

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D1031794	(X3) Date Survey Completed 12/17/2024
Name of Provider or Supplier Alaska Regional Hospital Poc Testing	Street Address, City, State 2801 Debarr Road, Anchorage, AK	
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 an on-site review of the laboratory's 2023 American Proficiency Institute (API) proficiency testing (PT) results and an interview with Technical Consultant (1), the laboratory failed to enroll in PT for the first event of 2023, and did not submit results for BUN and Creatinine for the second event of 2023. Findings include: 1. The laboratory was successfully enrolled in proficiency testing from WSLH Proficiency Testing in 2022. 2. A request was made to review the PT results for the first event of 2023 and PT enrollment could not be provided or verified. There was no documentation or corrective actions concerning the lack of PT enrollment. 3. A request was made to review the PT results for the second event of 2023, revealing the laboratory had enrolled in PT with American Proficiency Institute, but did not perform PT for BUN and Creatinine. There was no documentation or corrective actions concerning the lack of PT performance for BUN and Creatinine. 4. An on-site interview with TC 1 conducted on 12/17/24 at 3:30 PM confirmed the laboratory did not enroll in PT for the first event of 2023. 5. The laboratory reports performing approximately 7,000 BUN and Creatine tests annually.</p>
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on a review of competency assessments and an interview with Technical Consultant 1 (TC 1) the laboratory did not include direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing in the Siemens epoc Blood Analysis System annual competency checklist. Findings include: 1. A review of the epoc Blood Analysis Competency Checklist showed the annual checklist tasks failed to include direct observations of routing patient test performance. 2. An on-site interview with TC 1 conducted on 12/17/24 at 3:30 PM confirmed that the annual epoc Blood Analysis Competency Checklist was missing the direct observations. 3. The laboratory reports 41 epoc users performing 7,000 patient tests on the epoc annually.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of testing personnel educational credentials and an interview with Technical Consultant 1 (TC 1) the laboratory did not have a diploma or transcript on file for four of fourteen testing persons. Findings include: 1. A request was made to review the diplomas or transcripts of fourteen randomly selected testing persons and four were unable to be provided by the facility's human resources department. 2. An on-site interview with TC 1 conducted on 12/17/24 at 3:30 PM confirmed the diplomas or transcripts were not on file. 3. The laboratory reports performing, approximately 29,000 patient tests annually.