ANTI FY^a (DUFFY^a)

I. PRINCIPLE

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.

II. CLINICAL SIGNIFICANCE

UnityPoint-Health Pekin laboratory personnel will utilize this procedure to test red blood cells for the presence or absence of Duffy^a (Fy^a) antigen.

III. SPECIMEN

A. No special preparation of the patient is required prior to specimen collection. Collect all blood samples using accepted aseptic techniques.
B. Fresh cells are preferred for testing and may be collected in EDTA (pink top tube). Samples collected in EDTA may be tested for up to 10 days from collection. Donor cells collected in CPDA–1 or CPD may be tested up to the expiration date of the unit.
C. EDTAspecimens should be stored at 2°C to 8°C if not used immediately. Citrated specimens (donor segments) should be stored at 1° to 6°C.
D. For test procedure, cells should be washed one time and prepared as a fresh 2-5% suspension in saline.
E. Blood specimens exhibiting gross hemolysis or contamination should not be used.

IV. REAGENT

A. 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. Preservative: 0.1% Sodium azide, 0.08g/L Sodium arsenite.

B. Precautions:

1. For in vitro diagnostic use.
2. Store at 2 to 8°C.
3. Do not use beyond the expiration date.
4. Do not use if turbid.
5. Handle and dispose of reagents as potentially infectious.
6. Caution: Do not pipette by mouth. The absence of all viruses has not been determined.

7. Caution: This product contains natural rubber latex which may cause allergic reactions.
8. 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.
9. 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.

V. PROCEDURE:

A. Label one 12 x 75 mm test tube for each sample to be tested. Label additional tubes for known Fy^a + and Fy^a - controls. (Screen cells or panel cells may be used.)
B. Label each tube with first and last initial of patient being tested. (Lengthen the minimum letters to differentiate patients with the same initials, if necessary.)
C. Placel drop of Anti-Fy^a reagent in each test tube.
D. Add 1 drop of 2-5% red cell suspension in saline of cells to be tested.
E. Mix well.
F. Incubate at 36-38° C for 30-60 minutes.
G. Wash three times with saline (may use cell washer).
H. Add two drops anti-IgG coombs, mix well, and centrifuge 20 seconds.
I. Gently resuspend the cells completely and examine immediately for macroscopic agglutination. Negative reactions may be examined with an agglutination viewer.
J. Add one drop of Coombs control cells to all tubes with negative results. Centrifuge for 20 seconds, read and record results. If the control cells are agglutinated, the antigen result is valid.

VI. REPORTING RESULTS

A. Agglutination = positive test result, antigen present.
B. No Agglutination = negative test result, absence of antigen.

%Frequencies	Caucasians	African-Americans
Fy (a+b-)	20	10
Fy (a-b+)	32	20
Fy (a-b-)	0	67
Fy (a+b+)	48	3

VII. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. 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.
B. Stored red blood cells may exhibit weaker reactions.
C. 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.
D. Some conditions that may cause false positive results are:
    1. Contamination of sample or reagents
    2. Autoantibodies
    3. Improper storage or preparation of red blood cells
    4. Antibodies to antibiotics or other reagents
    5. Cold antibodies

VIII. REFERENCES

A. Bio-Rad Medical Diagnostics GmbH, Dreieich, Germany, Blood Grouping Reagent Anti-Fy^a (FY1) Seraclone® Human Monoclonal, 186285/09, Rev. 08/2014.

POLICY CREATION :	***Date***
Author: Sharrol Brisbin, MT (ASCP)	***02/01/2001***
Medical Director: Kathryn Kramer, MD	***02/01/2001***

MEDICAL DIRECTOR		
DATE	**NAME**	**SIGNATURE**
5-10-18	Kathryn O. Kramer MD	
SECTION MEDICAL DIRECTOR		
	N/A	

Reviewed by

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date