ARUP LABORATORIES
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Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	5/20/1980
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

Paroxysmal Nocturnal Hemoglobinuria (PNH), High Sensitivity, RBC and WBC

ARUP test code 2005006

Neutrophil PNH Phenotype	Not Detected	(Ref Interval: Not Detected)
FLAER and CD157-deficient neutrophils	<0.008 %	(Ref Interval: 0.000-0.008)
Monocyte PNH Phenotype	Not Detected	(Ref Interval: Not Detected)
FLAER and CD157-deficient monocytes	<0.200 %	(Ref Interval: 0.000-0.200)
RBC PNH Phenotype	Not Detected	(Ref Interval: Not Detected)
Total (II and III) CD59-deficient RBC	<0.008 %	(Ref Interval: 0.000-0.008)

H=High, L=Low, *=Abnormal, C=Critical

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 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 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.

H=High, L=Low, *=Abnormal, C=Critical

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Neutrophil PNH Phenotype	23-080-120877	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
FLAER and CD157-deficient neutrophils	23-080-120877	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Monocyte PNH Phenotype	23-080-120877	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
FLAER and CD157-deficient monocytes	23-080-120877	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
RBC PNH Phenotype	23-080-120877	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total (II and III) CD59-deficient RBC	23-080-120877	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical