Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0231426	02/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Carilion Childrens Pediatric Medicine - Postal	4040 Postal Drive, Roanoke, VA	

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
D0000	An announced CLIA Recertification on-site survey was conducted at the Carilion Children's Pediatric Medicine- Postal on February 24, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on January 22, 2021 with off-site record review of documentation and a follow-up phone conference on February 19, 2021. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, Laboratory Personnel Report form (CLIA) (CMS-209 Form), and an interview, the laboratory failed to rotate PT among the twelve (12) testing personnel (TP) for three (3) of 6 events reviewed. Dates of record review include all 3 events in 2019 and 2020. Findings include: 1. The review of the American Academy of Family Physicians (AAFP) PT records revealed that the testing personnel (TP) A performed all 3 events in 2020. See attached personnel code list. 2. Review of the CMS 209 laboratory personnel form revealed 12 TP performing patient testing in from January 1, 2019 and up to the date of survey on February 24, 2021. 3. An interview with the primary TP, technical consultant and lab director on February 24, 2021 at approximately 12:05 PM confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of daily patient testing log, electronic medical records (EMR), policy and procedures (P&P), and interview, the laboratory failed to follow the established P&P for reporting urine colony count results for two (2) of 8 patients reviewed in 2020 and 4 of 7 patients reviewed in 2019. Findings include: 1. Comparison of the daily patient testing log for the Uricult colony counts and the EPIC EMR results revealed the following: 01/07/20- Patient 1- Uricult Colony Count log had a handwritten result of "negative" for the colony count. The EPIC EMR lacked documentation of urine colony count ordered and performed. Notes within the patient record indicate that a urine culture was performed. 01/11/20- Patient 2- Uricult Colony Count log had a handwritten result of "negative" for the colony count. The EPIC EMR lacked documentation of urine colony count ordered and performed. Notes within the patient record indicate that a urine culture was performed. 03/18/19- Patient 1- Uricult Colony Count log had a handwritten result of "1,000/neg" for the colony count. The EPIC EMR had a result of negative for the urine colony count. 06 /20/19- Patient 2- Uricult Colony Count log had a handwritten result of "1,000" for the colony count. The EPIC EMR had a result of negative for the urine colony count. 10/23/19- Patient 3- Uricult Colony Count log had a handwritten result of "POS/10 ^5 " for the colony count. The EPIC EMR had a result of "POS" for the urine colony count. 11/16/19- Patient 4- Uricult Colony Count log had a handwritten result of "10 ^4" for the colony count. The EPIC EMR had a result of "POS" for the urine colony count. 2. Review of the P&P for the Uricult and Urine Colony Count revealed the following statements: "Uricult Procedure Manual (signed by the lab director with no date) page 5, Interpretation of Results- In making the determination, the number of colonies and not the dimensions of the individual colonies should be considered. Match the "colony density" on the agar surface with the printed example it most closely resembles on the Colony Density Chart. Page 6, Reportable Ranges- Uricult culture paddles are capable of detecting bacteriuria in the range of 10 ^3(1,000) to 10 ^7(10,000,000) CFUs/ml." "Test- Urine Colony Count (signed by the lab director with no date), VII. Resulting- After interpretation of results by doctor, the results are recorded on the patient log book and placed in the patient's EMR." 3. During an interview with the lab director and primary testing personnel on February 24, 2021 at approximately 12:05, the inspector asked about the discrepancies with the handwritten log and the EPIC EMR. They stated the urine colony counts are to be ordered in the EPIC EMR system and the lab is to report results as negative (for no growth) or as 10 ^ 3-7 CFU/ml after comparing the paddles to the Uricult pictures on the cabinet. In addition, a handwritten result of 1,000/neg is to be reported as 10 ^3 CFU/ml. They confirmed the discrepancies in reporting results.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 the review of daily patient testing log, electronic medical records (EMR), policy and procedures (P&P), quality assurance records and interview, the established quality assessment plan failed to identify the result discrepancies of urine colony count results for two (2) of 8 patients reviewed in 2020 and 4 of 7 patients reviewed in 2019. Cross Reference D5401. Findings include: 1. Comparison of the daily patient testing log for the Uricult colony counts and the EPIC EMR results revealed discrepancies between the handwritten logs and the final patient results in the EPIC EMR. Cross Reference D5401. 2. Review of the P&P revealed the following statements: "Quality Assurance (QA) Program (signed by the lab director with no date) Patient Test Management- Minimum of 5 random patients' charts will be reviewed monthly with the following focus: a. Are all the test requisitions written or in EMR? e. Do the results in EMR match the results on the patient logs and report printouts?" 3. Review of the available QA records revealed that at least one patient result for urine colony counts was reviewed for each month in 2019 and 2020. 4. An interview with the lab director and main testing personnel on February 24, 2021 at approximately 12:05 confirmed that result discrepancies were identified during the survey and that the current QA plan failed to identify and address the errors.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP and the technical consultant (TC), the TC failed to perform and document the annual competency assessments for five (5) of 12 TP in 2019 and 1 of 12 in 2020. Findings include: 1. Review of the CMS-209 form revealed there were a total of 12 TP performing patient testing. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of the annual competency assessments for the following: TP B- 2019, TP C- 2019, TP D- 2019, TP E- 2019, TP F- 2019 and TP G- 2020. See attached TP code sheet. 3. An interview with the lab director, technical consultant and main testing personnel on February 24, 2021 at approximately 12:05 confirmed the findings.