| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>36D0336272 | (X3) Date Survey Completed<br><br>12/06/2022 |
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| **Name of Provider or Supplier**<br><br>Southwest Urology, Llc | **Street Address, City, State**<br><br>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 |
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| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interviews with the General Supervisor (GS) and Testing Personnel (TP) #3, the laboratory failed to enroll in a proficiency testing (PT) program for the sub-specialty of bacteriology. All 860 patient PCR (Polymerase Chain Reaction) urine and rectal pathogenic organism identification and antibiotic resistance testing performed in this laboratory from 09/27/2021 to 12/06/2022 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to enroll in a proficiency testing (PT) program for PCR organism identification and antibiotic resistance testing in urine and rectal specimens. (Refer to D2001) |
| **D2001** | ENROLLMENT<br>CFR(s): 493.801(a)(1)(2)(i)<br><br>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more |

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| | than one proficiency testing program approved by CMS;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interviews with the General Supervisor (GS) and Testing Personnel (TP) #3, the laboratory failed to enroll in a proficiency testing (PT) program for PCR organism identification and antibiotic resistance testing in urine and rectal specimens. All 860 patient PCR (Polymerase Chain Reaction) urine and rectal pathogenic organism identification and antibiotic resistance testing performed in this laboratory from 09/27/2021 to 12/06/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policies" procedure, unapproved via signature and date by the Laboratory Director and provided for the inspection, did not find any mention of the organism identification and antibiotic resistance testing conducted. 2. The Inspector requested the laboratory's enrollment documentation for 2021 and 2022 from the GS and TP#3. On 12/06/2022 at 10:35 AM, the GS and TP#3 provided the Laboratory Director's summary of the laboratory's 2022 alternative PT activities. 3. The GS and TP#3 confirmed that the laboratory did not include urine and rectal PCR organism identification and antibiotic resistance testing in their PT policy and procedure, was not enrolled with an HHS approved PT provider for this regulated testing and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 12/06/2022 at 10:42 AM. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interviews with the General Supervisor (GS) and Testing Personnel (TP) #3, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS), at a frequency determined by the laboratory, as specified in the personnel requirements in subpart M. All patient bacteriology, routine chemistry, urinalysis and hematology testing performed in this laboratory from 06/15/2021 to 12/06/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's competency assessment policy and procedure titled "Laboratory Competency Policy", unapproved by the Laboratory Director and provided for the inspection, did not find any mention of the assessment of the CC, TS and GS based on the responsibilities of each position, at a frequency determined by the laboratory. 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 12/08/2022, revealed three different individuals listed and qualified by the Laboratory Director to function; one individual as the CC, the second individual as the TS and the third individual as the GS. 3. Review of the laboratory's 2021 and 2022 competency assessment documentation, provided for the date of the inspection, did not find any assessment documentation for the CC, TS or GS based on the responsibilities of each position. 4. The Inspector requested the laboratory's policy and procedure for the assessment of the CC, TS and GS and any competency assessment documentation for the CC, TS and GS based on the responsibilities of each position from the GS. The GS and TP#3 |

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| | confirmed the laboratory did not establish a policy and procedure for the assessment of the CC, TS and GS, did not assess the competency of the CC, TS and GS based on the responsibilities of each position, at a frequency determined by the laboratory and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 12/06/2022 at 11:30 AM. |
| **D6088** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)<br><br>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interviews with the General Supervisor (GS) and Testing Personnel (TP) #3, the Laboratory Director failed to ensure that the laboratory was enrolled in an HHS-approved proficiency testing (PT) program for PCR organism identification and antibiotic resistance testing in urine and rectal specimens. All 860 patient PCR (Polymerase Chain Reaction) urine and rectal pathogenic organism identification and antibiotic resistance testing performed in this laboratory from 09/27/2021 to 12/06/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policies" procedure, unapproved via signature and date by the Laboratory Director and provided for the inspection, did not find any mention of the organism identification and antibiotic resistance testing conducted. 2. The Inspector requested the laboratory's enrollment documentation for 2021 and 2022 from the GS and TP#3. On 12/06/2022 at 10:35 AM, the GS and TP#3 provided the Laboratory Director's summary of the laboratory's 2022 alternative PT activities. 3. The GS and TP#3 confirmed that the laboratory did not include urine and rectal PCR organism identification and antibiotic resistance testing in their PT policy and procedure, was not enrolled with an HHS approved PT provider for this regulated testing and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 12/06/2022 at 10:42 AM. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the General Supervisor (GS), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing procedures performed in the specialties of Microbiology, Chemistry and Hematology. All patient urine and rectal PCR organism identification and antibiotic resistance, urinalysis, urine microscopic, prostatic specific antigen (PSA) and post-vasectomy testing procedures performed from the implementation of the new Laboratory Director on 06/22/2021 to 12/06/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures provided for the date of the inspection, revealed policies and procedures were unapproved via signature and date by the new Laboratory Director and prior to patient testing on 06/22/2021. 2. The Inspector |

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| | requested the laboratory's approved policies and procedures upon the new directorship and prior to patient testing on 06/22/2021. The GS confirmed the new Laboratory Director, as of 06/22/2021, did not approve all of the laboratory policies and procedures via signature and date prior to patient testing procedures on 06/22/2021 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/06/2022 at 9:45 AM. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interviews with the General Supervisor (GS) and Testing Personnel (TP) #3, the Technical Supervisor (TS) failed to evaluate the competency of 22 out of 22 testing personnel (TP) in 2021 to assure they maintained their competency to perform moderate and high complexity test procedures and report test results promptly, accurately, and proficiently. All 16,941 patient testing procedures performed in 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 12/08/2022, found one individual in addition to the Laboratory Director listed as a TS. Further review of the laboratory's Form CMS-209 revealed an individual who was newly hired, credentialed, listed and began functioning in the GS role upon their hire date on 04/18/2022. 2. Review of the laboratory's "Laboratory Competency Policy" found the following statements: "1. An initial Orientation Competency Checklist of Lab Tests that will be conducted before the employee can perform any patient testing." "3. A Six Month & Annual Laboratory Competency Assessment will be conducted yearly on each employee performing patient testing." 3. Review of the laboratory's 2021 and 2022 competency assessment documentation, provided on the date of the inspection, did not find any documented testing personnel competency assessments from 2021 for the moderate and/or high complexity testing procedures performed. 4. The GS and TP#3 confirmed the laboratory's 2021 testing personnel competency assessments were not conducted as required. The interviews occurred on 12/06/2022 at 11:30 AM. |