood bank reagents.

Reactivity Testing Serums: Prepared from murine monoclonal antibodies (Anti-A, Anti-B) and human blood (diluted in 6 % bovine albumin if necessary) with sodium azide (1:1000) as preservative.

1. BBQA II Anti-A
2. BBQA II Anti-B
3. BBQA II Antisera: Anti-human globulin reactive antibody designed to be reactive with all screening cells

Items 1 and 2 are a constant part of the package; the specificity provided for item 3 will be alternated periodically by Medion Diagnostics AG.

Store at 2 – 8°C when not in use. **Do not freeze.**

Ready to use. **Do not dilute.**

Indication of deterioration: turbidity which may be caused by microbial contamination or improper handling.

Warning: These reagents contain sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into sink, flush with a large volume of water to prevent azide buildup.

Reference Red Blood Cells: Suspensions of human erythrocytes in buffered isotonic medium with neomycin and chloramphenicol as preservatives. Included are 3 ± 1 % suspensions of:

4. BBQA II group A₂ D Negative
5. BBQA II group B D Negative
6. BBQA II O D Positive

Store at 2 – 8°C when not in use. **Do not freeze.**

Resuspend before using.

Indication of deterioration: turbidity and/or notable hemolysis which may be caused by microbial contamination or improper handling.

The pipette of the vial contains natural rubber latex which may cause allergic reactions.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents. The absence of murine virus in the monoclonal source material has not been determined.

Procedure

Reagents Provided (Total of six vials)

1. One vial each of Reactivity Testing Reagents (Anti-A, Anti-B, IgG Reactive Anti-body)
2. One vial each of Reference Red Blood Cells (A₂ D Negative, B D Negative, O D Positive)

Materials Required but Not Provided

1. Reagent red blood cells
 - a. Reverse grouping cells
 - b. Antibody screening cells
2. Blood grouping reagents
 - a. Anti-A reagent
 - b. Anti-B reagent
 - c. Anti-AB reagent
 - d. Anti-D (anti-Rh₀) reagent and Rh control
3. Anti-human globulin(s)
 - a. Anti-IgG, -C3d; polyspecific
 - b. Anti-IgG (monospecific)
4. Coombs control cells
5. Potentiator
6. Physiologic saline
7. Disposable test tubes (12 x 75 mm or 10 x 75 mm)
8. Centrifuge calibrated for 1000 rcf* or for 150 rcf*

Note: To ensure proper centrifugation, each individual centrifuge should be calibrated for the specific test procedure being performed.³
9. Waterbath or heating block calibrated at 37°C
10. Optical aid⁴

Procedure Outline

The Testing Chart gives procedures for the quality assurance testing which may be performed using BBQA II Testing Reagents. Reactions obtained with reagents being tested should be graded 0 – 4 + to monitor reactivity throughout the dating period. Optional testing may be included when evaluation a new lot of reagent or if a reagent problem is suspected.

Results

Consult the Testing Chart for expected results and for interpretation of results obtained. Discrepancies between the expected results and the results actually obtained in any tube mean that one or more of the reagents or the technique used in that tube is suspect. The questionable result should be further investigated. This may require repeat testing, but since the amount of each BBQA II reagent is limited, indiscriminate repeat testing should be avoided as it can result in early depletion of the reagent.

Limitations of Procedures

False negative results may occur if:

1. cells are not properly washed or human globulins are present as contaminants in glassware. These residual globulins will neutralize the globulin-reactive antibodies present in antiglobulin serums.
2. antibody elutes from cells during incubation or washing.
3. erythrocytes and/or serums are stored improperly and lose reactivity.
4. reagents are inadvertently omitted.
5. tests are improperly centrifuged.
6. incubation times or temperatures are incorrect for proper cell sensitization.
7. resuspension technique is too vigorous to preserve agglutination of weakly sensitized erythrocytes.
8. room temperature is too high.

* rcf = 0.00001118 x rotating radius (cm) x rpm²

False positive results may occur if:

1. test cells which have a positive Direct Antiglobulin Test are used for Indirect Antiglobulin Testing.
2. test cells or serums have microbial contamination.
3. tests are improperly centrifuged.

Specific Performance Characteristics

Reactivity Testing Reagents are formulated to mimic weak patient or donor antibodies in giving relatively weak reactions with even the strongest antigens on reagent red blood cells. Thus, diminished reactivity of antigens on reagent red blood cells may be readily detected by daily testing during the dating period of the cells. In addition, since the BBQA II Reactivity Testing Reagents include representative antibodies reactive by major Blood Bank serologic techniques (immediate spin, saline/potentiator-37°C and antiglobulin), they provide a means for verifying the validity of these procedures and proper performance of all reagents and equipment used.

BBQA II Reactivity Testing Reagents and Reference Red Blood Cells are not designed to determine the absolute potency of corresponding antigens/antisera in the absence of appropriate reference materials. However, they may be utilized to determine relative potencies for identical antigen/antibody specificities and to detect overt deterioration of antigen/antiserum reactivity when compared with initial or expected results. In these applications, differences in relative potency or overt deterioration may be indicated by significant (> 1+) differences in reaction strengths in replicate assays. The Reference Red Blood Cells may not be used to compare potencies of antibodies with different specificities.

Some licensing agencies may require negative, as well as positive control testing each day of use. It is recommended that each laboratory review the requirements from their accrediting institution.

Testing Chart

Tube No.	Procedure	Expected Results	Interpretation	
1	ABO Grouping Reagents Follow manufacturer's instructions for reagent:	Add 1 drop BBQA II:	Obtaining the expected results confirms the identity and relative potency of the ABO grouping reagents.	
	Anti-A	A ₂ D – cells		IS +
	Anti-B	B D – cells		IS +
	Anti-A, B	A ₂ D – cells		IS +
4		B D – cells	IS +	
5	Reverse Grouping Cells Follow manufacturer's instructions for reagent:	Add 1 drop BBQA II:	Obtaining the expected results confirms the identity and relative potency of the A and B antigens on the A ₁ , A ₂ and B reverse grouping cells.	
	A ₁ cells	Anti-A		IS +
	6** A ₂ cells	Anti-A		IS +
	7 B cells	Anti-B		IS +
8	D (Rh₀) Grouping Reagent Follow manufacturer's instructions for reagent:	Add 1 drop BBQA II:	Obtaining the expected results confirms the identity, specificity and relative potency of the anti-D (anti-Rh ₀) reagent.	
	Anti-D (anti-Rh ₀)	A ₂ D – cells		IS 0 AG 0
	9	0 D + cells		IS +
	10	Rh Control		0 D + cells
Convert tubes 8 and 10 to weakD test following manufacturer's instructions.				
11	Antibody Screening Cells Follow manufacturer's instructions for reagent:	Add 1 drop BBQA II:	Obtaining the expected results (see manufacturer's package inserts for antigen profiles) confirms the identity of the screening cells. At least 1 ^w reactions where indicated confirm relative potency of the corresponding cell surface antigens.	
	Screening Cell I	IgG Reactive Antibody		AG +
	12 Screening Cell II	IgG Reactive Antibody		AG +
	13 Screening Cell III	IgG Reactive Antibody		AG +
If potentiators are used routinely, add potentiator to tubes 11–13 and incubate according to manufacturer's instructions. Note: For LISS procedures requiring 2 drops of serum, add 1 drop of physiologic saline along with the 1 drop of BBQA II antiserum to achieve the desired ionic strength. Perform antiglobulin testing with polyspecific anti-human globulin serum or anti-IgG (whichever is routinely used).				

** Optional if A₂ reagent red blood cells are not routinely used.

IS = Immediate spin: Shake tubes to mix reagents and immediately (within 5 minutes) centrifuge.

AG = Antiglobulin test: Perform according to anti-human serum manufacturer's instructions.

Bibliography

1. Myhre, B.A. Quality control in blood banking. New York: John Wiley & Sons; 1974: 58.
2. Technical manual of the American Association of Blood Banks. 14th ed.; 2002, Chapter 1.
3. Ibidem: 765–767.
4. Ibidem: 667–668.

Warranty

These products are warranted to perform as described in their labeling and in the product literature, and Medion Diagnostics AG disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event shall Medion Diagnostics AG be liable for any consequential damages arising out of the aforesaid express warranty.

Cat. No.	Product	Pkg.
070210	Blood Bank Quality Assurance (BBQA II) Testing Reagents (Reactivity Testing Serums and Reference Red Blood Cells)	Set of 6 vials (3 vials antisera and 3 vials red blood cells)
070223	Data-Cyte® Plus Reagent Red Blood Cells (3 ± 1 %)	11 x 4 ml
070221	Search-Cyte® Plus Reagent Red Blood Cells I and II (3 ± 1 %)	2 x 10 ml
070220	Search-Cyte® Reagent Red Blood Cells I and II (3 ± 1 %)	2 x 10 ml
070222	Search-Cyte® TCS Reagent Red Blood Cells I, II and III (3 ± 1 %)	3 x 10 ml
070201	Reverse-Cyte® Reagent Red Blood Cells (Groups A ₁ , A ₂ and B) (3 ± 1 %)	3 x 10 ml
070205	Coombs Control Cells	1 x 10 ml