Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D1009618	07/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ahvi Cath Lab/Asc	3220 Providence Drive E3-083, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency records, review of policies and procedures, and an interview with the Cath Lab Director (RN1), the laboratory failed to evaluate the competency for five (5) of twelve (12) personnel hired since May 2025. The findings include: 1. Review of the Competency Assessment for Clinical Laboratory Personnel records revealed four (4) of eleven (11) personnel did not have completed competency records. a. Two (2) of four (4) staff (TP2 and TP3) hired since May 2025 did not have documentation of completed competency assessment. b. Two (2) of four (4) competency assessments reviewed (TP1 and TP4) did not have the six procedures of competency assessed. Competency assessments did not include "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples". c. Two (2) of four (4) staff (TP1 and TP4) did not have a competency assessment twice in the first year. 2. A request was made for competency assessments for one (1) of one (1) technical consultant but none was available. 3. A review of policies and procedures showed the laboratory has a policy for performing routine competency assessment for testing personnel but was not being followed and there was no policy for performing competency assessment for the technical consultant. 4. An interview with RN1 on 7/1/2026 at 10:00 AM confirmed the competency assessments were not completed and no assessment was performed for the technical consultant. 5. The laboratory reports performing 485 tests annually.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of policies and procedures, the lack of written procedures, and interview with the Cath Lab Director (RN1), the laboratory failed to include required information written in two (2) of two (2) test procedures since the previous survey on 7 /9/2024. The findings include: 1. Review of "Quality Control Measures for Laboratory Services" document showed the procedures lacked information for the following: a. The section on Oxicom 3000 was missing patient preparation, specimen, and acceptability; reagent preparation and storage; corrective actions when control results fail; limitations and interfering substances; laboratory process for recording/entering patient results; and actions to take if system is inoperable. b. The section on Abbott i-STAT was missing corrective actions when control results fail; limitations and interfering substances; laboratory process for recording/entering patient results; and actions to take if system is inoperable. 2. A request was made for other policies and procedures describing the testing process but were not available. 3. In an interview with RN1 on 7/1/26 at 11:00 AM confirmed no other procedures/documents were available. 4. The laboratory reports performing 485 tests annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observations, the lack of thermometer maintenance procedures, and an interview with the Cath Lab Director (RN1), the laboratory failed to establish maintenance protocols for thermometers used to monitor temperature and humidity where testing is performed and reagents are stored in the laboratory for ACT

	(Activated Clotting Time) and % Oxygen Saturation. The findings include: 1. During a lab tour on 7/1/2026 at 12:00 PM, the surveyor observed two thermometers in use. a. The Extech thermometer (SN 445703) used for monitoring the temperature and humidity of the testing area and reagents did not have a calibration sticker. b. The Fischer Traceable thermometer (SN 240071983) used for monitoring temperature of reagents had a calibration sticker indicating calibration was due 1/24/2026. 2. A request was made for maintenance documents, calibration certificates, or procedures developed to ensure the accuracy of temperature results but were not available. 3. An interview with RN1 on 7/1/2026 at 11:00 AM confirmed the findings. 4. The laboratory reports performing 485 tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of policies and procedures, lack of documentation, and an interview with the TP5, the laboratory failed to establish a system to evaluate test results performed on two (2) of two (2) Abbott i-STAT instruments twice a year since the previous survey on 7/9/2024. The findings include: 1. Based on a review of policies and procedures the laboratory failed to establish a system to compare instrument results when performing the same testing. 2. A request was made for documentation of comparison of ACT (Activated Clotting Time) results between two (2) of two (2) Abbott i-STAT analyzers used for patient testing and there was no documentation. 3. In an interview with TP5 7/1/2026 at 1145, the testing personnel described the process for performing ACT on patient samples using either i-STAT and confirmed no comparison of results was performed. 4. The laboratory reports performing 339 ACT tests annually.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel educational documents, and an interview with the Cath Lab Director (RN1), the laboratory failed to have a technical consultant who meets the qualifications fulfill the responsibilities as defined at 42 C.F.R.493.1411. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license

issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel educational documents, competency assessments, and an interview with the Cath Lab Director (RN1), the laboratory failed to have a qualified technical consultant performing ACT (Activated Clotting Time) and % Oxygen Saturation competency assessments in 2024 and 2025 who met the educational requirements as defined at 42 C.F.R.493.1411. The findings included: 1. Review of the CMS-209 form listed RN1 as Technical Consultant (TC). 2. Review of educational documents and lab experience documentation showed the personnel listed on the CMS-209 as TC lacked the minimum requirements to qualify for technical consultant (493.1411 (3)(i)(B) or 493.1411 (4)(i)(B)). 3. A review of competency assessment documents showed eight (8) of twelve (12) competency assessments performed on testing personnel between 3/1/2024 and 4/30/2025 were signed by staff who was not designated on the CMS-209 and did not meet the qualifications for

	technical consultant. 4. An interview with RN1 on 7/1/2026 at 10:00 confirmed the findings. 5. The laboratory reports performing 485 tests annually.