

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2274373	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Associated Lab Physicians Sc Outreach Pathology	Street Address, City, State 1 Ingalls Dr, Harvey, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the federal Casper Report 0096D, laboratory proficiency testing (PT) records, patient test reports, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory failed to enroll in PT challenges for Cell Identification [765] from the beginning of testing in 2023 to the date of the survey, 02/07/2024, in the specialty of hematology. Findings include: 1. Review of the federal Casper Report 0096D and laboratory PT records revealed the laboratory failed to enroll in PT testing for the analyte Cell Identification from the beginning of testing in 2023 to the date of the survey, 02/07/2024, in the specialty of hematology. 2. Review of four of four peripheral blood smear testing patient reports reviewed confirmed the laboratory was reporting results for Cell Identification testing. Date: Accession #: 04/13/2023 APB23-36 05/01/2023 AOBM23-55 04/29/2024 APB24-31 07/03/2024 AOBM24-92 3. Interviews with the LD and laboratory representative at 1:43 pm, on 02/07/2025, confirmed the laboratory failed to enroll in PT challenges for Cell Identification from the beginning of testing in 2023 to the date of the survey, 02/07/2024, in the specialty of hematology.</p>
D5805	TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, patient test reports, and interviews with the laboratory director (LD) and the laboratory representative, the laboratory failed to include the name and address of the laboratories that performed the technical component of testing for six of six patient test reports reviewed from the beginning of testing in 2023 to the date of survey, 02/07/2025, in the specialties of hematology and histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the manual titled, "Associated Laboratory Physicians SC Outreach Pathology Manual", which stated, under "Diagnostic Services Provided:" - "D. Flow Cytometry Interpretation (Hematology):The flow cytometry technical component ...is performed at an outside reference laboratory: American Medical Laboratories, Chicago Ridge, IL. A second ("backup") laboratory is also in place to run flow cytometry samples: NeoGenomics Laboratories, Carlsbad, CA - E. Bone Marrow Biopsy and Peripheral Blood Smear Interpretation (Histopathology):The bone marrow biopsy components are processed in the laboratory at 1 Ingalls Drive, Harvey, ILThe tissue processing protocol will yield the following components for histopathologic analysis: -Bone marrow core biopsy, hematoxylin and eosin-stain - Bone marrow aspirate, Giemsa stain -Bone marrow touch imprints, Giemsa stain - Bone marrow clot section, hematoxylin and eosin-stain -Peripheral blood smear - Immunohistochemical stains, not limited to CD3, CD20, CD34, CD138, and CD117." 2. Review of six of six patient test reports found the laboratory failed to indicate the name and address of the laboratory location where the specimen processing was performed. Date: Accession #: Test(s) Performed: 04/13/2023 APB23-36 Peripheral Blood Smear 05/01/2023 AOBM23-55 Bone Marrow Biopsy Peripheral Blood Smear Flow Cytometry 08/09/2023 AFLW23-157 Flow Cytometry 04/29/2024 APB24-31 Peripheral Blood Smear 06/13/2024 AFLW24-122 Flow Cytometry 07/03/2024 AOBM24-92 Bone Marrow Biopsy Peripheral Blood Smear Flow Cytometry 3. Interviews with the LD and laboratory representative at 1:43 pm, on 02/07/2025, confirmed the laboratory failed to include the name and address of the laboratories that performed the technical component of testing from the beginning of testing in 2023 to the date of survey, 02/07/2025.