

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0932574	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier East Louisville Pediatrics, Psc	Street Address, City, State 6112 Crestwood Station, Crestwood, KY	
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	A recertification survey was conducted on 01/12/2023, and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493. The condition at 42 CFR 493.1409, laboratories performing moderate complexity testing; technical consultant was not met and additional standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 interview and record review, it was determined the facility failed to complete the required competency assessment for one (1) of two (2) testing personnel (TP) whose competency documentation was reviewed (TP #2). The findings include: Review of the "Quarterly Quality Assurance" checklist, completed and signed by the Technical Consultant (TC) and Laboratory Director (LD) on 08/23/2022, revealed competency assessments were performed annually on TP as part of the laboratory quality assurance program. Review of TP #2's "Competency Assessment Record" revealed competency assessments dated 11/16/2020 and 10/28/2021. The competency assessment form indicated testing was done at six (6) month and twelve (12) month intervals; however, there was no competency record for 2022. Interview with TP #1, the practice manager, on 01/12/2023 at 12:30 PM, revealed she did not know if the competency evaluation was completed. Interview with TP #2, on 01/12/2023 at 12:40 PM, revealed her competency assessment for 2022 was cancelled due to her being out sick. She stated the assessment was not rescheduled.</p>
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 interview and record review, it was determined the facility failed to have a procedure for performing Streptococcus (strep) cultures on different specimens other than the throat. Specifically, the laboratory tested a rash to Patient #1's perianal area for strep without a procedure for completing this type of culture. The findings include: Review of the "Microbiology Patient Log" for the first week of December 2022 revealed that on 12/06/2022, a perianal culture for strep was performed on Patient #1. The result was reported to the clinician on 12/07/2022 at 3:16 PM. Review of the "Procedure Manual" revealed the only procedure for culturing strep available was the "Throat Culture Procedure for the Presumptive Identification of Strep A". This procedure was dated as approved by the Laboratory Director (LD) on 05/14/2018, as documented on the procedure manual cover page. The "Procedure Manual" did not contain any procedures for the performance of strep cultures on specimens other than throat swabs. Interview with Testing Personnel (TP) #1, the practice manager, on 01/12/2023 at 12:15 PM, revealed she was shown the "Microbiology Patient Log" and the reported result for Patient #1. TP #1 explained that clinicians occasionally asked for cultures to be performed on a patient's rash to determine whether the rash was caused by strep. TP #1 stated there was no procedure in the procedure manual for the performance of strep cultures on specimens other than throat swabs.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on interview, record review and review of the facility's policies, the facility failed to ensure the Uricult media used to perform urine colony counts was examined or tested prior to use, to ensure each batch had the ability to support growth of microorganisms. The findings include: Review of the laboratory policy titled, "Laboratory Procedures" for urine culture, undated, revealed the policy did not include instructions for the performance of the required quality control and examination for each batch of Uricult media. Interview with Testing Personnel (TP) #1, the practice manager, on 01/12/2023 at 11:30 AM, revealed the laboratory was not performing quality control or physical examination of the Uricult media because they thought it was a waived test.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on interview and record review, it was determined the facility did not have a qualified Technical Consultant (TC). This failure had the potential to impact the quality of laboratory testing, as there was no one qualified to perform the duties of a TC. The findings include: Review of email correspondence the surveyor received from the TC of record, on 12/20/2022, revealed the TC was retiring effective 01/01/2023 and the facility should be contacted directly. Review of the "Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA)" document, dated 01/03/2023, revealed the facility's Laboratory Director (LD) was listed as the TC. Interview with the LD, on 01/12/2023 at 12:52 PM, revealed the former TC gave notice before the holidays (late December 2022) and retired on 01/01/2023. The LD stated she was serving as the TC until the position could be filled; however, the LD stated she did not meet the experience requirement (one year experience performing laboratory testing) for the TC.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on interview and record review, it was determined the facility did not have a qualified Technical Consultant (TC). This failure had the potential to impact the quality of laboratory testing, as there was no one qualified to perform the duties of a TC. The findings include: Review of email correspondence the surveyor received from the TC of record, on 12/20/2022, revealed the TC was retiring effective 01/01/2023 and the facility should be contacted directly. Review of the "Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA)" document, dated 01/03/2023, revealed the facility's Laboratory Director (LD) was listed as the TC. Interview with the LD, on 01/12/2023 at 12:52 PM, revealed the former TC gave notice before the holidays (late December 2022) and retired on 01/01/2023. The LD stated she was serving as the TC until the position could be filled; however, the LD stated she did not meet the experience requirement (one year experience performing laboratory testing) for the TC.