

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1013993	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Muddy Creek Pediatrics Llc	Street Address, City, State 6400 Thornberry Ct, Ste 610, Mason, OH	
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 record review and an interview with the Practice Administrator (PA), the laboratory failed to follow their written policies and procedures to assess the competency of Testing Personnel (TP) performing moderately complex throat culture procedures. This deficient practice had the potential to affect 2459 patients tested in the subspecialty of bacteriology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 02/26/2019, revealed fifteen individuals listed as TP. 2. The surveyor requested all TP competency assessment records for 2017-2019 from the PA. The PA was unable to provide competency assessment records for all TP as requested. 3. Review of the laboratory's "Muddy Creek Pediatrics Throat Culture Quality Assessment Procedure", approved via signature and date by the Laboratory Director in 12/16/2013 and provided on the date of the inspection, found the following statement: "To test our throat culture quality we will: ... Maintain competency records for staff" 4. The PA confirmed the laboratory did not follow their own policy and procedure, and did not maintain competency records as stated in the procedure. The interview occurred on 02/26/2019 at 2:00 PM.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on document review, and an interview with the Practice Administrator (PA), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. This deficient practice had the potential to affect 2459 patients tested in the subspecialty of bacteriology. Findings include: 1. Review of the "MCP Policy and Procedure Clinical Department - Documenting In-House Test Results Policy no: CD-SO010", found the following statement under Quality Control: "1. The Clinical Nurse Manager and/or designee will audit this process through observation of MA technique at least once annually and will also audit a minim of 5 charts of patients who have had a test listed above to be sure the process was completed in accordance with the established procedure." 2. No quality assessment documentation was found for 2018 or 2019. 3. An interview with the PA on 02/26/19 at 3:00 PM, confirmed quality assessment was not performed at the intervals stated in their policy and procedure.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Practice Administrator (PA), the laboratory failed to review the effectiveness of their quality assessment program of the general laboratory systems. This deficient practice had the potential to affect 2459 patients tested in the subspecialty of bacteriology. Findings were as follows: 1. Review of the laboratory's "Muddy Creek Pediatrics Throat Culture Quality Assessment Procedure", provided on the date of the inspection, found the following instructions: "...In order to accomplish this goal a triannual QA review will be completed. This will involve: A planned review of the policy and procedure for its effectiveness. Identification of any problems through this review process Corrective action taken to prevent future problems Follow-up review of the effectiveness of corrective actions" 2. The surveyor requested 2018-2019 documentation of a triannual review from the PA. The PA confirmed the laboratory did not have documentation of a review for 2018-2019 and the laboratory did not effectively indicate and correct the problems identified during the onsite CLIA inspection. The interview occurred on 02/26/2019 at 3:00 PM.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Practice Administrator (PA) and Testing Personnel (TP) #4, (as listed on the Laboratory Personnel Report (CLIA) Form CMS-209 signed by the Laboratory Director), the Laboratory Director failed to ensure that prior to testing patients' specimens, TP, who were responsible for moderately complex testing procedures, had documentation of training and that they had demonstrated they could perform bacteriology testing reliably to provide and report accurate results. This deficient practice had the potential to affect 2459 patients tested in the subspecialty of bacteriology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 02/18/2019 and provided on the date of the inspection, revealed ten out of fifteen individuals newly listed as TP, since the last CLIA inspection on 04/12/2017, to perform moderately complex testing procedures. 2. Review of the laboratory's 2017-2019 competency assessment documentation provided on the date of inspection titled "page 2 of 3 New Employee Training Competency Checklist-Medical Assistant", found no date of assessments, no page one and no page three. 2. Further review of the laboratory's 2017-2019 competency assessment documentation, provided on the date of the inspection, revealed TP#10, TP#12, TP#13, TP#14 and TP#15 had no training and assessment documentation prior to moderate complexity testing of patients specimens independently. 3. The Surveyor requested the laboratory's 2017-2019 complete training and assessment documentation prior to testing patients specimens for TP#10, TP#12, TP#13, TP#14 and TP#15 from the PA and TP#4. The PA confirmed the laboratory did not have complete training and assessment documentation prior to testing patients specimens independently and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 02/26/2019 at 1:54 PM.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the Form CMS-209, and an interviews with the Practice Administrator (PA) and Testing Personnel (TP) #4, (as listed on the Laboratory Personnel Report (CLIA) Form CMS-209 signed by the Laboratory Director), the Technical Consultant (TC) failed to evaluate and document the competency assessment of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens. This deficient practice had the potential to affect 2459 patients tested in the subspecialty of bacteriology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 02/18/2019, revealed ten out of 15 TP newly listed and credentialed by the Laboratory Director to perform

moderately complex throat culture testing procedures. 2. The Surveyor requested the laboratory's semiannual competency assessment documentation for the newly listed TP from the PA and TP#4. The PA and TP#4 stated they were unable to locate the semiannual competency records for all newly listed TP and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 02/26/2019 at 1:50 PM.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the Form CMS-209, and an interviews with the Practice Administrator (PA) and Testing Personnel (TP) #4, (as listed on the Laboratory Personnel Report (CLIA) Form CMS-209 signed by the Laboratory Director), the Technical Consultant (TC) failed to annually evaluate and document the competency assessment of individuals responsible for moderate complexity testing. This deficient practice had the potential to affect 2459 patients tested in the subspecialty of bacteriology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 02/18/2019, revealed 15 TP listed and credentialed by the Laboratory Director to perform moderately complex throat culture testing procedures. 2. The Surveyor requested the laboratory's 2017-2018 annual competency assessment documentation for all TP from the PA and TP#4. The PA and TP#4 stated they were unable to locate the annual competency records for all listed TP and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 02/26/2019 at 1:59 PM.