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Patient Report

Patient Age/Sex: 40 years Female

Specimen Collected: 19-Jun-22 20:18

PNH Panel, High Sensitivity, (RBC, WBC) | **Received: 19-Jun-22 20:18** | **Report/Verified: 19-Jun-22 20:30**

Procedure	Result	Units	Reference Interval
Neutrophil PNH Phenotype	Not Detected		Not Detected
FLAER and CD157-deficient neutrophils	<0.008 f1	%	0.000-.008
Monocyte PNH Phenotype	Not Detected		Not Detected
FLAER and CD157-deficient monocytes	<0.200 f2	%	0.000-0.200
RBC PNH Phenotype	Detected		Not Detected
Total (II and III) CD59-deficient RBC	**1.000 H f3**	%	0.000-.008

PNH RBC TYPE | **Received: 19-Jun-22 20:19** | **Report/Verified: 19-Jun-22 20:30**

Procedure	Result	Units	Reference Interval
Type II CD59-deficient RBC	1.000	%	
Type III CD59-deficient RBC	1.000	%	

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.

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.

f3: Total (II and III) CD59-deficient RBC

INTERPRETIVE INFORMATION: PNH Panel, High Sensitivity, (RBC, WBC)

This test is preferred for the initial diagnosis of PNH, and 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 test includes high-sensitivity WBC and RBC analysis with a lower limit of quantification of 0.02 percent for PNH RBCs and 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 RBCs and PMNs is 0.008 percent and for PNH monocytes 0.2 percent. For severely pancytopenic patients, the WBC assay sensitivity will be much lower.

WBC analysis is the most accurate measurement of the PNH clone size. FLAER and CD157 are used as GPI-linked markers; CD15 (PMNs) and CD64 (monocytes) are used as lineage-specific markers. RBC analysis quantifies Type II and Type III RBC clones when the percentage of PNH RBCs is greater than 1 percent. Glycophorin A (CD235a) is used to gate the RBC population, and CD59 is the GPI-linked antigen. Recent RBC transfusions may decrease the percentage of PNH cells measured in RBCs (Cytometry 2000; 42:223). 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).

Patient Retesting Recommendations: The frequency of testing is dictated by clinical and hematological

Result Footnote

f3: Total (II and III) CD59-deficient RBC 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.