Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0871859	**(X3) Date Survey Completed** 07/25/2024
Name of Provider or Supplier Jdc Pediatrics	**Street Address, City, State** 1824 Good Hope Rd, Suite 201, Enola, 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	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Supervisor, (CS), the laboratory failed to ensure that a qualified general supervisor was on-site during all normal scheduled working hours, in which tests were performed from 10/20/2022 through the day of the survey as required by PA state regulations. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 07/25/2024 at 10:00 AM, review of the PA laboratory personnel report revealed that the Laboratory Director also serves as a general supervisor. 3. Interview with the CS revealed that a qualified general supervisor was not on site when the Laboratory Director was not on site during all hours of testing from 10/20 /2022 to the day of survey. 4. The CS confirmed the findings above on 07/25/2024 during the survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, and interview with Clinical Supervisor (CS), the laboratory failed to provide a complete procedural manual for Microbiology test Uricult from 10/20/2022 to the date of survey. Findings include: 1. On the day of survey, 07/25/2024, the laboratory failed to provide a complete QC procedure for the Microbiology test Uricult. Missing from the Uricult procedure: - Corrective action to take when calibration or control results fail to meet the laboratory ' s criteria for acceptability. - The QC procedure failed to identify criteria for acceptability. - The QC procedure failed to identify the ATCC# in use for positive or negative qualitative controls. 2. The CS confirmed the findings above on 07/25/2024 at 11:30 am.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the Clinical Supervisor (CS), the laboratory failed to record QC characteristics for all media used for Microbiology test Uricult from 10/20/2022 to the date of survey. Findings include: 1. The procedure manual approval page signed and dated by the Laboratory Director (LD) 6/12/2024, stated "The lab documentation for quality control results and patient lab results are reviewed monthly by the Lab Director. Presently the Director is Sherie Love, MD. The check mark at the bottom of each page indicates the results have been checked. The signature below indicates the lab director has reviewed the lab quality control procedures in place to make sure they are correct. " 2. Document review QC records revealed that the laboratory failed to identify the ATCC# in use for positive or negative qualitative controls. 3. Document review of QC records revealed that the LD failed to review the quality control results from 10/20/2022 to the date of survey. 4. The CS confirmed the findings above on 07/25/2024 at 11:30 am.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of documentation, and interview with the Clinical Supervisor (CS), the Laboratory Director (LD) failed to specify, in writing, the duties and responsibilities of the technical consultant (TC), clinical consultant (CC) and testing personnel (TP) involved in the preanalytic, analytic, and postanalytic phases of Uricult testing from 10/20/2022 to the date of the survey. Findings include: 1. On the date of the survey, 04/25/2024 at 10:40 am, the laboratory failed to provide written job responsibilities and duties for the following laboratory personal involved in the preanalytic, analytic, and postanalytic phases of patient testing from 10/20/2022 to 07/25/2024: - 10 Testing Personnel (CMS 209 #1, #2, #3, #4, #5, #6, #7, #8, #9, #10) - 1 Technical Consultant (CMS 209 #1) - 1 Clinical Consultant (CMS 209 #1) 2. The CS confirmed the findings above on 06/30/2024 around 10:42 AM.