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For Immediate Release

**ACUPATH OFFERS “FLAER” REAGENT FOR DIAGNOSING PNH**  
***New Diagnostic Process Identifies Rare Blood Disease More Accurately***

**Plainview, NY, September 2010** -- Acupath Laboratories Inc. has announced it is now offering flow cytometry testing using the FLAER reagent for paroxysmal nocturnal hemoglobinuria (PNH), an acquired genetic blood disorder.

PNH is a progressive and destructive disease that can cause thrombosis, end organ damage, and increased mortality. Only recently approved from the New York State Department of Health, Acupath is one of the few labs in the tri-state area to use the new FLAER reagent for the diagnosis of PNH, along with the traditional CD55 and CD59 antibody staining.

PNH affects 8,000-10,000 people in North America and Europe, typically striking men and women in their early 30s. It develops without warning and, because it is so rare, PNH often goes unrecognized, with delays in diagnosis ranging from one to more than 10 years. PNH patients tend to survive 10-15 years from the time they are diagnosed.

Dr. Zsuzsanna Vegh-Goyarts, Ph.D., co-director of flow cytometry and tumor markers for Acupath Laboratories, a leader in hematological pathology, explained that PNH is a hematopoietic stem cell disorder caused by a somatic mutation of a single gene. “This mutation may occur in PNH, as well as in aplastic anemia and myelodysplasia or Myelodysplastic syndrome (MDS) resulting in PNH-like clones. Patients with the defective gene have a partial or complete deficiency of the GPI anchor proteins -for example CD55 and CD59-, that are protecting cells from lysis,” she explains. “These proteins are lost in PNH clones that causes the lysis of the red blood cells in PNH patients. The loss of these cell surface molecules is detectable by flow cytometry,” says Dr Vegh-Goyarts. “Traditionally the red blood cell CD55 and CD59 were the diagnostic targets, however testing only the red blood cells will lead to false negative results, since they are sensitive to lysis and may not be detectable. “The second lineage of choice for testing is the granulocytes. One can test for CD55 and CD59 on the granulocytes as well, but research in recent years lead to a more specific reagent, FLAER, ” she explains.

The fluorescent version of the protein aerolysin, FLAER selectively binds to all the GPI anchor proteins on the surface of all white blood cells. In testing at the National Institutes of Health, FLAER has been shown to more accurately and more specifically identify PNH clones. The absence of CD55 and CD59 on the red blood cells, and the absence of CD55, CD59 or other GPI anchor molecules and/or FLAER binding on the white blood cells (e.g. on granulocytes) define the presence of a PNH positive clone.

“While PNH is an extremely rare disorder,” says Dr. Vegh-Goyarts, “we do get requests from physicians for this test. We felt it was important for our hematology department to make PNH testing and the new FLAER reagent available to our current clients as well as new ones, especially since very few private labs locally offer this test.”

“The FLAER molecule is the most reliable reagent to diagnose PNH because it is more specific and the test has greater sensitivity. “When we say small PNH clones are detectable, we are actually talking about 1%, or in some cases less than 1% PNH cells that are detectable with this method”- says Dr Vegh-Goyarts. “FLAER use has as another added advantage. If combined with other antibodies, it can help to identify aplastic anemia and myelodysplastic syndrome with very small PNH-like clones because of the increased specificity and sensitivity.” – continues Dr. Vegh-Goyarts.

One reason that doctors are using newer, more accurate tests for PNH recently is the launch of a new drug therapy, Soliris, which was approved by the FDA in 2007 and is extremely effective at treating symptoms of PNH. The drug, from Alexion Pharmaceuticals, works by blocking the reaction that causes hemolysis. Additional

treatments may include bone marrow transplant, transfusions and steroids. Follow up of patients during and after treatment with the sensitive FLAER reagent has a great advantage over the traditional PNH testing methods.

*About Dr. Zsuzsanna Vegh-Goyarts: With ample experience in the field of tumor biology and immunology, Dr. Zsuzsanna Vegh-Goyarts, Ph.D. serves as the co-director of the flow cytometry and tumor markers department at Acupath Laboratories. Prior to Acupath, she was an assistant professor in immunology research at the State University of New York (SUNY) at Stony Brook and served as a consulting assistant director of flow cytometry at Enzo Clinical Laboratories, Inc. She spent her postdoctoral years in prestigious research institutes, including the Immunology Department of Albert Einstein College of Medicine, New York, and the Tumor Biology Department of the Karolinska Institute in Stockholm, Sweden. Dr. Vegh-Goyarts' research has appeared in an extensive list of peer reviewed publications in various scientific journals. She holds a Certificate of Qualification in Oncology-Sera and Soluble Tumor Markers, Diagnostic Immunology and all four areas of Cellular Immunology/Flow Cytometry from the New York State Department of Health (NYSDOH). Dr. Vegh-Goyarts received her Ph.D. in Medical Science and Immunology in Budapest, Hungary.*

*Acupath Laboratories, Inc. located in Plainview, New York, is an anatomic pathology and cancer genetics laboratory. Acupath's mission is to deliver fast, accurate pathology, molecular and cytogenetic analysis in a way that enhances the quality of medical care provided by practitioners while minimizing the risk of error. The research and development team continuously innovates, designing new ways for doctors and patients to access, exchange, record and analyze medical information. Acupath is committed to improve efficiencies of practice, superior service and greater patient knowledge and satisfaction. Acupath is accredited by the College of American Pathologists (CAP), the Occupational Safety and Health Administration (OSHA), Joint Commission, and certified by the New York State Department of Health (DOH). [www.acupath.com](http://www.acupath.com)*