

Patient Report | FINAL

AR P°

Client: Example Client ABC123 123 Test Drive Salt Lake City, UT 84108

Physician: Doctor, Example

UNITED STATES

**Patient: Patient, Example** 

DOB 4/6/1995 Gender: Female

Patient Identifiers: 01234567890ABCD, 012345

**Visit Number (FIN):** 01234567890ABCD **Collection Date:** 00/00/0000 00:00

## Paroxysmal Nocturnal Hemoglobinuria, High Sensitivity, RBC

ARUP test code 2004366

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

4848



INTERPRETIVE INFORMATION: PNH, High Sensitivity, RBC

This high-sensitivity RBC assay tests for CD59 expression on erythrocytes using flow cytometry. It 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 RBCs (based on 250,000 cells analyzed). The lower limit of detection for PNH RBCs is 0.008 percent.

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).

For the most accurate measurement of the PNH clone size, order Paroxysmal Nocturnal Hemoglobinuria, High Sensitivity, WBC (ARUP test code 2005003) to assist with therapeutic decisions in conventional PNH.

For initial diagnosis of PNH and analysis of both RBCs and WBCs, order Paroxysmal Nocturnal Hemoglobinuria (PNH), High Sensitivity, RBC and WBC (ARUP test code 2005006).

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.

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VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
RBC PNH Phenotype	23-077-106752	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total (II and III) CD59-deficient RBC	23-077-106752	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

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