

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2302307	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Cleveland Men's Health Group	Street Address, City, State 6500 Rockside Road, Suite 180, Independence, OH	
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on record review of proficiency testing (PT) records from the American Proficiency Institute (API) and an interview with a corporate office representative (COR), the laboratory failed to successfully participate in two out of three consecutive PT events for prostate specific antigen (PSA) in the subspecialty of Routine Chemistry. This affected two out of three PT testing events completed for the third testing event of 2025 and the second testing event of 2026 resulting in unsuccessful PT participation. Findings Include: 1. The laboratory failed to successfully participate in two out of three consecutive PT events for prostate specific antigen (PSA) in the subspecialty of Routine Chemistry for the third testing event of 2025 and the second

	testing event of 2026 resulting in unsuccessful PT participation. (Refer to D2096) 2. An interview with the COR, on 08/19/2026 at 2:21 PM, confirmed the laboratory did not achieve satisfactory PT performance with a score of at least 80% (percent) for the analyte PSA in the third testing event of 2025 and the second testing event of 2026. 3. Review of laboratory records revealed 100 patient PSA tests were performed from the third PT event tested on 09/04/2025 through the date of the CLIA inspection, 08/19/2026.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of proficiency testing (PT) records from the American Proficiency Institute (API) and an interview with a corporate office representative (COR), the laboratory failed to successfully participate in two out of three consecutive PT events for prostate specific antigen (PSA) in the subspecialty of Routine Chemistry. This affected two out of three PT testing events completed from the third testing event of 2025 and the second testing event of 2026 resulting in unsuccessful PT participation. Findings Include: 1. Review of the laboratory's CMS-116, approved by the Laboratory Director via signature and date on 08/17/2026 and provided on the date of inspection revealed the laboratory conducted PSA and Testosterone testing in the specialty of Chemistry. 2. Review of the laboratory's "Qualigen FastPack IP System For PSA and Testosterone (TESTO) Testing" policy and procedure found the following: "Proficiency Testing Procedures ...Check the instructions in the PT kit and follow any special storage or handling requirements...Submit your completed results via online portal back to API by the due date." 3. Review of the laboratory's API documentation for the third PT event of 2025 found PSA was scored 0% (percent) due to not submitting the PT event test results by the due date required by API. Review of the second PT event of 2026 found PSA was scored 40%. 4. An interview with the COR, on 08/19/2026 at 2:21 PM, confirmed the laboratory did not achieve satisfactory PT performance with a score of at least 80% for the analyte PSA in the third testing event of 2025 and the second testing event of 2026. 5. Review of laboratory records revealed 100 patient PSA tests were performed from the third PT event tested on 09/04/2025 through the date of the CLIA inspection, 08/19/2026.