



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003827 M 07/08/1978

Collected: 12/28/2023 14:34

Received: 12/28/2023 2:34 PM

PNH WITH FLAER

Source : Peripheral Blood

Flow Cytometry Interpretation :

No flow cytometric evidence of PNH.

Comment :

No evidence of aberrant loss of GPI-linked markers tested.

Granulocytes- No decreased/absent expression of CD157 and FLAER.

Monocytes- No decreased/absent expression of CD157 and FLAER.

Methodology:

FLAER reagent and antibodies directed against CD157, as well as CD45, CD15, and CD64 (for gating) were used for flow cytometric assessment of glycosylphosphatidylinositol (GPI)-linked molecules. Reported percentages within different blood cell populations are based on the scattergram of CD45, forward scatter, side scatter, and phenotypic cluster analysis. This high-sensitivity assay can detect as few as 1 in 10,000 GPI-deficient neutrophils in a mixed population and can be used for sequentially monitoring disease levels in patients with paroxysmal nocturnal hemoglobinuria (PNH). PNH cells are seen in <.003% of normal neutrophils.

References:

1. Borowitz, M., et al; Guidelines for the diagnosis and monitoring of Paroxysmal Nocturnal Hemoglobinuria and Related Disorders by Flow Cytometry. Cytometry Part B (Clinical Cytometry) 78B:211-230 (2010).
2. Sutherland, D., et al; Use of a FLAER-Based WBC Assay in the Primary Screening of PNH Clones. Am J Clin Pathol 132:564-572 (2009).
3. Sutherland, D., et al; Use of CD157 in FLAER-Based Assays for High-Sensitivity PNH Granulocyte and PNH Monocyte Detection. Cytometry Part B (Clinical Cytometry) 86B:44-55 (2014).

Reviewed by :

Kajal V. Sitwala, MD, PhD

12/28/2023 14:40

Antibodies performed :

CD15, CD45, CD64, CD157, FLAER

This test was developed and its performance characteristics determined by Warde Medical Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Performing Site:

WMRL: Warde Medical Laboratory 300 West Textile Road Ann Arbor MI 48108 (800)876-6522

F628000020

WMF-23-60

Ordered By: KAJAL V SITWALA, MD

Report Date: 12/28/2023 14:40

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Kajal V. Sitwala, MD, PhD - Medical Director