

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0454140	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Adult And Pediatric Urology & Urogynecology Pc	Street Address, City, State 10707 Pacific Street, Suite 101, Omaha, NE	
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
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory space and interview with technical supervisor #3, as listed on the CMS 209 form, the laboratory failed to have a uni-directional workflow in the laboratory for quantitative polymerase chain reaction testing. 1. Surveyor observation of the laboratory revealed the laboratory performs specimen preparation, amplification, and reagent preparation on the same laboratory bench. 2. Interview with technical supervisor #3, as listed on the CMS 209 form, on 6/10/2025 at 2:56 PM, confirmed the laboratory performs specimen preparation, amplification, and reagent preparation without following a uni-directional workflow.</p>
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 review of patient sample report, review of proficiency testing documentation, and interview with the technical supervisor #3, as listed on the CMS 209, the laboratory failed to have a system for verifying the accuracy of <i>Citrobacter freundii</i>, <i>Citrobacter braakii</i>, <i>Enterococcus faecium</i>, <i>Enterococcus faecalis</i>, <i>Klebsiella</i></p>

pneumoniae, Klebsiella oxytoca, Proteus mirabilis, Proteus vulgaris, and resistance genes at least twice annually for 2024 and 2025. Findings are: 1. Review of the laboratory's list of tests performed revealed the laboratory performs Citrobacter freundii, Citrobacter braakii, Enterococcus faecium, Entereococcus faacalis, Klebsiella pneumoniae, Klebsiella oxytoca, Proteus mirabilis, Proteus vulgaris, and resistance genes quantitative polymerase chain reaction (qPCR) testing. 2. Interview with technical supervisor #3, as listed on the CMS 209 form, on 6/10/2025 at 12:35 PM , confirmed the laboratory did not have documentation of verification of accuracy for Citrobacter freundii, Citrobacter braakii, Enterococcus faecium, Entereococcus faacalis, Klebsiella pneumoniae, Klebsiella oxytoca, Proteus mirabilis, Proteus vulgaris, and resistance genes quantitative polymerase chain reaction (qPCR) testing performed in 2024 and 2025.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of laboratory's general policies and procedures, surveyor review of specimen documentation, and interview with the technical supervisor #3, as listed on the CMS 209 form, the laboratory failed to follow its policies and procedures. 1. Review of laboratory's general policies and procedures on specimen rejection criteria indicate "abnormal results from temperature, specific gravity, pH, or creatinine indicate an invalid specimen." 2. Surveyor review of specimen documentation did not include testing of sample temperature and creatinine. 3. Interview with the technical supervisor #3, as listed on the CMS 209 form, confirmed the laboratory did not follow the laboratory's policies and procedures.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on lack of uni-directional workflow (Refer to 3005), lack of twice annual accuracy verification (Refer to 5217), lack of establishing performance specifications (Refer to 5423), lack of comparison of test results (Refer to 5775), and lack of corrective action (Refer to 5891) the laboratory failed to monitor and evaluate the overall quality of testing.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of patient reports, review of established performance specifications, and interview with the technical supervisor #3, as listed on the CMS 209 form, the laboratory failed to establish microbial load performance specifications based on review of patient reports from 2025. 1. Review of the laboratory's validation panel did not include an established microbial load. 2. Interview with the technical supervisor #3 on 12:53 PM on 6/10/2025, as listed on the CMS 209 form, confirmed the laboratory did not establish microbial load. 3. Review of patient reports from March 2025, April 2025, and May 2025 revealed fifteen patient results resulted as a microbial load. Based on surveyor observation of laboratory panels, review of establish performance specifications, and interview with the technical supervisor #3, as listed on the CMS 209 form, the laboratory failed to establish performance specifications on two out of three panel versions used for testing. 1. Surveyor observation of laboratory panels in the laboratory revealed V3 panel plate and V4 panel plate. 2. Review of the laboratory's validation panel revealed the established performance specifications was performed on V2 panel plate. 3. Interview with the technical supervisor #3, as listed on the CMS 209 form, on 6/10/2025 at 12:30 PM confirmed the laboratory did not establish complete performance specifications for V3 panel plate and V4 panel plate. 4. Interview with the technical supervisor #3, as listed on the CMS 209 form, on 6/10/2025 at 12:30 PM confirmed the V3 panel plate was used from approximately December 2024 - February 2025 and the V4 panel plate was used from approximately March 2025 - May 2025.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or 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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's list of tests performed, lack of documentation, and interview with technical supervisor #3, as listed on the CMS 209, the laboratory failed to have a system that twice annually evaluated the relationship between test results using different methodologies for candida, Gardnerella vaginalis, and Trichomonas vaginalis from April 2023 - June 2025. Findings are: 1. Review of the laboratory's list

	<p>of tests performed revealed the laboratory performs candida, Gardnerella vaginalis, and Trichomonas vaginalis testing on the affirm platform and on quantitative polymerase chain reaction (qPCR) platform. 2. Review of documentation presented at time of survey revealed the laboratory did not perform method comparison between the affirm and qPCR platforms. 3. Email communication with the technical supervisor #3, as listed on the CMS 209, on 6/25/2025 at 3:22 PM confirmed no method comparison was performed between the affirm and qPCR platform.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on documentation of corrective action, interview with the technical supervisor #3, as listed on the CMS 209 form, the laboratory failed to follow corrective action and continue to monitor ongoing issues from March 2024 - November 2024. 1. Review of incident report revealed corrective action stating the laboratory "will issue corrective reports." 2. Interview with the technical supervisor #3, as listed on the CMS 209 form, the laboratory did not issue corrected reports from March 2024 - November 2024.</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of 2024 and 2025 competencies, surveyor review of the CMS 209 form, and interview with technical supervisor #3, as indicated on the CMS 209, the technical supervisor failed to perform semiannual competency on one out of two high complexity testing personnel. Findings are: 1. Surveyor review of 2024 and 2025 competencies for TP #1, as listed in the CMS 209 form, revealed the semiannual competency was performed by an individual not qualified as a technical supervisor. 2. Interview with technical supervisor #3, as indicated on the CMS 209, on 6/10/2025 at 3:20 PM confirmed the semiannual competency was performed by an individual not qualified as a technical supervisor.</p>
<p>D6128</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of 2024 and 2025 competencies, surveyor review of the CMS 209 testing personnel report, and interview with technical supervisor TS #3, as indicated on the CMS 209, the technical supervisors failed to perform 2025 annual competency on one out of two high complexity testing personnel. Findings are: 1. Surveyor review of 2024 and 2025 competencies for TP #1, as listed in the CMS 209 form, revealed the 2025 annual competency was performed by an individual not qualified as a technical supervisor. 2. Interview with technical supervisor #3, as indicated on the CMS 209, on 6/10/2025 at 3:20 PM confirmed the 2025 annual competency was performed by an individual not qualified as a technical supervisor.