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Tracy I. George, MD, Chief Medical Officer

Patient Age/Sex: 67 years Male

Specimen Collected: 17-Jun-22 16:13

PNH, High Sensitivity, WBC		Received: 17-Jun-22 16:27	Report/Verified: 17-Jun-22 17:04
Procedure	Result	Units	Reference Interval
Neutrophil PNH Phenotype	Detected		Detected
FLAER and CD157-deficient neutrophils	1.000 ^{H #f1}	%	0.000-.008
Monocyte PNH Phenotype	Detected		Detected
FLAER and CD157-deficient monocytes	1.000 ^{H #f2}	%	0.000-0.200

Result Footnote

f1: FLAER and CD157-deficient neutrophils

Suboptimal number of events were collected for PMN's. This may affect the sensitivity of the assay. Please interpret with caution.

INTERPRETIVE INFORMATION: PNH, High Sensitivity, WBC

WBC analysis is the most accurate measurement of the PNH clone size. In this high-sensitivity assay FLAER and CD157 are used as GPI-linked markers; CD15 (PMNs) and CD64 (monocytes) are used as lineage-specific markers. The assay was developed according to published guidelines (Cytometry B Clin. Cytom. 2010; 78:211) and as updated in 2018 (Cytometry B Clin. Cytom. 2018; 94B:49). The lower limit of quantification is 0.02 percent for PNH PMNs (based on 250,000 cells analyzed) and 0.5 percent or better for PNH monocytes (based on 10,000 cells analyzed). The lower limit of detection for PNH PMNs is 0.008 percent and for PNH monocytes 0.2 percent. For severely pan-cytopenic patients, the WBC assay sensitivity will be much lower.

The presence of a subclinical PNH population in myelodysplastic bone marrow disorders, such as aplastic anemia or refractory anemia, may correlate with a positive immunotherapeutic response (Blood 2006; 107, 1308-1314).

For initial diagnosis of PNH, order High Sensitivity RBC and WBC Panel (ARUP test code 2005006).

For delineation of RBC Types II and III populations when the RBC clone size is greater than 1 percent, order PNH, High Sensitivity, RBC (ARUP test code 2004366).

Patient Retesting Recommendations. The frequency of testing is dictated by clinical and hematological parameters. Repeat testing is indicated upon any significant change in clinical or laboratory parameters and is suggested at least annually for routine monitoring. In the setting of aplastic anemia, international guidelines recommend screening for PNH at diagnosis, and every 3 to 6 months initially, reducing the frequency of testing if the proportion of GPI-deficient cells has remained stable over an initial two year period (Int J Lab Hematol 2019;41 Suppl 1:73-81).

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

f2: FLAER and CD157-deficient monocytes

Suboptimal number of events were collected for monocytes. This may affect the sensitivity of the assay. Please interpret with caution.

*=Abnormal, #=Corrected, C=Critical, f=Result Footnote, H=High, i=Test Information, L=Low, t=Interpretive Text, @=Performing lab

Unless otherwise indicated, testing performed at:**ARUP Laboratories**

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Laboratory Director: Tracy I. George, MD

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