Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D1011050	06/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Physicians Of Laramie, Llc	2710 Harney St Ste 202, Laramie, WY	

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
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: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of the American Academy of Family Physicians (AAFP) and the American Association of Bioanalysts (AAB)-Medical Laboratory Evaluation (MLE) proficiency tests into the patient workload for 5 of 7 proficiency testing events reviewed from January 2021 through May 2023. The findings were: 1. Review of the AAFP and the AAB-MLE proficiency testing records failed to include an attestation statement signed by the laboratory director for the following events: a. AAFP-2021-C b. AAFP-2022-A c. AAFP-2022-B d. AAFP-2022-C e. AAB-MLE-2023 event #1 2. Interview with the laboratory manager on 6/21/23 at 3:18 PM confirmed the attestation statements for the proficiency testing events had not been signed by the laboratory director. The laboratory director acknowledged the deficiency during a telephone interview on 6/21 /23 at 4:35 PM.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing (PT) results for 2 of 7 PT events reviewed from January 2021 through May 2023. The findings were: 1. Review of the American Academy of Family Physicians-2022-C PT records showed the following concern: a. Review of the PT evaluation showed the laboratory scored an 80% on alanine transaminase. There was no documentation the laboratory had investigated the cause of the 80% score. In addition, there was no evidence the laboratory director had reviewed the proficiency testing event. 2. Review of the 2023 American Association of Bioanalysts-Medical Laboratory Evaluation event #1 PT records showed the following concerns: a. The laboratory scored an 80% on thyroid stimulating hormone. The failed sample was reran and an acceptable value was obtained; however, an investigation into the cause of the initial failure was not completed. b. The laboratory scored a 50% on testosterone. The failed sample was reran and remained out of the established range. There was no evidence an investigation into the cause of the failure was completed. c. The laboratory scored an 80% on the hematology blood granulocyte cell count. There was no evidence an investigation into the cause of the failure was completed. d. The laboratory scored a 50% on prostate specific antigen. The failed sample was reran and an acceptable value was obtained; however, an investigation into the cause of the intial failure was not completed. e. Review of the PT records showed no evidence the laboratory director and reviewed the PT results. 3. Interview with the laboratory manager on 6/21/23 at 3: 18 PM confirmed the unsatisfactory PT scores had not been thoroughly investigated and the laboratory director had not reviewed the proficiency testing events. The laboratory director acknowledged the deficiency during a telephone interview on 6/21 /23 at 4:35 PM.
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% for 1 of 7 American Academy of Family Physicians (AAFP) and American Association of Bioanalysts (AAB)-Medical Laboratory Evaluation (MLE) proficiency testing events reviewed from January 2021 through May 2023. The findings were: 1. Review of the AAFP-2022-B proficiency testing evaluation form showed the laboratory received an artificial score of 100% on the analyte of total bilirubin due to the analyte not being graded by the proficiency testing program. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 2. The laboratory director acknowledged the deficiency during a telephone interview on 6/21/23 at 4:35 PM.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use, patient test reports, calibration records, and staff interview the laboratory failed to follow the Medonic complete blood count (CBC) instrument manufacturer's instructions to perform instrument calibration every 6 months for approximately 16 months of testing reviewed. The laboratory performed approximately 6,500 CBCs per year. In addition, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method used on 5 of 5 patient PSA test reports reviewed from January 2023 to May 2023. The laboratory performed approximately 321 PSA tests per year. The findings were: 1. Review of the Qualigen FastPack test system manufacturer's instructions showed "The results reported by the laboratory to the physician must include the identity of the PSA assay method used". The following concerns were identified: a. The test report for PSA #101112311314 tested on 1/11 /23, #102062311729 tested on 2/6/23, #102212312012 tested on 2/21/23, #05102313396 tested on 5/10/23, and #105302313685 tested on 5/30/23 failed to include the test assay method. b. Interview with the laboratory manager on 6/21/23 at 3:18 PM confirmed the patient's test reports did not include the test assay method. 2. Review of the Medonic manufacturer's instructions showed "Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months". The following concerns were identified: a. Review of the Medonic hematology calibration records showed the last calibration was performed on 11/1/22. There was no evidence a calibration had been performed in May of 2023 or anytime thereafter. c. Interview with the laboratory manager on 6/21/23 at 2:40 PM confirmed the hematology analyzer had not been calibrated every 6 months as required. 3. The laboratory director acknowledged the deficiency during a telephone interview at 4:35 PM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on new test method verification study review, lack of documentation, and staff interview, the laboratory failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing for 3 of 3 new test verification studies reviewed (Alfa Wasserman Axcel uric acid, Qualigen FastPack testosterone, and Qualigen FastPack prostate specific antigen). The findings were: 1. Review of the Alfa Wasserman Axcel verification study for the analyte of uric acid, dated 3/29/22 to 4/20 /22, failed to show the performance specification for precision and the reportable

	range had been verified by the laboratory prior to testing patient samples. In addition, the laboratory failed to confirm the manufacturer's normal values were appropriate for the laboratory's population. The laboratory had performed an accuracy study for the analyte of uric acid; however, this document was not signed by the laboratory director. 2. Review of the Qualigen FastPack testosterone and prostate specific antigen verification studies failed to show the manufacturer's normal values had been evaluated and were appropriate for the laboratory's population. 3. Interview with the laboratory manager on 6/21/23 at 3:18 PM confirmed there was no further documentation related to the new test verification studies. The laboratory director acknowledged the deficiency during a telephone interview on 6/21/23 at 4:35 PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for thyroid stimulating hormone (TSH), prostate specific antigen (PSA), and testosterone using the Qualigen FastPack test system, and the general chemistry analytes performed on the Alfa Wasserman Axcel analyzer for 1 of 2 years reviewed (2021, 2022). The laboratory performed approximately 45,000 routine chemistry and endocrinology patient tests per year. The findings were: 1. Review of the laboratory's records showed the last calibration verification study was performed for the TSH analyte on 1/26/22. There was no documentation a calibration verification study had been completed at anytime thereafter. 2. Review of the laboratory's records showed the verification study for the PSA and testosterone analytes was approved on 7/12/22. There was no documentation a calibration verification study had been completed at anytime thereafter. 3. Review of the laboratory's records showed the last calibration verification study for the routine chemistry analytes performed on the Alfa Wasserman Axcel analyzer was last completed on 7/21/22. There was no documentation a calibration verification study had been completed at anytime

	thereafter. 4. Interview with the laboratory manager on 6/21/23 at 3:09 PM confirmed the calibration verification studies had not been completed as required. The laboratory director acknowledged the deficiency during a telephone interview on 6/21/23 at 4:35 PM.
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 review of quality control (QC) and calibration records, review of the patient accession log, and staff interview, the laboratory failed to perform two levels of QC each day of patient testing for the Qualigen FastPack testosterone analyte for 24 weeks of patient testing reviewed (1/3/23 to 6/21/23). This failure affected 57 patient testosterone tests. The findings were: 1. Review of the testosterone QC and calibration records showed quality control was performed every 15 days. 2. Review of the patient accession log showed a total of 66 patient tests were performed between 1/3/23 and 6 /21/23. 57 of the patient tests were performed on days when QC had not been performed. 3. Interview with the laboratory manager on 6/21/23 at 3:18 PM revealed an individual quality control plan had not been developed for the testosterone analyte and confirmed QC was not performed each day of patient testing. The laboratory director acknowledged the deficiency during a telephone interview on 6/21/23 at 4:35 PM.
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 review of the new test method verification studies, lack of documentation, proficiency testing records, the individualized quality control plan, calibration and quality control records, the patient accession log, the CMS-209 Laboratory Personnel Report form, personnel records, and staff interview, the laboratory director failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to testing patient samples (D6013); failed to attest to the routine integration of the American Academy of Family Physicians and the American Association of Bioanalysts-Medical Laboratory Evaluation proficiency tests into the patient workload (D6016); failed to review and evaluate proficiency testing results (D6018); failed to ensure the quality control program was established and maintained (D6020); and failed to ensure competency assessments were completed to ensure testing personnel that performed moderate complexity testing were evaluated for competency to process specimens, perform test procedures, and report test results promptly (D6030).

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on new test method verification study review, lack of documentation, and staff interview, the laboratory director failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing for 3 of 3 new test verifications studies reviewed (Alfa Wasserman Axcel uric acid, Qualigen FastPack testosterone, and Qualigen FastPack prostate specific antigen). The laboratory performed approximately 321 prostate specific antigen tests, 69 testosterone tests, and 84 uric acids tests annually. Refer to D5421.
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of the American Academy of Family Physicians and the American Association of Bioanalysts-Medical Laboratory Evaluation proficiency tests into the patient workload for 5 of 7 proficiency testing events reviewed from January 2021 through May 2023. Refer to D2009.
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to review and evaluate proficiency testing results for 2 of 7 proficiency testing events reviewed from January 2021 through May 2023. Refer to D5211.
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 review of the individualized quality control plan (IQCP), calibration and quality control records, patient accession log, and staff interview the laboratory director failed to ensure a quality control program was established and maintained for 2 of 3 analytes reviewed (prostate specific antigen, testosterone). The findings were: 1. Review of an unsigned and undated IQCP showed 2 levels of controls were to be performed every 15 days, every change of lot number, after calibration, and after calibration verification for the analytes of prostate specific antigen (PSA) and testosterone. There was no evidence the laboratory had performed a risk assessment for the analyte of testosterone prior to implementing the quality control plan. In addition, the laboratory director had not signed or dated the PSA quality control plan before it was implemented. 2. Review of the testosterone QC and calibration records showed quality control was performed every 15 days. Review of the patient accession log showed a total of 66 testosterone patient tests were performed between 1/3/23 and 6/21/23. 57 of the patient tests were conducted on days when QC had not been performed. 3. Interview with the laboratory manager on 6/21/23 at 3:18 PM revealed an IQCP risk assessment had not been developed for the testosterone analyte and confirmed QC was not performed each day of patient testing. The laboratory director acknowledged the deficiency during a telephone interview at 4:35 PM.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:

	Based on review of the CMS-209 Laboratory Personnel Report form, staff interview, and review of personnel records, the laboratory director failed to ensure competency assessments were completed by qualified personnel to ensure testing personnel that performed moderate complexity testing were evaluated for competency to process specimens, perform test procedures, and report test results promptly and proficiently for 5 of 5 testing personnel reviewed (TP #1, TP #2, TP #3, TP #4, TP #5). The findings were: 1. Review of the personnel file for TP #1 showed competency assessments were completed in 2021, 2022, and 2023 and signed and dated by an unqualified staff member. 2. Review of the personnel file for TP #2 showed unsigned and undated competency assessments were completed in February of 2021 and in 2022. In addition, competency assessments were completed in August of 2021 and 2023 which were signed and dated by an unqualified staff member. 3. Review of the personnel file for TP #3 showed an unsigned and undated competency assessment was completed in February 2021. In addition, competency assessments were completed in August of 2021, 2022, and 2023 which were signed and dated by an unqualified staff member. 4. Review of the personnel file for TP #4 showed competency assessments were completed in February and August of 2021, 2022, and 2023 which were signed and dated by an unqualified staff member. 5. Review of the personnel file for TP #5 showed a competency assessment was completed in 2021 and 2022 and were signed and dated by an unqualified staff member. 6. Interview with the practice manager on 6 /21/23 at 11 AM revealed she was unaware competency assessments were to be completed by personnel which met the federal regulation requirements. The laboratory director acknowledged the deficiency during a telephone interview on 6/21 /23 at 4:35 PM.