

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0689588	(X3) Date Survey Completed 06/21/2021
Name of Provider or Supplier Fairview Specialists - Urology - Fairview Park Dr	Street Address, City, State 200 Fairview Park Drive, Dublin, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on June 21, 2021. Condition and Standard level Citations were found. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on the review of American Proficiency Institute (API) Proficiency Testing (PT) documents for the analyte Prostatic Specific Antigen (PSA), for the year 2021 1st event, showed that the laboratory failed to participate by not submitting results. This is a condition level citation. REFERENCE: D2094, D6017</p>

<p>D2094</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Testing (API), Proficiency Testing (PT) documents for the year 2021, 1st event for the analyte Prostatic Specific Antigen (PSA) showed that the laboratory failed with a score of 0%, for non-participation by not submitting results. Findings: 1. Review of the API PT documents for 2021, for the analyte PSA, showed that the laboratory failed to submit results for the 1st event. 2. Interview with the practice manager, Staff #2 (CMS 209 form), and representatives from HCA Healthcare, on June 21, 2021, in the conference room, confirmed that the results were not submitted, and stated that the samples were not received at the office, and no followup was done, until after the evaluation report was returned.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Testing (API), Proficiency Testing (PT) documentation and staff interview, the laboratory failed to provide Correction Action in 2020, for event 2, for the analyte Prostatic Specific Antigen (PSA). Findings: 1. Review of the PSA documents from API for the year 2020, event 2, the laboratory failed to provide corrective action for a score of 50%. Any score that is less than 100%, corrective action must be provided. 2. Interview with the office manager, Staff #2(CMS 209 form), and representatives from HCA Healthcare on June 21, 2021 in the conference room at approximately 5 pm, confirmed that there was no corrective action provided for the API 2nd event, for PSA score of 50%.</p>
<p>D6017</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT)</p>

documents, and staff interview, the Laboratory Director (LD) failed to ensure the arrival of specimens, for the first event of 2021, for the analyte Prostatic Specific Antigen (PSA) for timely submission. Findings: 1. Review of the API PT documents, for the 1st event for the analyte PSA, showed that the laboratory failed to submit results for evaluation due to not receiving the samples. There is no documentation that the LD had the laboratory follow-up with API or request off-schedule testing samples. 2. Interview with staff #2 (CMS form 209), the Office Practice Manager, and HCA Healthcare employees, on June 21, 2021, confirmed the aforementioned statements.