Diagnose Earlier Paroxysmal Nocturnal Hemoglobinuria (PNH)

Clinical laboratory services supporting hematology-oncology, nephrology, and other specialties for improved patient outcomes[1,2]

ALEXION®

CATCH PNH earlier in high-risk patient populations[3,4]

PNH is a life-threatening rare disease characterized by progressive morbidities and premature mortality.[5] Diverse and common symptomology of PNH can delay diagnosis.[6] Estimates of patient mortality range from ~20% to 35% within 6 years of diagnosis, despite historical supportive care.[7,8]

Testing for PNH is recommended in patients with hemolysis, bone marrow dysfunction, and unexplained thrombosis.[1,3,9,10] The diagnostic pathway for PNH testing should include high-sensitivity flow cytometry on peripheral blood.[1]

Bone Marrow Dysfunction		Unexplained Thrombosis	Hemolysis with elevated LDH, reticulocytes, or bilirubin with decreased haptoglobin	
C	**A**	**T**	**C**	**H**
Cytopenia (unexplained) with hemolysis or thrombosis	Aplastic anemia (AA) / refractory myelodysplastic syndrome (MDS)	Thrombosis with cytopenia and/or hemolysis	Coombs-negative hemolytic anemia	Hemoglobinuria
Incidence of PNH Clones in High-Risk Conditions[10]				
22.4% (with anemia) **5.1%** (without anemia)	**44.9%** (AA) **9.8%** (MDS)	**13.7%**	**18.6%**	**47.9%**

High-Risk Conditions by ICD-10 Codes[11]

D61.1 Aplastic anemia, drug-induced	**I82.411 – I82.413** **I82.421 – I82.423** **I82.431 – I82.433** **I82.4Y1 – I82.4Y3** **I82.419 – I82.439** Acute embolism and thrombosis, vein-specific
D61.2 Aplastic anemia, other external agents	
D61.3 Aplastic anemia, idiopathic	
D61.89 Aplastic anemia, other specified, other MDS	
D59.9 Acquired hemolytic anemia, unspecified	
D59.5 Paroxysmal nocturnal hemoglobinuria	**D46.1, D46.0** Refractory anemia, with or without sideroblasts
D59.6 Hemoglobinuria, other external causes	**D46.20, D.46.21, D46.22** Refractory anemia with excess of blasts
D59.8 Hemolytic anemias, other specified	**D46.A, D46.B** Refractory cytopenia with multilineage dysplasia
I82.0 Budd-Chiari syndrome	**D46.4** Refractory anemia, unspecified
182.91 Chronic embolism and thrombosis, unspecified	**D46.C** Myelodysplastic syndrome with isolated 5q deletion
	D46.9 Myelodysplastic syndrome, unspecified
	D46.Z Other MDS

Obtain PNH clone results

Reference labs employing high-sensitivity flow cytometry

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Specimen Collection and Transport

Obtain fresh peripheral blood specimen.

Testing should be completed within 48 hours of specimen collection.

1. Draw **1 to 3 mL** peripheral blood.
2. Use 5 mL EDTA (lavender) or heparin (green) tubes.
3. Ship specimen according to laboratory instructions.
4. Refrigerated storage 4°C up to **48 hours**. Do not freeze specimen.

Alexion purchases fully anonymized test information from testing laboratories, including some of the laboratories listed to the right. Testing laboratories' provision of data to Alexion did not play a role in the inclusion of those laboratories listed herein. Alexion is committed to compliance with state and federal privacy laws. To learn more about Alexion's commitment to privacy, please visit https://alexion.com/Legal#privacynotice.

Each laboratory on the list was included based on the laboratory's representation that it provides high-sensitivity flow cytometry assays and offers results reported as a percentage of PNH clones from granulocyte, monocyte, and erythrocyte populations to a cutoff of 0.01% clone size. Alexion does not warrant or guarantee the laboratories' representations.

Laboratory	Contact Info	Test Code
ARUP LABORATORIES 500 Chipeta Way Salt Lake City, UT 84108	**800-522-2787** www.aruplab.com clientservices@aruplab.com	**2005006**
CSI LABORATORIES 2580 Westside Parkway Alpharetta, GA 30004	**800-459-1185** www.csilaboratories.com clientservice@csilaboratories.com	**PNH High-Sensitivity**
DAHL-CHASE DIAGNOSTIC SERVICES 417 State St., Ste. 540 Bangor, ME 04401	**877-PNH-FLOW (877-764-3569)** www.dahlchase.com customerservice@dahlchase.com	**AA-00231**
HEMATOGENIX LABORATORY SERVICES 8150 W. 185th St., Ste. A Tinley Park, IL 60487	**888-HEMATO-1 (888-436-2861)** www.diagnostics.hematogenix.com clientservices@hematogenix.com	**Paroxysmal Nocturnal Hemoglobinuria (PNH) Panel / High Sensitivity**
LABCORP 531 S. Spring St. Burlington, NC 27215	**800-874-8532** www.labcorp.com www.integratedoncology.com	**502251**
MAYO CLINIC LABORATORIES 3050 Superior Dr. NW Rochester, MN 55901	**800-533-1710 / 507-266-5700** www.mayocliniclabs.com mcl@mayo.com	**PLINK**
MOLECULAR PATHOLOGY LABORATORY NETWORK 250 E. Broadway Maryville, TN 37804	**800-932-2943** www.mplnet.com services@mplnet.com	**FLOW PNH**
NEOGENOMICS LABORATORIES 12701 Commonwealth Dr., Ste. 9 Fort Myers, FL 33913	**866-776-5907, option 3** www.neogenomics.com client.services@neogenomics.com	**High Sensitivity PNH Evaluation**
QUEST DIAGNOSTICS 2501 S. State Highway 121, Ste. 1100 Lewisville, TX 75067	**866-MYQUEST (866-697-8378)** www.questdiagnostics.com	**94148**

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CATCH PNH earlier.
Improve patient outcomes.

1. **CATCH high-risk patients earlier** by underlying comorbidities.[4]

2. Ask your clinical laboratory director for **high-sensitivity flow cytometry** testing of PNH clones, reported as the clone size of neutrophils, monocytes, and erythrocytes, using a **0.01% PNH clone sensitivity** threshold.[1]

3. Ask for erythrocytes to be reported as the proportion of Type I (normal), Type II (partial CD59 deficiency), and Type III (complete CD59 deficiency) cells.[1]

4. Select a high-sensitivity flow cytometry testing provider from the list provided if your clinical laboratory does not perform this test. **Testing should be completed within 48 hours** of specimen collection.[1]

5. **New patients with detectable clone size ≥0.01% should be monitored every 3 months.** Test patients before initiating therapeutic agents that may affect hematopoiesis to minimize risk of false negative results.[12,13]

This algorithm is intended as educational information for healthcare providers. It does not replace a healthcare provider's professional judgment or clinical diagnosis.

References

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