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FLOW CYTOMETRY REPORT – PNH EVALUATION

SAMPLE REPORT

Name:	PNH, Negative			Pathology Number:	F-15-99999
DOB:	11/09/1956	Sex: M	MR #: 987654321	Date of Procedure:	3/10/2007
Facility:	Ordering Facility			Date of Accession:	3/10/2007
Dept:	Outpatient				

Physician: Ordering Provider, M.D.
Ordering Facility
Street Name
City, State Zip code
(999) 123-4567

Copies to: Other Providers/clinicians

TISSUE/SPECIMEN: Peripheral Blood in EDTA

DIAGNOSIS: NO PHENOTYPIC EVIDENCE OF PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

Comment: Flow cytometric analysis does not show any evidence of a PNH clone based upon analysis of a variety of GPI-linked antibodies on red blood cells, monocytes and granulocytes. These findings do not support a diagnosis of PNH. Clinical correlation is recommended.

Reference: 1. Borowitz et al: Guidelines for the Diagnosis and Monitoring of PNH and Related Disorders, Clin Cytometry 2010, 211-230
2. Sutherland et al: Practical guidelines for the high-sensitivity detection and monitoring of PNH clones by flow cytometry. Cytometry B Clin Cytom 2012; 82:195-208.
3. http://www.pnhsource.com/physicians

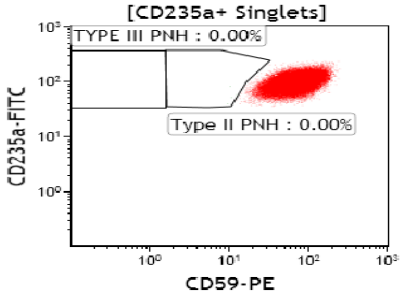
Flow Results: ***Immunophenotypic analysis*** was performed using gating antibodies CD45, CD15, CD64, CD235a, GPI-linked antibodies CD59, CD14, CD24, as well as fluorescent Aerolysin (FLAER).

Red Blood Cells: No evidence of decreased or absent CD59 expression

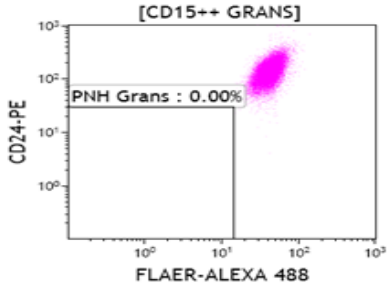
Monocytes: No evidence of decreased or absent expression of FLAER or CD14

Granulocytes: No evidence of decreased or absent expression of FLAER or CD24

Sensitivity for our PNH Assay analyzing granulocytes and red blood cells is 0.01%



Sample histogram of a typical patient with no evidence of PNH in RBC's



Sample histogram of a typical patient with no evidence of PNH in Granulocytes

The markers used for this flow cytometric analysis are labeled as Analyte Specific Reagents (ASR) and are used for clinical purposes. The performance characteristics of these markers have been determined by DCDS-Flow Cytometry Laboratory. Their use has not been approved by the U.S. Food and Drug Administration; the FDA has determined that such approval is not necessary.

Electronic SignaturePathologist
Date