

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0415480	(X3) Date Survey Completed 08/18/2021
Name of Provider or Supplier Advocate Medical Group - Elgin Urology	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the office manager and testing personnel (TP2), the laboratory failed to verify the accuracy of the Prostate Specific Antigen (PSA) tests it performs for the years of 2019 and 2020. Findings include: 1. The American Proficiency Institute (API) proficiency testing (PT) program records for 2019 to 2021, the PSA analyzer quality control (QC) and patients' result logs, and procedures manual were reviewed. 2. The laboratory manual and API-PT reports showed the laboratory had enrolled into API's "Chemistry - Endocrinology" PT program as the method to verify the accuracy of its PSA testing. 3. Further review revealed the laboratory received the following scores: *Event 2 of 2019 scored 67%; *Event 3 of 2019; Event 1 of 2020; and Event 2 of 2020-received "no score" due to non-participation' *Event 3 of 2020 scored 50% 4. Review of the Patients' results and QC logs from 04/2019 to 08/2020 showed that patients were tested and reported during the time period of the PT failures and non-participation. 5. The laboratory failed to follow its PT policies and procedure to continually participate in the API-PT program and failed to evaluate PT events which received failure scores (below 80%) and 'no scores' due to non-submission, during the years of 2019 through 2020. 6. On a Recertification survey conducted on 08/18/2021 at 12:45 PM, office manager and TP2 confirmed the above findings.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or</p>

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 direct observation, record review and an interview with the office manager and testing personnel (TP2), the laboratory failed to evaluate and define the relationship between test results using multiple instruments and document their test result comparison activities for the years of 2019 through 2021. Findings include: 1. On 08/18/2021 at 11:45 AM during a tour of the laboratory, the surveyor observed 2 Qualigen analyzers labeled Machine #1 and Machine #2 performing Prostate Specific Antigen (PSA) testing. 2. The quality control (QC) logs and quality assurance (QA) records for the years of 04/2019 through 07/2021, and procedures manual were reviewed. 3. The QC logs showed the laboratory performed calibration verifications on both Machine #1 and Machine #2 on the following dates: *09/23/2019, 03/30/2020, 10/02/2020, and 06/03/2021. 4. The QA records revealed the laboratory failed to perform and document a comparison evaluation (comparing Machine #1 to Machine #2) from the calibration results listed in findings #3. 5. The laboratory failed to include in their QA policy and procedures the requirement to perform and document bi-annual comparison evaluations for their 2 PSA analyzers. 6. On a Recertification survey conducted on 08/18/2021 at 12:45 PM, office manager and TP2 confirmed the above findings.

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 record review, lack of documentation, and an interview with the office manager and testing personnel (TP2), the LD failed to ensure 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 during the years of 2019 to 2020. Findings: 1. The American Proficiency Institute (API) proficiency testing (PT) program documents from 04/2019 to 07/2021 and the laboratory's PT policy and procedures were reviewed. 2. The PT reports showed the laboratory use API's "Chemistry - Endocrinology" PT program as the method to verify the accuracy of its PSA testing. 3. Review of the PT records revealed the laboratory received the following scores: *Event 2 of 2019 scored 67%; and Event 3 of 2020 scored 50% *Event 3 of 2019; Event 1 of 2020; and *Event 2 of 2020 received "no score" due to non-participation. 4. Further review showed the LD failed to implement PT procedures to investigate the PT failure scores and "no scores" results. 5. The LD failed to follow established PT policies and procedures which require the evaluation and investigation of PT results to ensure any problems are identified and, if needed,

corrective action implementation. 6. On a Recertification survey conducted on 08/18/2021 at 12:45 PM, office manager and TP2 confirmed the above 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 record review and an interview with the office manager and testing personnel (TP2); the LD failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. Findings include: The laboratory's proficiency testing (PT) and quality assurance (QA) policies and procedures, and monthly QA records from 04/2019 to 08/2021 were reviewed. 1. The LD failed to follow written procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the following systems: *PT failures and "no scores" due to non-participation. See D5217. *General Laboratory systems - Verifying the accuracy of Prostate Specific Antigen (PSA) testing. 2. The LD failed to establish and follow bi-annual comparison evaluations procedures for their 2 PSA analyzers. See D5775 3. On a Recertification survey conducted on 08/18/2021 at 12:45 PM, office manager and TP2 confirmed the above findings.