Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0942072	01/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Endocrinology Center Plc	15640 N 28th Dr, Phoenix, 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
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 (PT) records from 2022 and 2023 and interview with testing personnel (TP-2), the laboratory director failed to sign the PT attestation statements. Findings include: 1. The laboratory performs testing in the specialties of Chemistry and Hematology with an annual test volume of 254,739. 2. The PT attestation statements presented for review for the first, second, and third testing events of 2022 and 2023 lacked the signature of the laboratory director. 3. The TP-2 interviewed on 1/24/24 at 10:40 AM confirmed the laboratory director failed to sign the PT attestation statements for the events indicated above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 patient reports and interview with testing personnel (TP-2), the laboratory failed to have a policy and procedure in place for performing and reporting manual dilutions on patient specimens. The findings include: 1. The laboratory performs patient testing under the specialty of Chemistry with an annual reported test volume of 237,573. 2. It is the practice of the laboratory to perform manual dilutions on specimens whose results are greater than the reference range. 3. The laboratory failed to create a policy and procedure for manual dilutions that indicates: the specimen criteria, a step-by step performance of the dilution procedure including test calculations, and interpretation of results, and a system for reporting patient results. 4. The TP-2 interviewed on 1/24/24 at 12:53 PM confirmed the laboratory failed to have a policy and procedure for performing and reporting dilutions on patient specimens.
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 lack of performance specification documentation for the BioRad D-10 analyzer and interview with testing personnel (TP-2), the laboratory failed to verify the reportable range for the BioRad D-10 analyzer prior to reporting patient test results. Findings include: 1. The laboratory began using the BioRad D-10 analyzer to perform HbA1C testing on patients on 9/1/23. 2. The laboratory failed to demonstrate that it can obtain the reportable range comparable to that established by the manufacturer for the BioRad D-10 analyzer prior to reporting patient test results. 3. The TP-2 interviewed on 1/24/24 at 10:40 AM confirmed the laboratory failed to verify the reportable range for the BioRad D-10 analyzer prior to reporting patient test results. 4. The laboratory's annual test volume under the subspecialty of Routine Chemistry is 220,660.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For 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 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. The laboratory must 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 lack of a policy and procedure and interview with the Testing Personnel (TP-2), the laboratory failed to establish a maintenance and calibration protocol for the pipettes that ensures equipment performance which is necessary for accurate and reliable test results and test result reporting. Findings include: 1. The laboratory performs patient testing in the specialty of Chemistry with an annual reported test volume of 237,573. 2. The laboratory utilizes two pipettes in conjunction with patient testing, a 1-5 Millimeter (mL) adjustable pipette, serial# V01300 and a 100-1000 Microliter (L) adjustable pipette, serial# CH57329. 3. No documentation was presented for review during the survey conducted on 1/24/24 to indicate the laboratory established a maintenance and function protocol for the pipettes listed above. 4. The TP-2 interviewed on 1/24/24 at 12:54 PM confirmed the laboratory failed to establish a maintenance and calibration protocol for the pipettes indicated above.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) policies and procedures, analytic test records, and interview with testing personnel (TP-2), the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with the lack of a policy and procedure for dilutions for testing performed under specialty of Chemistry. See D5403 for findings. 2. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with the lack of performance specification documention for testing performed under the subspecialty of Routine Chemistry. See D5421 for findings. 3. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with the lack of a policy and procedure for pipette calibration for testing performed under specialty of Chemistry. See D5433 for findings. 4. The TP-2 interviewed on 1/24/24 at 12:00 PM confirmed the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the analytic systems.
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: The Condition of Laboratory Director was found to be not met based on: D6003- failure to 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.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 possess qualifications that are equivalent to those required for such certification; 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current

license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
Based on lack of a qualified laboratory director at the time of the survey conducted on 1/24/24 and interview with the testing personnel (TP-2), the laboratory failed assign a qualified laboratory director to manage and direct the laboratory personnel and the performance of moderate complexity tests. Findings include: 1. During the onsite survey conducted on 1/24/24, it was determined that the laboratory director listed in the CMS database for CLIA# 03D9042072 at the time of the survey was no longer

	affiliated with the laboratory since June 2023. 2. The laboratory failed to provide notification of a change in laboratory director within 30 days of the change, as required under C.F.R.493.51(a)(4). 3. The TP-2 interviewed on 1/24/24 at 9:30 AM confirmed the laboratory failed to provide notification of a laboratory director change within 30 days of the change, and failed to have qualified laboratory director from July 2023 through the date of the onsite survey.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of test verification documentation for HbA1C performed on the BioRad D-10 analyzer, and interview with the testing personnel (TP-2), the technical consultant failed to ensure the verification of performance specification documentation was signed and approved by a qualified laboratory director or qualified technical consultant prior to the start of patient testing. 1. The laboratory began using the BioRad D-10 analyzer to perform HbA1C testing for patient testing on 9/1/23. 2. The HbA1C test verification documentation reviewed during the survey on 1/24/24 lacked the signature and approval of the laboratory director or technical consultant. 3. The TP-2 interviewed on 1/24/24 at 10:40 AM confirmed the HbA1C performance specification documentation failed to include the approval and signature of the laboratory director or technical consultant prior to the start of patient testing 4. The laboratory's annual test volume under the subspecialty of Routine Chemistry is 220,660.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a record review of competency assessments from 2023, and interview with the testing personnel (TP-2), the technical consultant failed to evaluate the competency of two of two testing personnel. Findings include: 1. The laboratory failed to provide evidence that indicated a qualified technical consultant performed and evaluated the 2023 annual competencies for two of two testing personnel. 2. The TP-2 interviewed on 1/24/24 at 10:00 AM confirmed the technical consultant failed to evaluate the competency of two of two testing personnel in 2023.