Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0942072	11/30/2018
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's established Quality Assessment (QA) policies, review of QA records and interview with the facility personnel, the laboratory failed to identify errors found with personnel competency and employee training. Findings include: 1. The laboratory performs patient testing under the specialties of Hematology, Chemistry and Diagnostic Immunology, with an approximate annual test volume of 239,038. The laboratory hired a new testing personnel in July 2017. 2. The laboratory performs a "Monthly Quality Assurance Checklist" that includes a section for Personnel. The Personnel section states, "New employees have a personnel file; Testing analyst have been checked for competency prior to reporting patient results; Semi-annual and annual evaluations have been performed; Continuing Education documentation is readily available." 3. Review of the Monthly QA Checklists from January 2017 through the date of the survey conducted on November 30, 2018 revealed that the laboratory marked a "Y(yes)"next to each area of the personnel section on each monthly form, however no documentation of initial training or semi-annual competency evaluation was presented for review during the survey for the testing personnel hired in July 2017. See D6029 and D6053 for findings. 4. The facility personnel confirmed that the laboratory's QA process was not effective in identifying errors found during the survey with regard to employee competency and training.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) 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)(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 training documentation and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. The laboratory performs patient testing in the specialties of Diagnostic Immunology, Chemistry and Hematology, with an approximate annual test volume of 239,038 2. No initial training documentation was presented for review for one out of one testing personnel who began patient testing in July 2017. 3. The facility personnel confirmed that the testing personnel indicated above did not have documentation of initial training. .
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 lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one testing personnel who began patient testing in July 2017. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the testing personnel indicated above.