

| Laboratory | Sensitivity | Sample Information | Contact Information |
|---|-------------|---|--|
| ARUP Paroxysmal Nocturnal Hemoglobinuria (PNH), High Sensitivity, RBC and WBC ¹ | High | https://ltd.aruplab.com/Tests/Pub/2005006 | 1-800-522-2787 clientservices@aruplab.com |
| BioReference Laboratories PNH by Flow Cytometry ² | NR | https://www.bioreference.com/physicians/resources/test-directory/?tc=5564 | 1-800-229-5227 https://www.bioreference.com/contact/ |
| Cleveland Clinic Laboratories High-Sensitivity Flow Cytometry for PNH ³ | High | https://clevelandcliniclabs.com/high-sensitivity-flow-cytometry-for-paroxysmal-nocturnal-hemoglobinuria/ | 1-800-628-6816/1-216-444-5755 https://clevelandcliniclabs.com/contact-us/ |
| CSI Laboratories PNH High-Sensitivity ⁴ | High | https://www.csilaboratories.com/flow/pnh-high-sensitivity/ | 1-800-459-1185 clientservice@csilaboratories.com |
| Dahl-Chase Diagnostic Services ^{5,6} PNH Analysis | High | https://dahlchase.host4kb.com/article/AA-00231/15/ | 1-207-941-8200/1-800-660-1626 cservice@dahlchase.com |
| Hematogenix ⁷ | High | https://hematogenix.com/technologies/flow-cytometry | 1-708-444-0444 ClientServices@hematogenix.com |
| Inform Diagnostics ⁸ | High | https://www.informdx.com/wp-content/uploads/MLS-20-0100.4-Client-Resource-Guide.pdf | 1-888-354-8168 https://www.informdx.com/contact-us/ |
| Labcorp PNH Evaluation ⁹ | High | https://oncology.labcorp.com/tests/zzIQ-295/pnh-evaluation | 1-800-447-5816 https://oncology.labcorp.com/contact-us |
| Mayo Clinic Laboratories PLINK ^{10,11} | High | https://www.mayocliniclabs.com/test-catalog/overview/62139#Specimen | 1-800-533-1710/1-507-266-5700 mcl@mayo.edu |
| Michigan Medicine Laboratories Flow Cytometric Immunophenotyping ¹² | NR | https://mlabs.umich.edu/tests/pnh-marker-panel | 1-800-862-7284 https://mlabs.umich.edu/form/contact |
| Molecular Pathology Lab Network PNH—High Sensitivity by Flow ^{13,14} | High | https://www.mplnet.com/test-menu | 1-865-380-9746 services@mplnet.com |
| NeoGenomics High Sensitivity PNH Evaluation ¹⁵ | High | https://neogenomics.com/test-menu/high-sensitivity-pnh-evaluation | 1-866-776-5907, option 3 Client.Services@neogenomics.com |
| Oregon Health & Science University Lab Services PNH Test (High Sensitivity) ¹⁶ | High | https://www.ohsu.edu/lab-services/pnh-test-high-sensitivity | 1-503-494-7383 1-888-375-4636 https://www.ohsu.edu/about/contact-us |
| PathGroup PNH Analysis (Flow Cytometry) ¹⁷ | High | https://pathconnect.pathgroup.com/testmenu/#/testinfo/UE5IRQ%3D%3D | 1-615-562-9300/1-888-474-5227 http://www.pathgroup.com/company/contact/ |
| Quest Diagnostics PNH With FLAER (High Sensitivity) ¹⁸ | High | https://testdirectory.questdiagnostics.com/test/test-detail/94148/paroxysmal-nocturnal-hemoglobinuria-pnh-with-flaer-high-sensitivity?cc=MASTER | 1-866-697-8378 https://www.questdiagnostics.com/contact-us |
| UF Pathology Laboratories PNH—FLAER, Granulocytes/Monocytes ¹⁹ | NR | https://pathlabs.ufl.edu/tests/test-directory-p/paroxysmal-nocturnal-hemoglobinuria-pnh-cd55-59-erythrocytes-flaer-granulocytes-monocytes/ | Main: 1-352-265-9900 Jacksonville: 1-904-427-0865 Toll-Free: 1-888-375-5227 https://pathlabs.ufl.edu/contact-us/ |
| University of Iowa Diagnostic Laboratories PNH Screening ²⁰ | NR | https://www.healthcare.uiowa.edu/path-handbook/rhandbook/test1123.html | Local: 1-319-384-7212 Toll-Free: 1-866-844-2522 https://medicine.uiowa.edu/uidl/about-us |
| University of Pittsburgh Department of Pathology Clinical Flow Cytometry—PNH Evaluation ²¹ | NR | https://www.path.pitt.edu/divisions/section-laboratory-medicine/division-clinical-hematopathology/clinical-flow-cytometry-0 | 1-412-864-6173 https://www.path.pitt.edu/contact-us |
| University of Texas Medical Branch PNH, High Sensitivity, RBC and WBC ²² | High | https://www.utmb.edu/lsg2/Home/Details?id=1366 | 1-409-772-2222 1-800-917-8906 https://www.utmb.edu/contact |
| UW Medicine Laboratory Medicine and Pathology PNH by Flow Cytometry ²³ | NR | https://dlmp.uw.edu/test-guide/view/PNHFLQ | 1-206-520-4600 1-800-713-5198 commserv@uw.edu |

 **Expected TATs for these tests range from 1 to 7 days^a**

The laboratories listed in the table above offer tests to identify patients with PNH. Novartis does not endorse the use of any specific laboratory or test. This information is intended for reference only. There may be additional laboratories that conduct PNH testing. Conduct your own research and verify the capabilities and services of laboratories for your specific needs.

FLAER, fluorescein-labeled proaerolysin; NR, not reported; RBC, red blood cell; TAT, turnaround time; WBC, white blood cell.
^aHematogenix, BioReference Laboratories, and PathGroup do not report the TAT of their PNH testing.

ROUTINE LABORATORY TESTING ALONG WITH HIGH-SENSITIVITY FLOW CYTOMETRY IS ESSENTIAL TO GUIDING THERAPEUTIC DECISIONS²⁴⁻²⁹



Diagnosis of PNH

- Timely and accurate diagnoses are critical for making appropriate treatment decisions for patients with PNH^{24,26-29}
- Biomarker testing using flow cytometry is a fundamental component of the diagnostic workup^{24-26,29}



Comorbidities Associated With PNH

- PNH is not mutually exclusive with BMF, and a substantial number of patients are positive for both PNH and BMF²⁴
 - ~63% of patients with PNH have a history of BMF, with 23% to 38% of patients having a history of AA and 4% to 11% of patients having a concurrent diagnosis of MDS³⁰⁻³⁴
 - 50% to 61% of patients with AA are positive for PNH^{35,36}
 - 10% to 20% of patients with MDS are positive for PNH^{35,37}
- Flow cytometry is the only test that can differentiate PNH from AA and MDS^{38,39}



Importance of Routine Monitoring in PNH

- Consider monitoring PNH clone size at regular intervals using high-sensitivity flow cytometry; any change in clinical or hematologic parameters may require more frequent monitoring^{24,39,40}
- Changes in clone size may reflect a changing clinical picture and/or progression from subclinical to hemolytic PNH⁴⁰
- Consider analysis of PNH clone size at least every 6 months for the first 2 years, and then once a year thereafter if the disease is being treated and is stable⁴¹
- Testing for clone size expansion in patients with AA and/or “minor” PNH clones can be conducted every 3 to 6 months for the first 2 years, and then annually thereafter if the clone size remains stable³⁹

High-sensitivity flow cytometry is the gold standard in diagnosing PNH and is used to monitor patient response to treatment^{24,39,40}

AA, aplastic anemia; BMF, bone marrow failure; MDS, myelodysplastic syndrome.

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