Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1097848	01/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Northern Arizona Medical Group	3555 Western Ave, Kingman, AZ	

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
D0000	A recertification survey was performed on January 7, 2026 for Northern Arizona Medical Group. The following condition level deficiency existed: 42 C.F.R. 493.1215 Condition: Hematology
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for Complete Blood Count (CBC) testing performed on the Horiba ABX Pentra 60 C+ hematology analyzer and testing personnel interview on 1/07/26 at 4:10 PM, the laboratory failed to meet the requirements for the specialty of Hematology as specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299, as evidenced by: 1. The laboratory failed to provide evidence of an approved procedure manual for CBC testing performed on the Horiba ABX Pentra 60 C+ hematology analyzer. (Refer to D5401) 2. The laboratory failed to provide evidence of the background count performed on the Horiba ABX Pentra 60 C+ hematology analyzer for 205 out of 228 testing dates during 2025. (Refer to D5431) 3. The laboratory failed to provide evidence of 3 levels of quality control performance for the Horiba ABX Pentra 60 C+ hematology analyzer for 192 out of 228 testing dates from 2/5/25 through 11/04/25. (Refer to D5445) 4. The laboratory failed to verify the manufacturer's established control ranges for 7 out of 7 control lots used on the Horiba ABX Pentra 60 C+ hematology analyzer from 2/1/25 through 1/07/26. (Refer to D5469) 5. The laboratory failed to perform and document Quality Assessment activities for the analytic test

	systems, specifically the Horiba ABX Pentra 60 C+ hematology analyzer during 2025. (Refer to D5791) 6. The laboratory reports an annual test volume of 22,000 in the specialty of Hematology.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of a written procedure manual for review and interview with the testing personnel (TP-1) on 1/07/26 at 2:06 PM, the laboratory failed to provide evidence of a written procedure manual for Complete Blood Count (CBC) testing performed on the Horiba ABX Pentra 60 C+ analyzer in the specialty of Hematology. Findings include: 1. The laboratory began CBC testing on January 30, 2025 on the Horiba ABX Pentra 60 C+ analyzer, with a reported annual test volume of 22,000. 2. No evidence of an approved procedure manual for CBC testing performed on the Horiba ABX Pentra 60 C+ analyzer was presented for review during the survey conducted on 1/07/26. 3. TP-1 interviewed on 1/07/26 at 2:06 PM confirmed that the laboratory failed to have an approved, written procedure manual for CBC testing performed on the Horiba ABX Pentra 60 C+ analyzer.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on review of hematology test records and interview with the testing personnel (TP-1) on 1/07/26 at 3:27 PM, the laboratory failed to provide evidence of the background count performed on the Horiba ABX Pentra 60 c+ hematology analyzer for each day of patient testing for 205 out of 228 testing dates in 2025. Findings include: 1. The laboratory began Complete Blood Count (CBC) testing on the Horiba ABX Pentra 60 C+ analyzer on 1/30/2025, and reports an annual test volume of 22,000. 2. The laboratory failed to provide documentation to indicate the background count was performed on the Horiba ABX Pentra 60 C+ analyzer prior to patient testing for 205 out of 228 testing dates in 2025 (2/5/25 through 8/07/25 and 8/12/25 through 11/21/25). 3. The number of patient tests performed on the dates indicated above could not be determined at the time of the survey. 4. TP-1 interviewed on 1/07 /26 at 3:27 PM confirmed the laboratory failed to have documentation of the background count performed on the analyzer each day prior to testing patients on the testing dates listed above.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for Complete Blood Count (CBC) testing performed on the Horiba ABX Pentra 60 C+ analyzer and interview with the testing personnel (TP-1) on 1/07/26 at 3:25 PM, the laboratory failed to produce evidence of quality control performance for each day of patient testing that occurred on 192 out of 228 testing dates from 2/05/2025 through 11/04/2025. Findings include: 1. The laboratory began CBC testing on the Horiba ABX Pentra 60 C+ analyzer on 1/30/2025, and reports an annual test volume of 22,000. 2. It is the practice of the laboratory to test 3 levels (Low, Normal, High) of control material each day of patient testing. 3. The laboratory failed to provide evidence of 3 levels of QC performance for each day of patient testing that occurred from 2/05/25 through 11/04 /25. The laboratory performed patient testing on approximately 192 days during that timeframe. 4. TP-1 interviewed on 1/07/26 at 3:25 PM confirmed the laboratory failed to produce evidence of three levels of external control material performed on each day of patient testing that occurred on 2/05/25 through 11/04/25. TP-1 stated that all QC records from 2/05/25 through 11/04/25 were deleted from the analyzer when TP-2 entered a new lot of control on the analyzer on 1/05/26. TP-1 stated that the QC information (values, ranges, lot specific information) for the Horiba ABX Pentra 60 C+ analyzer does not interface to the Laboratory Information System (LIS), SchuyLab. 5. The number of patients tested on the Horiba ABX Pentra 60 C+ analyzer from 2/05/25 through 11/04/25 could not be determined at the time of the survey.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of hematology test records, review of quality control assay sheets

	and interview with the testing personnel (TP-2) on 1/07/26 at 3:54 PM, the laboratory failed to verify that its control results correlate with the established limits of the manufacturer's quality control (QC) materials for 7 out of 7 control lots used on the Horiba ABX Pentra 60 C+ hematology analyzer from 2/01/25 through 1/07/26. Findings include: 1. The laboratory began Complete Blood Count (CBC) testing on the Horiba ABX Pentra 60 C+ analyzer on 1/30/2025, and reports an annual test volume of 22,000. 2. The laboratory utilizes the Difftrol Hematology Reference Controls which have control ranges established by the manufacturer. Each lot contains control materials for 3 levels of QC including Low, Normal and High. 3. No documentation was presented for review to indicate the laboratory verified that its control results correlate with the established limits of each lot of Difftrol QC material for 7 out of 7 lots used on the analyzer from 2/01/25 through 1/07/26. The lot numbers used include: PX451, PX452, PX453, PX454, PX455, PX456 and PX457. 4. TP-2 interviewed on 1/07/26 at 3:54 PM confirmed the laboratory failed to verify each of the 7 lots of quality control material used on the hematology analyzer from 2/01/25 through 1/07/26.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) documentation and interview with the testing personnel (TP-1) on 1/07/26 at 4:05 PM, the laboratory failed to perform and document analytic QA activities from January 2025 through December 2025. Findings include: 1. It is the policy of the laboratory to complete a quarterly QA Review to include the monitoring of Quality Control and other analytic activities for each analyzer used by the laboratory. 2. The laboratory failed to provide evidence of documented QA Review activities for 4 out of 4 quarters from January 2025 through December 2025, including but not limited to, review of Quality Control records, review of background counts for the Horiba ABX Pentra 60 C+ analyzer, and review of lot verification records for each lot of QC used on the Horiba ABX Pentra 60 C+ analyzer. 3. TP-1 interviewed on 1/07/26 at 4:05 PM confirmed the laboratory failed to provide evidence of documented QA activities during the timeframe listed above, to indicate the laboratory monitored, assessed and corrected problems identified with testing performed on the Horiba ABX Pentra 60 C+ analyzer, the Beckman Coulter AU480 chemistry analyzer and the Beckman Coulter Access 2 chemistry analyzer. 4. The laboratory reports an annual test volume of 54,000 tests in the specialty of Chemistry and 22,000 tests in the specialty of Hematology.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

	This STANDARD is not met as evidenced by: Based on lack of initial training documentation for two out of two testing personnel (TP-1 and TP-2) and interview with TP-1 on 1/07/26 at 1:55 PM, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for testing performed on the Horiba ABX Pentra 60 C+ hematology analyzer. Findings include: 1. The laboratory began testing on the Horiba ABX Pentra 60 C+ hematology analyzer on January 30, 2025. 2. No initial training documentation was presented for review for 2 out of 2 testing personnel (TP-1 and TP-2) who began patient testing on the Horiba ABX Pentra 60 C+ hematology analyzer on 1/30/25. 3. TP-1 interviewed on 1/07/26 at 1:55 PM confirmed the laboratory failed to provide documentation of initial training records for testing performed on the Horiba ABX Pentra 60 C+ hematology analyzer. 4. The laboratory reports 22,000 complete blood count (CBC) tests annually in the specialty of hematology.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of performance documentation from 2025 and interview with the testing personnel (TP-1) on 1/07/26 at 1:57 PM, the technical consultant (TC) failed to reevaluate and document the performance of 2 out of 2 testing personnel responsible for moderate complexity testing performed on the Horiba ABX Pentra 60 C+ hematology analyzer prior to reporting patient test results. Findings include: 1. The laboratory began using a new hematology analyzer, Horiba ABX Pentra 60 C+, on 1 /30/25. 2. The performance documentation forms presented for review from 2025 for 2 out of 2 testing personnel (TP-1 and TP-2) listed the hematology analyzer as the "Sysmex XS1000i", and the forms indicated that the TC completed performance evaluations for each testing personnel on 1/16/25, 6/25/25 and 12/18/25. 3. The TC failed to reevaluate the performance of TP-1 and TP-2 during 2025, prior to reporting test results, for the new hematology analyzer, Horiba ABX Pentra 60 C+. 4. TP-1 interviewed on 1/07/26 at 1:57 PM confirmed that the forms used to document the performance of TP-1 and TP-2 during 2025 failed to include an evaluation specific to the new hematology analyzer, Horiba ABX Pentra 60 C+ hematology analyzer, and confirmed that the laboratory no longer used the Sysmex XS1000i analyzer once the new hematology analyzer was put into use in January 2025. 5. The laboratory reports an annual test volume of 22,000 for the specialty of Hematology.