

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2032238	<b>(X3) Date Survey Completed</b>  12/29/2025
<b>Name of Provider or Supplier</b>  Daniel D Cohen Md Pa	<b>Street Address, City, State</b>  315 N Lakemont, Winter Park, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA initial survey was conducted at Daniel D Cohen on December 16-29, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6076 493.1441 Condition: Laboratory Director
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform initial competency assessments for Technical Supervisor, General Supervisor, and Testing Personnel in 2025. Findings Included: 1. Review of Laboratory Personnel Report revealed Employee B was Testing Personnel, General Supervisor, and Technical Supervisor. 2. Review of Job Description: Testing Personnel and Technical Supervisor- Urinary Tract Infection Polymerase Chain Reaction (UTI PCR) laboratory signed by Laboratory Director on 9/9/2025 read, "Competency Assessment: Time Point: at hire Type of Assessment: Initial &amp; Direct Observation Conducted by: Technical Supervisor." 3. Review of Competency Assessment Policy revealed no documentation of a policy on how competency assessments for Testing Personnel, General Supervisor, and Technical Supervisor. 4. Review of competency assessments revealed no initial competency assessments were completed for Testing Personnel, General Supervisor, and Technical Supervisor in 2025. 5. On 12/17/2025 at 3:12 PM, the Laboratory Director and Technical Supervisor confirmed no initial competency assessments were performed for Technical Supervisor, General Supervisor, or Testing Personnel in 2025.</p>

**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 observation, record review and interview, the laboratory failed to record and label ranges of temperatures for fridge, freezer, room temperature, and humidity for 14 days in December, 23 days in November and 17 days in October in 2025, failed to store molecular reagents at manufacturer's requirements (See D5413); failed to complete performance specifications for urine specimen collection, failed to test pass stability, accuracy, precision, analytical sensitivity, analytical specificity for urinary tract infection (UTI) polymerase chain reaction (PCR) testing (See D5423); and failed to run negative control and internal control in September, October, November and December in 2025 for urinary tract infection (UTI) polymerase chain reaction (PCR) testing (See D5455).

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to record and label ranges of temperatures for fridge, freezer, room temperature, and humidity for 14 days in December, 23 days in November and 17 days in October in 2025 and failed to store molecular reagents as per manufacturer's requirements. Findings included: 1. On 12/17/2025 at 9:42 AM, molecular reagents were stored in the freezer. The following reagents stored in freezer were: RT-PCR Grade Water store at -15 to -25 degrees Celsius (C) 96-Well 0.2 milliliter (ml) Spectral Calibration Plate 1 store at -20 degrees C 96-Well 0.2 mL Spectral Calibration Plate 2 stored at -20 degrees C 96-Well 0.2 mL Spectral Calibration Plate 3 stored at -20 degrees C qPlex Urinary Tract Profile stored at -20 degrees C BPX High Concentrated Positive Control store at -10 degrees C to -30 degrees C. 2. Review of Laboratory Temperature Log revealed the following: a. Temperature ranges were not labeled for fridge, freezer, room temperature and humidity. b. 14 out of 17 days of temperatures were not recorded in December 2025. c. 23 out of 30 days of temperatures were not recorded in November 2025. d. 17 out of 31 days of temperatures were not recorded in October 2025. e. 12/4/2025, 12/9/2025 and 12/5/2025 had freezer temperatures above -12 degrees f. 11/3

/2025, 11/5/2025, 11/6/2025, 11/7/2025, 11/13/2025, 11/20/2025 and 11/26/2025 had freezer temperatures above -16 degrees C. g. 10/1/2025,10/3/2025, 10/7/2025, 10/8/2025, 10/1/2025, 10/13/2025 , 10/15/2025, 10/16/2025, 10/17/2025, 10/21/2025, 10/22/2025, 10/29/2025, 10/28/2025 and 10/30/2025 had freezer temperatures above -13.6 degrees C. 3. On 12/17/2025 at 2:02 PM, the Office Manager stated 119 patients were tested for UTI PCR. 4. On 12/17/2025 at 3:12 PM, the Laboratory Director and Technical Supervisor confirmed the laboratory failed to record and label ranges of temperatures for fridge, freezer, room temperature and humidity for 14 days in December, 23 days in November and 17 days in October in 2025 and molecular reagents were not stored at manufacturer requirements.

**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 observation, record review and interview, the laboratory failed to complete performance specifications for urine specimen collection and tested pass stability, accuracy, precision, analytical sensitivity, analytical specificity for urinary tract infection (UTI) polymerase chain reaction (PCR) testing. Finding Included: 1. On 12/17/2025 at 9:30 AM, 3 urine specimens were stored in the fridge. Urine specimen #1 was collected on 12/16/2025. Urine specimen #2 was collected on 12/15/2025. Urine specimen #3 was collected on 12/5/2025. 2. Review of SOP Urine Specimen Collection for BXP Urine Tract Profile read, "Store specimens at 2-8 Celsius (C) if testing will occur within 24 hours. This is the recommendation condition to maintain Deoxyribonucleic Acid (DNA) integrity and assay accuracy. Validated Room Temperature Stability: Specimens may be kept at room temperature (15-25 C) for up to 3 days without compromising results. After extraction, DNA may be stored at room temperature for up to 7 days based on validation studies." 3. Review of Summary Performance Report for Urinary Tract Infection V1 using the applied Biosystems Quant Studio 5 96-Well Format signed by the Laboratory Director on 09/09/2025 revealed the instrument data did not correlate with the analytical accuracy, interference, Precision Intraassay Reproducibility, limit of Detection, Linear Dynamic Range and specimen stability. No specimen stability study for urine specimens stored in fridge for 2 to 8 degrees C past 24 hours. No temperature records for stability study. No documentation of serial numbers and expiration dates for Quantio Studio 5 96 well, UTI V1, BioPathogenix (BPX)-Direct Detect, Biological safety Cabinet, Molecular Biology grade Rnase/DNase free water, Refrigerator, Freezer, Centrifuge and Vortex Mixer. 4. Review of UTI Patient reports revealed the following: a. Patient #1 was collected on 10/29/2025, accession on 11/5/2025 and reported on 11/07/2025 for UTI PCR testing. b. Patient #2 was collected on 11/26/2025, accession on 12/4/2025 and reported on 12/15/2025 for UTI PCR testing. c. Patient #3 was collected on

12/01/2025, accession on 12/4/2025 and reported on 12/15/2025 for UTI PCR testing. 5. On 12/17/2025 at 2:02 PM, the Office Manager stated 119 patients were tested for UTI PCR. 6. On 12/17/2025 on 3:12 PM, the Laboratory Director and Technical Supervisor confirmed incomplete performance specifications for UTI PCR testing.

**D5455**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(v)(g)

(d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to run negative controls and internal controls in September, October, November and December in 2025 for urinary tract infection (UTI) polymerase chain reaction (PCR) testing. Findings Included: 1. Review of UTI Controls revealed the following: a. Negative controls and internal controls were not carried out on the following days: 9/17/2025 9/24/2025 9/26/2025 9/30/2025 10/1/2025 10/7/2025 10/15/2025 10/22/2025 10/24/2025 10/28/2025 10/29/2025 11/3/2025 11/5/2025 11/7/2025 11/13/2025 11/20/2025 11/26/2025 12/4/2025 12/9/2025 12/15/2025 2. Review of SOP PCR Setup SOP effective date 09/08/2025 approved by the Laboratory Director read, "Controls Positive control: confirms amplification and detection Negative control (No Template control): detects contamination includes controls on every plate run." No documentation of a policy for internal control to prevent contamination through the entire molecular testing process. 3. On 12/17/2025 at 2:02 PM, the Office Manager stated 119 patients were tested for UTI PCR. 4. On 12/17/2025 on 3:12 PM, the Laboratory Director and Technical Supervisor confirmed negative controls and internal controls were not run for September, October, November and December in 2025 for UTI PCR testing.

**D5821**

**TEST REPORT**

CFR(s): 493.1291(k)

(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have the correct urine specimen collection dates and laboratory name on 3 out of 3 final patient reports reviewed. Findings Included: 1. Review of Patient requisitions revealed the following: a. Patient 1 urine specimen was collected on 10/13/2025 at 2:50 PM. b. Patient 2 urine specimen had no collection time. c. Patient 3 urine specimen was collected on 10/21/2025 at 5:49 PM. 2. Review of Patient Final Report revealed the following: a. Patient

	<p>1 urine specimen was collected on 10/15/2025 at 12:00 PM and another named laboratory on report. b. Patient 2 urine specimens were collected on 10/15/2025 at 12:00 PM and another named laboratory on report. c. Patient 3 urine specimens were collected on 10/24/2025 at 4:00 PM and another named laboratory on report. 3. Review of SOP Quality Assurance (QA) Standard Operating Procedure Urine PCR Laboratory effective date 09/17/2025 approved by the Laboratory Director revealed there was no policy for correcting patient reports and what the requirements were for final patient reports. 4. On 12/17/2025 at 3:12 PM, the Laboratory Director and Technical Supervisor confirmed uncorrected final patient reports for 3 out of 3 patients reviewed.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview, the Laboratory Director failed to complete performance specifications for urine specimen collection and tested pass stability, accuracy, precision, analytical sensitivity, analytical specificity for urinary tract infection (UTI) polymerase chain reaction (PCR) testing (See D6086) and failed to run negative controls and internal controls in September, October, November and December in 2025 for urinary tract infection (UTI) polymerase chain reaction (PCR) testing (See D6093).</p>
<p><b>D6086</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory director failed to complete performance specifications for urine specimen collection and tested pass stability, accuracy, precision, analytical sensitivity, analytical specificity for urinary tract infection (UTI) polymerase chain reaction (PCR) testing. Findings included: 1. See D5423 2. On 12/17/2025 at 3:12 PM, the Laboratory Director confirmed incomplete performance specifications for UTI PCR testing.</p>
<p><b>D6093</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to run negative</p>

controls and internal controls in September, October, November and December in 2025 for urinary tract infection (UTI) polymerase chain reaction (PCR) testing. Findings Included : 1. See D5455 2. On 12/17/2025 on 3:12 PM, the Laboratory Director confirmed negative controls and internal controls were not run for September, October, November and December in 2025 for UTI PCR testing.