

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315529	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Children's Clinic Pa Of West Tennessee, The	Street Address, City, State 264 Coatsland Dr, Jackson, TN	
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
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 observation of the laboratory, review of the laboratory's personnel policy, testing personnel records and patient records, and interview with the laboratory lead, the laboratory failed to follow its' own testing personnel competency procedures in 2020, 2021 and 2022 for moderately complex patient testing for four of four testing personnel, twelve of twelve competencies performed. The findings include: 1. Observation of the laboratory on 02/08/2023 at 8:15 am revealed the following moderately complex test systems in use for patient testing: Beckman Coulter AcT Diff Complete Blood Count (CBC) instrument, a microscope in use for performing urine microscopy and an Advanced Instrument BR-2 instrument used for performing total and direct bilirubin on neonates. 2. Review of the laboratory's policy titled "Personnel Competency" revealed the following statement: "Those personnel who perform testing on patient specimens are required to have the six required procedures in their competency assessment." All six required elements were included in the policy. 3. Review of testing personnel records and patient testing records revealed the following: Testing person #1: No documentation of problem solving on three of three annual competencies performed in 2020, 2021, and 2022 for the CBC and urine microscopies in 2020, 2021 and 2022, and for the bilirubin testing in 2020. Testing person #2: No documentation of problem solving on annual competency performed for CBC, Urine microscopies, and bilirubin in 2020, no problem solving for CBC and urine microscopies for the annual competency assessment performed in 2021, and no annual competency for urine microscopy performed for the 2022 annual competency with patient testing for urine microscopies performed by testing person #2 in 2022</p>

(patient 196093 on 03/24/22 and patient 89305 on 11/14/22.) Testing Person #3: No documentation of Record Review or blind testing for CBC and urine microscopic for annual competency performed in 2020; No documentation of problem solving for CBC, urine microscopics, or bilirubin for annual competency in 2020. No documentation of record review, blind testing or problem solving for CBC, urine microscopics, or bilirubin for the annual competency done in 2021; no documentation of problem solving for the competency performed in 2022 for the CBC and urine microscopic. Testing Person #4: No documentation of record review, QC review, blind testing or problem solving for CBC and urine microscopic on initial competency done on 06/30/21; no problem solving for interim competency done on 09/28/21 for CBC and urine microscopic; no problem solving for annual competency done on 09/23/22 for CBC and urine microscopic. 4. Interview with the laboratory lead on 02/07/23 at 1:30 pm confirmed the laboratory failed to follow its' own testing personnel policies in 2020, 2021, and 2022 for four of four testing personnel and twelve of twelve competencies performed.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's proficiency testing (PT) records and interview with the laboratory lead, the laboratory failed to evaluate non-graded proficiency testing results for one of one ungraded PT results for 2022 event two. The findings include: 1. Review of the laboratory's proficiency testing records revealed a non-graded score for slide CMP-14 (urine sediment) for 2022 event two. There was no documentation the ungraded score had been evaluated for accuracy. 2. Interview with the laboratory lead on 02/07/23 at 1:00 pm confirmed the laboratory did not evaluate non-graded PT scores for one of one result that was not scored in 2022. She further stated she did not know the non-graded scores had to be evaluated.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's proficiency testing (PT) records, the laboratory's proficiency testing policy and interview with the laboratory lead, the laboratory director failed to ensure the laboratory's corrective action plan was followed for unacceptable proficiency testing scores for 2021 event two urine microscopy. The findings include: 1. Review of the laboratory's proficiency testing records revealed an unacceptable score for urine sediment slide # USP-04 from PT event 2021 event two.

The report was signed by the lab director 11/12/2021 with no corrective action performed. 2. Review of the laboratory's policy for PT revealed the following: "If a score of less than 100% is received, an investigation should be performed to determine why a sample or samples fell outside the acceptable range." "Remedial actions will be taken to determine the cause, correct the problem and document the actions." 3. Interview with the laboratory lead on 02/07/2023 at 1:00 pm confirmed the laboratory director failed to ensure the PT policy for investigation of unacceptable PT results was followed for urine sediment for 2021 event two, slide USP-04.