Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0415480	01/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advocate Medical Group - Elgin Urology	745 Fletcher Dr - Ste 301, Elgin, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel; the laboratory failed to be enrolled in an HHS approved proficiency testing (PT) program for its Prostate Specific Antigen testing. Findings include: 1. On 01/14/19 at 2:00 PM, the surveyor requested PT records for the years 2017, 2018, and 2019. 2. There were no PT records available for review for 2017, 2018, or 2019. 3. There was no documentation to show that the laboratory was enrolled in a PT program for 2019. 4. On 01/14/19 at 2:15 PM, testing personnel confirmed the surveyor's findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel; the laboratory failed to retain its proficiency testing (PT) records for at least 2 years.

	Findings include: 1. On 01/14/19 at 2:00 PM, the surveyor requested PT records for the years 2017, 2018, and 2019. 2. There were no PT records available for review for 2017, 2018, or 2019. 3. On 01/14/19 at 2:15 PM, testing personnel confirmed the surveyor's findings.
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 laboratory procedures manuals, laboratory records, personnel records and interview; the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory director did not ensure that the laboratory was enrolled an HHS approved proficiency testing program for 2019. See tag D6015. 2. There was a lack of documentation to show that the laboratory established a Quality Assessment program for its laboratory testing procedures. See tag D6021 3. The laboratory director did not ensure that new personnel were qualified, through education and training, to perform testing reliably. See tag D6029 4. The laboratory director did not ensure that there was an approved procedures manual that included all steps applicable to the test from ordering the test through reporting of results. See tag D6031 5. The laboratory director did not specify the duties and responsibilities of each consultant nor which tests each person is authorized to perform. See tag D 6032.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel; the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for its Prostate Specific Antigen testing. 1. On 01/14/19 at 2:00 PM, the surveyor requested PT records for the years 2017, 2018, and 2019. 2. There were no PT records available for review 2017, 2018, and 2019. 3. On 01/14/19 at 2:15 PM, in an interview with testing personnel, it was revealed that the laboratory was not enrolled in PT for 2019. 4. On 01/14/19 at 2:30 PM, testing personnel confirmed the surveyor's findings.
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 review of laboratory records and interview with the laboratory director, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services. Findings include: 1. There was no documentation to show that the laboratory director performed quality assessments reviews of the laboratory's overall operations. 2. On 01/14/19 at 3:00 PM, the laboratory director confirmed the surveyor's findings.
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 review of pre-survey documents; Laboratory Personnel Report - CLIA (FORM CMS 209); and personnel records; and interview with the laboratory director; the laboratory director failed to ensure that prior to testing patient's specimens, all personnel have the appropriated education and experience, received the appropriated training for the type of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of pre-survey documents and FORM CMS 209 revealed that the laboratory has a total of 3 testing personnel who perform moderate complexity testing in the laboratory. One of 3 testing personnel was a new testing person in the laboratory. 2. There was no documentation to show the highest level of education acheived for 1 of 1 new testing personnel. 3. There was no documentation of training to show that 1 of 1 new testing personnel was trained to perform Prostate Specific Antigen testing in the laboratory. 4. There was no documentation to show that competency assessments were performed on 3 of 3 testing personnel in 2017, 2018, and 2019. 5. There were no other personnel records available for review. 6. On 01/14/19 at 3:00 PM, the laboratory director confirmed the surveyor's findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals and interview with the laboratory director; the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for Prostate Specific Antigen (PSA) testing. Findings include: 1. On 01/14/19 at 1:15 PM, the surveyor made a request to review the laboratory's procedures manual. There were a total of 3 separate Qualigen Procedures given to the surveyor. 2. Review of Qualigen Procedures manuals revealed that there were blank sections where the laboratory director is to complete, sign, and date. On one page of the Qualigen Procedures, there is a space where the laboratory director is instructed to "approve, sign, and date" the procedures. The spaces where the laboratory director is instructed to complete were left blank. 3. On 01/14/19 at 3: 00 PM, the laboratory director confirmed the surveyor's findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report - CLIA (CMS FORM 209); laboratory's testing menu, procedures manuals, personnel records and interview with the laboratory director; the laboratory director failed to specify in writing the responsibilities and duties of each consultant and which examinations and procedures each individual is authorized to perform, and whether consultant or director review is required prior to reporting patient test results. Findings include: 1. Review of CMS FORM 209 revealed that the laboratory director was listed as the person who fulfills the responsibility and duties of Laboratory Director; Clinical Consultant; and Technical Consultant. Three other persons are listed as moderate complexity testing personnel. 2. Review of the laboratory's testing menu revealed that the laboratory performed Prostate Specific Antigen Testing (moderate complexity tests) as well as waived Urinalysis Testing. 3. Review of procedures manuals revealed that the laboratory had 3 separate Qualigen Procedures manuals it used as its procedures manual. There was no documentation to show that the laboratory director assigned which tests each person is authorized to perform for 3 of 3 testing personnel. 4. There were no personnel records available for review. 5. On 01/14/19 at 3:00 PM, the laboratory director confirmed the surveyor's findings.