

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2022613	<b>(X3) Date Survey Completed</b> 12/16/2025
<b>Name of Provider or Supplier</b> Center For American Indian Resources	<b>Street Address, City, State</b> 221 W 4th Street, Duluth, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Center for American Indian Resources laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the complaint investigation performed on 12/16/25. The following condition-level deficiency was cited: 493.801 Enrollment and testing of samples .
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 2024 and 2025 Wisconsin State Laboratory of Hygiene proficiency testing attestation statements, data submission reports, laboratory testing records, and interview with laboratory personnel, the laboratory engaged in inter-laboratory communication with an affiliated laboratory in 2024. Refer to D2012 .</p>
<b>D2012</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b></p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.</p>

Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

. Based on review of 2024 and 2025 Wisconsin State Laboratory of Hygiene proficiency testing attestation statements, data submission reports, laboratory testing records, and interview with laboratory personnel, the laboratory engaged in inter-laboratory communication with an affiliated laboratory regarding one Hematology PT sample and two General Immunology PT samples prior to the PT event submission deadlines in 2024. Findings are as follows: 1. The Center for American Indian Resources (CAIR) performed Complete Blood Counts (CBC's), Amnisure Rupture of Fetal Membranes (ROM), and microscopic examinations for skin fungal elements, vaginal wet preps, and urine sediment as confirmed by the laboratory director (LD) during the entrance conference at 2:30 p.m. on 12/16/25. 2. An affiliated laboratory of CAIR, Min No Aya Win Human Services Center (MNAW), performed Complete Blood Counts (CBC's), Amnisure Rupture of Fetal Membranes (ROM), and microscopic examinations for skin fungal elements, vaginal wet preps, and urine sediment as determined during a routine survey completed on 12/11/25. 3. One individual held the Laboratory Director (LD), Technical Consultant and Testing Personnel (TP) position at both laboratories. Seven additional TP were employed by the organization; each had a primary location assignment but occasionally worked at the other location if needed. The LD and four TP were assigned to MNAW and three TP were assigned to CAIR. 4. Both CAIR and MNAW performed PT in 2024 and 2025 using the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing provider. The PT samples were distributed among the TP as much as possible at each location for each event. Entry of PT results at each location was performed by whomever performed each individual test. Each TP was responsible for entering their own results for each event. 5. Review of CAIR and MNAW 2024 and 2025 WSLH PT attestation statements, data submission reports, and laboratory testing records revealed former TP AD performed testing and submitted results for 3 WSLH PT samples at both MNAW and CAIR locations in 2024 as listed below: WSLH event Sample information 2024-HemeReg1 CBC sample AF5-4 2024-Semen2 ROM samples AE-3 and AE-4 Scope of communication 1/30 CBC challenges in 2024 and 2024 2/8 ROM challenges in 2024 and 2025 No other instances of an individual testing the same PT sample at both locations in 2024 and 2025 were found. 6. The Proficiency Testing Policy provided by the laboratory prohibited referral of PT samples to a reference laboratory for additional testing or confirmation of results. Prohibition of inter-laboratory communication was not included in the policy. 7. In an interview at 3:30 p.m. on 12/16/25, the LD confirmed the above findings. .