US

Blood Grouping Reagent

Anti-Fy^a (FY1)

Seraclone® Human Monoclonal
(DG-FYA-02)

FOR IN-VITRO DIAGNOSTIC USE
For Tube Testing
MEETS FDA POTENCY REQUIREMENTS
U.S. License Number: 1798

Package size
REF 808188100 VOL 2 mL Seraclone® Anti-Fy^a (FY1)

Intended Use
For the determination of the Fy^a (FY1) antigen of red blood cells using the tube test.

Summary
Antibodies to the Fy^a antigen are of the IgG class. Anti-Fy^a may cause hemolytic disease of the fetus and newborn (HDFN) and has been implicated in hemolytic transfusion reactions (HTR).1
The frequencies of the common phenotypes are shown in the table.

Phenotypes and Frequencies in the Duffy System[1]		
Phenotype	Whites	Blacks
Fy (a+b-)	17	9
Fy (a+b+)	49	1
Fy (a-b+)	34	22
Fy (a-b-)	Very rare	68

Biotest Seraclone® Anti-Fy^a Blood Group Reagent is used to test for the presence or absence of the Fy^a antigen. Biotest Seraclone® Anti-Fy^a is used principally in the resolution of antibody problems or in family studies.

Principle of the Test
The test principle is hemagglutination. The antibody in Seraclone® Anti-Fy^a (FY1) binds to the Fy^a antigen on red blood cells. This does not result in a direct agglutination reaction. By adding Anti-Human Globulin reagent the antibody coated red blood cells are linked to each other, visible as red blood cell agglutination.

Reagent
As the reactive component Seraclone® Anti-Fy^a (FY1) contains a human monoclonal antibody of the immunoglobulin class IgG. It is derived from cell culture supernatant and demonstrates the consistent specificity and reproducibility characteristic for monoclonal antibodies.
Antibodies are diluted in a buffered protein solution containing macromolecular potentiators.
The following antibody is produced using intermediate products produced for Biotest Medical Diagnostics GmbH in a shared manufacturing agreement with DIAGAST, Parc Eurasante, 251 av. Eugene Avinee-BP9, 59374 Loos Cedex France; License Number 1744.

Seraclone® Anti-Fy^a (FY1) clone DG-FYA-02 (IgG)

Preservative: 0.1% sodium azide, 0.08g/L sodium arsenite

Precautions
- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date.
- Do not use if turbid.
- Handle and dispose of reagents as potentially infectious
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Warning: Contains sodium azide (NaN_3), which may react with lead or copper plumbing to form explosive azides. If discarded in the sink, flush with large amounts of water to prevent the build-up of explosive metal azides.
- The bovine albumin used for the production of this reagent is purchased from BSE-free US sources, Boval Company L.P. in Cleburne, Tx, USA and Millipore in Kankakee, IL, USA.

Specimen collection
Fresh samples of clotted, EDTA or citrate anticoagulated whole blood collected following general blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA and clotted specimens should be stored at 2 to 8°C, citrated specimens (donor segments) at 1 to 6°C.
Blood specimens exhibiting gross hemolysis or contamination should not be used.
Clotted samples or those collected in EDTA may be tested within ten days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiration date of the donor unit.

Materials
Materials provided
- Seraclone® Anti-Fy^a (FY1)

Materials required but not provided
- Pipettes (drop volume 40 to 50 µl)
- Isotonic saline solution
- Anti-Human Globulin Anti-IgG (e.g. Biotest REF 804175100)
- IgG coated red blood cells (e.g. Biotest Coombscell-E REF 816030100)
- Glass tubes 10 x 75mm or 12 x 75 mm
- Serological Centrifuge
- Interval Timer
- Markers
- Optical aid (optional). The use of an optical aid for agglutination reading must be vaildated by the user.

Test Procedure
Tube test
1. Prepare a 3 to 5% suspension of red blood cells to be tested in isotonic saline.
2. Place one drop reagent into an appropriately labeled tube.
3. Add one drop of red blood cell suspension into the tube and mix.
4. Incubate at 37°C for 30 minutes.
5. Wash the red blood cells 3 times with isotonic saline. Completely decant the supernatant.
6. Follow the directions of the Anti-Human Globulin manufacturer.
7. Centrifuge for 20 seconds at 800 -1000 x g.
8. Gently dislodge red blood cell button and observe for agglutination.
9. Record results

Stability of the Reaction
Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Time delays may cause a dissociation of the antigen-antibody complexes resulting to false negative or more often weak positive reactions.

Quality Control
The reactivity of all blood typing reagents should be confirmed by testing with known positive and negative red blood cells on each day of use.
To confirm the reactivity or specificity of Biotest Monoclonal Anti-Fy^a Blood Grouping Reagent, it should be tested with antigen-positive (preferably from heterozygous individuals) and antigen-negative red blood cells, respectively. The reagent is satisfactory for use if it reacts only with antigen-positive red blood cells.
Negative results in an antiglobulin test should be verified with IgG coated red blood cells. Add one drop of IgG coated red blood cells, mix and centrifuge for 20 seconds at 800 -1000 x g. Positive result: The negative reaction in the indirect antiglobulin test is valid, reactive antihuman globulin is present. Negative result: A technical error was made and the test must be repeated.
It is recommended that a positive and a negative control be performed in parallel with testing.

Interpretation of results
Agglutination of the red blood cells is a positive result and indicates the presence of the corresponding antigen. No agglutination is a negative result and indicates the absence of the corresponding antigen.
An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technial Manual, 15th edition).
Frequencies in the population are listed in the "Summary" section.

Limitations
- Samples with a positive direct antiglobulin test, cold agglutinins, or rouleaux formation may show false positive results in testing with monoclonal antibodies. Results on these samples must be interpreted with caution. False positive results or reaction suspected to be due to cold agglutinins should be resolved according to in-house procedures. It is recommended that an appropriate control be tested in parallel.
- Stored red blood cells may exhibit weaker reactions.
- Insufficient or inappropriate washing can lead to false negative or false positive reactions. Small amounts of residual patient sera/plasma can neutralize the Anti-Human Globulin.
- Some conditions that may cause false positive results are:
  - Contamination of sample or reagents
  - Autoantibodies
  - Improper storage or preparation of red blood cells
  - Antibodies to antibiotics or other reagents
  - Cold Antibodies

Specific Performance Characteristics
Testing is performed in accordance with FDA recommended methods.
The final release testing is performed according to the product specific SOPs. Each lot of Biotest Blood Group Reagent is tested in the Quality control by package insert method against a panel of antigen positive red blood cells (heterozygous antigen expression and if possible weakened antigen expression) to insure suitable reactivity. The products meet FDA potency requirements. The specificity testing for the presence of contaminating antibodies is performed according to the product specific SOPs.
For the product performance it is necessary to adhere to the recommended method in the instructions for use.

The performance of the Biotest Anti-Fy^{a} was confirmed against a FDA approved reference reagent in a Multi Center Field Trial.

For Technical Support or further product information, contact Biotest Diagnostics Corporation at 800-522-0090.

Note
Each facility should verify the optimum spin time for the specific centrifuge in use.
Manual techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user.
Used tests must be discarded as hazardous material. Manage waste according to local, state and national regulations.

Glossary of Symbols

Symbol	Definition	Symbol	Definition
LOT	Batch Code	IVD	*In vitro* diagnostic medical device
⚠	Caution, consult accompanying documents		Consult instructions for use.
	Manufacturer		Use by YYYY-MM-DD
	Contains sufficient quantity for <n> tests.	REF	Catalog number
	Temperature limitation	VOL	Volume

Bibliography
1. Mark E. Brecher, MD et al. Technical Manual 15th Edition, Bethesda, MA: AABB, 2005.

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Biotest
Biotest Medical Diagnostics GmbH, Industriestr. 1,
D-63303 Dreieich, Germany, www.biotest.de, mail@biotest.de
Tel.: +49-6103-801-0, Fax: +49-6103-801-140