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: 1845
Rx only

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-)	20	10
Fy (a+b+)	48	3
Fy (a-b+)	32	20
Fy (a-b-)	0	67

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

PRINCIPLES 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

[IVD]
OBSERVABLE INDICATIONS.
Do not use if markedly turbid.
Do not use damaged vials.

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 Bio-Rad 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 sourced from donor animals of U.S. origin that have been inspected and certified by U.S. Veterinary Service inspectors to be disease free.
- Consult **downloads.bio-rad.com** to download the valid version of this instruction for use.

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.
Note: 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
- Isotonic saline or Phosphate Buffered Saline (PBS; pH 7.2 +/-0.1)
- Anti-Human Globulin Anti-IgG (e.g. Bio-Rad [REF] 804175100)
- IgG coated red blood cells (e.g. Bio-Rad Coombscell-E [REF] 816030100)
- Glass tubes 10 x 75mm or 12 x 75 mm
- Serological centrifuge
- Interval timer
- Markers
- Agglutination viewer (optional)

TEST PROCEDURE

Tube test

1. Prepare a 3 to 5% suspension of red blood cells to be tested in saline.
2. Place one drop reagent into an appropriately labelled tube.
3. Add one drop (approx. 40 to 50 µL) of red blood cell suspension into the tube and mix.
4. Incubate at 36 to 38°C for 30 to 60 minutes.
5. Wash the red blood cells 3 times with saline. Completely decant the supernatant.
6. Follow the directions of the Anti-Human Globulin manufacturer.
7. Centrifuge for:
a. 20 seconds at 800 to 1000 x g, or
b. at a time and speed appropriate for the centrifuge calibration.
8. Gently dislodge red blood cell button and observe for macroscopic agglutination. Negative reactions may be examined with an agglutination viewer, however, microscopic examination is not recommended.
9. Record results.
10. To control all negative antiglobulin tests, add red blood cells sensitised with IgG antibody, e.g., Coombscell E (see package insert for procedure).

STABILITY OF 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 Bio-Rad 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.

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 Technical Manual)[1].

Frequencies in the population are listed in the "Summary" section of this package insert.

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.
- Stored red blood cells may exhibit weaker reactions.
- Due to the nature of monoclonal antibodies, i.e. recognition of a single epitope, discrepant results or strengths of reaction may be found in comparison with human polyclonal test sera. This may be due to antigen variants.
- Grossly icteric blood samples, blood samples with abnormally high concentrations of protein or blood samples from patients who have received plasma expanders of high molecular weight may give false positive results.
- In case of ambiguous results it is recommended to wash red blood cells at least 2 times.
- 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
- Cross reaction with patient's medication (e.g. antibiotics)
- Mixed field reaction due to patients pre-transfusion history

SPECIFIC PERFORMANCE CHARACTERISTICS

Testing is performed in accordance with FDA recommended methods.
The final release testing is performed according to the product specific SOPs. As part of the release process, each lot of Bio-Rad Blood Grouping Reagent is tested in the Quality control according to the 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 product meets 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 Bio-Rad 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 Bio-Rad Laboratories, Inc., at 800-224-6723.

NOTE

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
!	Consult the instructions for use for important cautionary information such as warnings and precautions	I	Consult instructions for use
M	Manufacturer	e	Use by YYYY-MM-DD
s	Contains sufficient quantity for <n> tests	[REF]	Catalog number
t	Temperature limitation	[VOL]	Volume

BIBLIOGRAPHY

1. John D. Roback, MD et al. Technical Manual 17th Edition, Bethesda, MA: AABB, 2011.

Key: Underline = Addition of changes ◄ = Deletion of text