

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0336272	(X3) Date Survey Completed 04/08/2026
Name of Provider or Supplier Southwest Urology, Llc	Street Address, City, State 6900 Pearl Road, Suite 200, Middleburg Heights, 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	<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 a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report, the laboratory's 2025 and 2026 American Proficiency Institute (API) PT records and interviews with the Laboratory Director, the laboratory failed to successfully participate in two out of two consecutive PT events for prostate specific antigen (PSA) in the subspecialty of Routine Chemistry for the third testing event of 2025 and the first testing event of 2026 resulting in non-initial unsuccessful PT participation. Findings Include: 1. The laboratory failed to achieve satisfactory PT performance with a score of at least 80%</p>

(percent) for the analyte PSA in the third PT event of 2025 and the first PT event of 2026 in the subspecialty of Routine Chemistry. This results in non-initial unsuccessful PT participation. (Refer to D2096) 2. The Laboratory Director, via a telephone interview on 04/02/2026 at 1:21 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 first testing event of 2026. The Laboratory Director further confirmed via electronic mail (email) on 04/06/2026 at 11:13 AM that the laboratory did not cease patient testing. 3. This deficient practice had the potential to affect 1,300 out of 1,300 patient PSA tests from the last successful PT event (the second PT testing event of 2025 submitted on 05/13/2025) through 04/06/2026.

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 and interviews with the Laboratory Director, the laboratory failed to achieve satisfactory proficiency testing (PT) performance with a score of at least 80% (percent) for prostate specific antigen (PSA) in two out of two consecutive testing events which resulted in non-initial unsuccessful performance. Findings Include: 1. Review of the laboratory's American Proficiency Institute (API) documentation for the third PT event of 2025 and the first PT event of 2026, provided via electronic mail (email) on 04/02/2026 at 1:21 PM, revealed both testing events were scored 60% for the analyte PSA. 2. The Laboratory Director, via a telephone conversation on 04/02/2026 at 1:21 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 first testing event of 2026. The Laboratory Director further confirmed via electronic mail (email) on 04/06/2026 at 11:13 AM that the laboratory did not cease patient testing. 3. This deficient practice had the potential to affect 1,300 out of 1,300 patients tested from the last successful PT event (the second PT testing event of 2025 submitted on 05/13/2025) through 04/06/2026.