Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0538339	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Intermountain Healthcare - Wynn	4880 Wynn Rd, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on July 24, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) signed attestations, a review of the completed CMS-209 form, and an interview with the laboratory manager, the laboratory failed to ensure that the I-Stat Chem 8 PT specimens were performed by the patient testing personnel, and the laboratory failed to ensure that the 2023 Miscellaneous Chemistry events One and Two for microalbumin and creatinine were rotated among the staff. Findings include: 1. A review of the 2024 API PT signed attestations for the Chemistry Core test events one and two revealed that the personnel who performed the I-Stat Chem 8 PT specimen testing and signed the attestations were not the designated testing personnel listed on the CMS-209 form for the performance of the I-Stat testing. The laboratory manager confirmed that the testing personnel numbers 8 and 9 on the CMS-209 form were the designated testing personnel for the I-Stat testing. 2. A review of the 2023 API PT signed attestations for the Chemistry, Miscellaneous test events one and two revealed that testing personnel number 4 listed on the CMS-209 form performed the microalbumin and urine creatinine testing for both events. 3. These

	findings were confirmed during an interview conducted on July 24, 2024 at approximately 12:00 PM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: A review of the 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) chemistry core signed attestations, a review of the written director delegation of duties and an interview and email correspondence with the laboratory manager, the laboratory failed to ensure that the testing personnel performing the I-Stat Chem 8 testing signed the attestation, and the laboratory failed to ensure that the laboratory director or an assigned designee qualified as a technical consultant persuant to 42 CFR 493.1411 signed the attestation. Findings include: 1. A review of the 2023 API PT chemistry core signed attestations for test events two and three revealed that the personnel who performed the I-Stat Chem 8 testing failed to sign the attestations. 2. The 2024 API PT chemistry core test event one signed attestation for the I-Stat Chem 8 testing was not signed by the laboratory director. 3. The 2024 API PT chemistry core test event one signed attestation for the I-Stat Chem 8 testing was not signed by a designee delegated to perform that duty in writing by the director. The personnel who signed as a designee was not qualified as a technical consultant persuant to 42 CFR 493.1411. 4. A review of the policy entitled, "Delegation of Duties to Lab Manager and Lab Supervisor at Wynn Lab" revealed that the laboratory manager is designated the authority to review, sign and date proficiency testing records. 5. These findings were confirmed during an interview with the laboratory manager on July 24, 2024 at approximately 4:00 PM, and via an email received from the laboratory manager on July 29, 2024, which confirmed the personnel signing as the designee for the 2024 test event two was a high school graduate. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the 2023 and 2024 American Proficiency Institute (API) hematology Proficiency Testing (PT) records, and an interview with the laboratory manager, the laboratory failed to verify the accuracy of the submitted results for the hematology educational challenges. Findings include: 1. A review of the 2023 API hematology PT results for test event one revealed that the laboratory failed to evaluate

	and document the educational challenges for the Blood Cell Identification specimens ECI-01-ECI-05. The reported result for specimen ECI-02 was "Neutrophil, band (stab)." The reported result for specimen ECI-05 was "Eosinophil, all stages." The expected results column for specimens ECI-02 and ECI-05 stated "See commentary." 2. A review of the 2023 API hematology PT results for test event two revealed that the laboratory failed to evaluate and document the educational challenge for the Platelet estimate for specimen number DIF-02. The reported result for specimen DIF-02 was "Decreased." The Expected Result for specimen DIF-02 was "Adequate /Normal." 3. A review of the 2023 API hematology PT results for test event three revealed that the laboratory failed to evaluate and document the educational challenge for the Platelet estimate for specimen number DIF-03. The reported result for specimen DIF-03 was "Decreased." The Expected Result for specimen DIF-03 was "Decreased." 4. A review of the 2024 API hematology PT results for test event one revealed that the laboratory failed to evaluate and document the educational challenges for the Blood Cell Identification specimens ECI-01-ECI-05. The reported result for specimen ECI-05 was "Neutrophil, band (stab)." The expected results column for specimens ECI-05 was "Metamyelocyte (juvenile)." 5. The laboratory manager confirmed the findings during an interview conducted on July 24, 2024 at approximately 12:00 pm. The laboratory performs approximately 34,741 hematology tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) 2023 Chemistry Core event two Proficiency Testing (PT) records, and an interview with the laboratory manager, the laboratory failed to ensure that documentation of evaluation and corrective action of unsatisfactory scores for the I-Stat Chem 8 tests was complete to support the investigation conclusion. Findings include: 1. A review of the 2023 API Chemistry Core event two PT records revealed that the laboratory achieved a score of 60% for the I-Stat Chem 8, to include sodium, potassium, chloride, total carbon dioxide, glucose, blood urea nitrogen, creatinine, and ionized calcium. 2. The corrective action conclusion stated, "After reviewing proficiency results, we noted samples 7 & 8 may have been switched." There was no documentation of the evaluation of the results to demonstrate that that the samples were switched. It was not clear from the statement if it was the specimens that were switched during testing, or if it was the results that were switched when submitted to API. 3. The findings were confirmed during an interview with the laboratory manager on July 24, 2024 at approximately 11:30 AM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in

	493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Analytic Systems was not met. The laboratory failed to ensure that the proficiency testing samples were tested in the same manner at patient samples. The laboratory failed to ensure that two levels of quality control was performed each day of patient testing. (Refer to D5447) The laboratory failed to ensure that the I-Stat Chem 8 quality control samples were tested in the same manner as patient samples. (Refer to D5465) The laboratory failed to ensure that there was a system established to evaluate and define the relationship between test results using different test instruments or methodologies (Refer to D5775) The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of March 17, 2023 and July 3, 2024, a review of the manufacturer's instructions for the Quidel Triage D-Dimer test, and an interview with the laboratory manager and the laboratory supervisor, the laboratory failed to ensure that two levels of quality control was performed each day of patient testing or that a director approved Individualized Quality Control Program (IQCP) was developed for the D-Dimer test. Findings include: 1. A random patient audit between the dates of March 17, 2023 and July 3, 2024 revealed that two levels of quality control were not performed on November 27, 2023 when a patient was tested for a D-Dimer. 2. The manufacturer's instructions for the Quidel Triage D-Dimer test stated, "Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures." The instructions go on to state, "Users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control." 3. The laboratory manager and the laboratory supervisor confirmed during an interview conducted on July 24, 2024 at approximately 4:00 PM, that there was no written, director approved Individualized Quality Control Plan (IQCP) established for the D-Dimer test. The laboratory performs approximately 34,741 hematology tests annually.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) 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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of I-Stat Chem 8 quality control records, a review of the completed CMS-209 form, and an interview with the laboratory manager, the laboratory failed to ensure that the I-Stat Chem 8 quality control samples were tested by the patient testing personnel. Findings include: 1. A review of the I-Stat Chem 8 quality control records dated April 13, 2024 revealed that the quality control samples were not tested by the designated testing personnel listed on the CMS-209 form for the performance of the I-Stat testing. 2. The laboratory manager confirmed during an interview conducted on July 24, 2024 at approximately 3:30 PM that the testing personnel numbers 8 and 9 on the CMS-209 form were the designated testing personnel for the I-Stat testing. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology 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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on the absence of a director approved policy and procedure for instrument to instrument comparison of test results, the absence of records of instrument to instrument comparison of test results, and an interview with the laboratory manager, the laboratory failed to ensure that there was a system established and no criteria for acceptablility to evaluate the relationship between test results using different test instruments or methodologies between the two I-Stat instruments for testing the Chem 8 tests and between the I-Stats and the Vitros 5600 for the Chem 8 tests of sodium, potassium, chloride, total carbon dioxide, blood urea nitrogen, creatinine, glucose, and calcium and between the I-Stats and the Sysmex XN550 for the hemoglobin and hematocrit tests. Findings include: 1. There was no director approved policy and procedure for the performance of instrument to instrument comparison of test results, including criteria for acceptablility to evaluate the relationship between the Chem 8 tests on the two I-Stat instruments, between the I-Stat instruments and the Vitros 5600 Chem 8 tests of sodium, potassium, chloride, total carbon dioxide, blood urea nitrogen, creatinine, glucose, and calcium, and between the I-Stat instruments and the Sysmex XN550 Chem 8 tests of hemoglobin and hematocrit. 2. There were no records available at the time of the survey for instrument to instrument comparison of test results between the two I-Stat instruments, and between the I-Stat instruments and the Vitros 5600 Chem 8 tests sodium, potassium, chloride, total carbon dioxide, blood urea nitrogen, creatinine, glucose, and calcium, and between the I-Stat instruments and the Sysmex XN550 Chem 8 tests of hemoglobin and hematocrit. 3. The laboratory manager confirmed the findings during an interview conducted on July 24, 2024 at approximately 1:45 PM. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Moderate Complexity Laboratory Director is not met. The laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. The laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. (Refer to D6016) The laboratory director failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. (Refer to D6018) The laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. (Refer to D6019) The laboratory director failed to ensure that Quality Control (QC) programs were established and maintained to assure the quality of the laboratory services. (Refer to D6020) The laboratory director failed to ensure that Quality Assessment (QA) programs were established and maintained to assure the quality of the laboratory services. (Refer to D6021) The laboratory director failed to ensure that personnel signing a proficiency testing attestation as a designee was qualified as a technical consultant pursuant to 42 CFR 493.1411. (Refer to D6028) The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) signed attestations, a review of the completed CMS-209 form, a review of the written director delegation of duties the director failed to ensure that the I-Stat Chem 8 PT specimens were performed by the patient testing personnel, the director failed to ensure that the 2023 Miscellaneous Chemistry events One and Two for microalbumin and creatinine were rotated among the staff, the director failed to ensure that the testing personnel performing the I-Stat Chem 8 testing signed the attestation, and the director failed to ensure that the laboratory director or an assigned designee signed the attestation. Findings include: 1. A review of the 2024 API PT signed attestations for the Chemistry Core test events one and two revealed that the personnel who performed the I-Stat Chem 8 PT specimen testing and signed the attestations were not the designated testing personnel listed on the CMS-209 form for the performance of the I-Stat testing. The laboratory manager confirmed that the testing personnel numbers 8 and 9 on the CMS-209 form were the designated testing personnel for the I-Stat testing. 2. A review of the 2023 API PT chemistry core signed attestations for test events two and three revealed that the personnel who performed

	the I-Stat Chem 8 testing failed to sign the attestations. 3. A review of the 2023 API PT signed attestations for the Chemistry, Miscellaneous test events one and two revealed that testing personnel number 4 listed on the CMS-209 form performed the microalbumin and urine creatinine testing for both events. 4. The 2024 API PT chemistry core test event one signed attestation for the I-Stat Chem 8 testing was not signed by a designee delegated to perform that duty in writing by the director. The personnel who signed as a designee was not qualified as a technical consultant persuant to 42 CFR 493.1411. 5. The 2024 API PT chemistry core test event one signed attestation for the I-Stat Chem 8 testing was not signed by a designee delegated the duty in writing by the director. The policy entitled, "Delegation of Duties to Lab Manager and Lab Supervisor at Wynn Lab" revealed that the laboratory manager is designated the authority to review, sign and date proficiency testing records. 6. These findings were confirmed during an interview with the laboratory manager on July 24, 2024 at approximately 4:00 PM, and via an email received from the laboratory manager on July 29, 2024, which confirmed the personnel signing as the designee for the 2024 test event two was a high school graduate. (refer to D2007 and D2009) The laboratory performs approximately 111,322 chemistry tests annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the 2023 and 2024 American Proficiency Institute (API) hematology Proficiency Testing (PT) records, and an interview with the laboratory manager, the director failed to ensure that the laboratory verified the accuracy of the submitted results for the hematology educational challenges. Findings include: 1. A review of the 2023 API hematology PT results for test event one revealed that the laboratory failed to evaluate and document the educational challenges for the Blood Cell Identification specimens ECI-01-ECI-05. 2. A review of the 2023 API hematology PT results for test event two revealed that the laboratory failed to evaluate and document the educational challenge for the Platelet estimate for specimen number DIF-02. 3. A review of the 2023 API hematology PT results for test event three revealed that the laboratory failed to evaluate and document the educational challenge for the Platelet estimate for specimen number DIF-03. 4. A review of the 2024 API hematology PT results for test event one revealed that the laboratory failed to evaluate and document the educational challenges for the Blood Cell Identification specimens ECI-01-ECI-05. 5. The laboratory manager confirmed the findings during an interview conducted on July 24, 2024 at approximately 12:00 pm. (Refer to 5215) The laboratory performs approximately 34,741 hematology tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) 2023 Chemistry Core event two Proficiency Testing (PT) records, and an interview with the laboratory manager, the director failed to ensure that documentation of evaluation and corrective action of unsatisfactory scores for the I-Stat Chem 8 tests was complete to support the investigation conclusion. Findings include: 1. A review of the 2023 API Chemistry Core event two PT records revealed that the laboratory achieved a score of 60% for the I-Stat Chem 8, to include sodium, potassium, chloride, total carbon dioxide, glucose, blood urea nitrogen, creatinine, ionized calcium hemoglobin and hematocrit. 2. The corrective action conclusion stated, "After reviewing proficiency results, we noted samples 7 & 8 may have been switched." There was no documentation of the evaluation of the results to demonstrate that that the samples were switched. It was not clear from the statement if it was the specimens that were switched during testing, or if it was the results that were switched when submitted to API. 3. The findings were confirmed during an interview with the laboratory manager on July 24, 2024 at approximately 11:30 AM. (Refer to D5221) The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the completed CMS-209 form, the absence of a director approved Individualized Quality Control Plan (IQCP) for the Quidel Triage D-Dimer test, a review of the I-Stat quality control records, and interview with the laboratory manager, the director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. Findings include: 1. There was no director approved established IQCP for the Quidel Triage D-Dimer test. (Refer to D5447) 2. The I-Stat quality control was not performed by the testing personnel designated on the completed CMS-209 form. (Refer to D5465) 3. The findings were confirmed during an interview with the laboratory manager on July 24, 2024. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assessment records, the absence of instrument to instrument comparisons between the two I-Stat instruments for the Chem 8 tests, the absence of instrument to instrument comparisons between the I-Stat instruments and the Vitros 5600 chemistry analyzer for the Chem 8 tests sodium, potassium, chloride, total carbon dioxide, blood urea nitrogen, creatinine, and calcium, the absence of instrument to instrument comparisons between the I-Stat instruments and the Sysmex XN-550 for the hemoglobin and hematocrit tests, the lack of records of the I-Stat quality assessement, a review of the training and competency assessment records for the testing personnel performing the I-Stat testing, and an interview with the laboratory manager, the director failed to ensure that the established quality assessment program was maintained to assure the quality of the services provided by the laboratory. Findings include: 1. There were no records of the instrument to instrument comparisons between the I-Stats and the Vitros 5600 and the Sysmex XN-550 for the Chem 8. (Refer to D5775) 2. There were no records of the I-Stat Chem 8 quality assessment included in the laboratory quality assessment records, nor available separately in the home care department where the I-Stat records were maintained. 3. The laboratory quality assessment records reviewed between the months of October 2023 and May 2024 failed to detect that the semi-annual and annual training and competency assessment for one of two testing personnel designated for the performance of the I-Stat Chem 8 on the CMS-209 form was performed and documented. (Refer to D6053, D6054) 4. These findings were confirmed during interviews conducted with the laboratory manager on July 24, 2024. The laboratory performs approximately 111,322 chemistry tests, 34,741 hematology tests and 48 immunology tests annually.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a review of the completed CMS-209 form, the absence of the personnel records available for the I-Stat Chem 8 testing, a review of the 2024 American Proficiency Institute (API) Proficiency Testing (PT) records for the I-Stat Chem 8 and an interview with the laboratory manager on July 24, 2024 and email correspondence from the laboratory manager on July 29, 2024, the director failed to ensure that the personnel who signed I-Stat PT as a designee for lab director was qualified as a

	Technical Consultant pursuant to 42 CFR 493.1411 to provide appropriate consultation and properly supervise the testing personnel. Findings include: 1. The completed CMS-209 form did not include the personnel that signed as a designee for the director on the 2024 API I-Stat Chem 8 test event two attestation. 2. At the time of the survey, there were no personnel records available for the personnel that signed as a designee for the director on the 2024 API I-Stat Chem 8 test event two attestation. 3. An interview with the laboratory manager on July 24, 2024 at approximately 3:45 PM revealed that the personnel who signed the 2024 API I-Stat Chem 8 PT attestation possessed an Office Laboratory Assistant certification issued by the State of Nevada. 4. Email correspondence received from the laboratory manager on July 29, 2024 at approximately 9:38 AM revealed that the personnel that signed as the designee for the 2024 API I-Stat Chem 8 PT attestation was a high school graduate, and not qualified as a technical consultant. The laboratory performs approximately 111,322 chemistry tests and 34,741 hematology tests annually.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the completed CMS-209 form, a review of the personnel training and competency assessment records for two personnel in the performance of the I-Stat Chem 8 testing, and an interview with the laboratory manager, the technical consultant failed to ensure that semi-annual competency assessment during the first year of employment was performed and documented. Findings include: 1. There were no records of semi-annual competency assessment during the first year of employment for one of two testing personnel designated on the CMS-209 form for the performance of the I-Stat Chem 8 testing. 2. The findings were confirmed during an interview conducted on July 24, 2024 at approximately 3:45 PM. The laboratory performs approximately 111,322 chemistry tests, 34,741 hematology tests annually.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the completed CMS-209 form, a review of the personnel training and competency assessment records for two personnel in the performance of the I-Stat Chem 8 testing, and an interview with the laboratory manager, the technical consultant failed to ensure that annual competency assessment was performed and documented. Findings include: 1. There were no records of annual competency assessment for one of two testing personnel designated on the CMS-209 form for the performance of the I-Stat Chem 8 testing. 2. The findings were confirmed during an interview conducted on July 24, 2024 at approximately 3:45 PM. The laboratory performs approximately 111,322 chemistry tests, 34,741 hematology tests annually.