

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0873812	(X3) Date Survey Completed 12/09/2025
Name of Provider or Supplier J D C Pediatrics	Street Address, City, State 25 West Shore Drive, Camp Hill, PA	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on record review, lack of documentation, and interview with the Office Coordinator (OC), the laboratory failed to ensure Quality Control (QC) was performed as required per manufacturers (Siemens Multistix) and laboratory requirements when dipstick urinalysis examinations were performed for 2 of 2 years from 01/31/2024 to 12/09/2025. Findings include: 1. Manufacturer instructions for the Siemens Multistix 10SG urine dipstick stated, "Quality Control: Test known negative and positive specimens or controls whenever a new bottle is first opened". 2. The laboratory's Quality Assurance Policy for CLIA waived Testing stated, "For all other CLIA waived test kits, manufacturers recommendations are followed for quality controls." 3. On the day of survey, 12/09/2025 at 9:51 am, review of the laboratory's Urinalysis quality control (QC) records revealed the laboratory failed to perform a known negative control on the Siemens Multistix 10SG dipstick for 2 of 2 years from 1/31/2024 to 12/09/2025. 4. The laboratory performed 58 urine dipstick examinations from 1/31/2024 to 12/09/2025. (from OC, dated 12/19/2025). 5. The OC confirmed the above findings on 12/09/2025 at 1:00 pm. B. Based on lack of documentation and interview with the Office Coordinator (OC), the laboratory failed to monitor and document room temperature to ensure reagent storage conditions were met for 2 of 2 years when urinalysis testing was performed from 1/31/2024 to 12/09/2025. Findings include: 1. On the day of the survey, 12/05/2025 at 11:15 am, the laboratory failed to provide documentation for the room temperature readings performed to ensure storage conditions were met for the following reagent kits used for urinalysis testing for 2 of 2 years from 1/31/2024 to 12/09/2025: - Siemens Multistix 10SG dipstick (manufacturer storage temperature 15 to 30 Celsius). 2. The laboratory performed 58</p>

urine dipstick examinations from 1/31/2024 to 12/09/2025. (from OC, dated 12/19/2025). 3. The OC confirmed the above findings on 12/09/2025 at 1:00 pm.

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 in the laboratory, review of laboratory temperature records, and interview with the Office Coordinator (OC), the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage temperatures were maintained on weekends and holidays for EMB Uricult reagents stored for 203 of 678 days from 01/31/2024 to 12/09/2025. Findings include: 1. On the day of survey, 12/09/2025, at 9:51 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - EMB Uricult paddles, manufacturer storage requirements 45F to 77F. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage temperatures were maintained for 203 of 678 days from 01/31/2024 to 12/09/2025 when the laboratory was closed. 3. The laboratory performed 77 urine culture examinations in 2024 (CMS 116, estimated annual volume, dated 12/03/2025). 4. The OC confirmed the above findings on 12/09/2025 at 1:00 pm.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(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.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview with the Office Coordinator (OC), the laboratory failed to follow established written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 for 1 of 1 Testing Personnel (TP) that performed urine culture (colony count) testing in 2025. Findings include: 1. The laboratory's Quality Assessment Procedures stated, "All new staff will have monthly chart audits every 30 days for the first 90 days of employment to include lab documentation and performance, then quarterly if documentation is accurate." 2. On the day of survey, 12/09/2025 at 10:56 am, the laboratory failed to provide documentation for the monthly chart audits of urine culture (colony count) testing performed for the first 90 days of employment for TP #11 (CMS 209, dated 12

/03/2025) in 2025. 3. The laboratory performed 77 urine culture examinations in 2024 (CMS 116, estimated annual volume, dated 12/03/2025). 4. The OC confirmed the above findings on 12/09/2025 at 1:00 pm.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview with the Office Coordinator (OC), the laboratory failed to ensure established procedures for the twice annual verification of accuracy for urine culture (colony count) testing were followed for 38 of 100 peer review evaluations performed from 1/31/2024 to day of survey. Findings include: 1. The laboratory's Urine Colony Count Proficiency Testing policy stated "After the incubation period one physician will read a paddle and write the results. A second physician will read the same paddle and write the results. The lab director, the assistant director or the clinical supervisor will compare results to ensure results are the same". 2. On day of survey, 12/09/2025 at 9:56 am, review of the laboratory's urine colony count proficiency testing records revealed the laboratory failed to provide documentation for the review of 38 of 100 peer review evaluation records by a second physician for the twice annual verification of accuracy for urine culture (colony count) testing performed from 1/31/2024 to 12/09/2025. 3. The OC confirmed the above findings on 12/09/2025 at 1:00 pm.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview with the Office Coordinator (OC), the Technical Consultant (TC) failed to assess the competency of 10 of 10 Testing Personnel (TP) that performed urine culture (colony count) examinations in 2024. Findings Include: 1. The laboratory's Quality Assurance Policy stated, "7. Personnel Competency, Assessment: Conduct competency reassessments 6 months after hire and annually thereafter, or whenever there is a change in procedures." 2. On the day of survey, 12/09/2025 at 9:30 am, the laboratory failed to provide competency assessment records for 10 of 10 TP (CMS 209, TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, TP#10, dated 12/03/2025), that performed urine culture examinations in 2024. 3. The laboratory performed 77 urine culture (colony count) examinations in 2024 (CMS 116, estimated annual volume, dated 12/03/2025). 4. The OC confirmed the above findings on 12/09/2025 at 1:00 pm.