

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0691478	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier Leitchfield Pediatric Clinic Psc	Street Address, City, State 901 Wallace Avenue, Leitchfield, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on interview with the Laboratory Director on 04/19/2022 and desk review of Hematology proficiency testing results from the Wisconsin State Laboratory of Hygiene (WSLH) and American Academy of Family Physicians (AAFP) proficiency testing agencies on 04/21/2022, it was determined the laboratory failed to successfully participate in the Cell ID or White Blood Cell (WBC) Differential analyte in three out of five consecutive testing events. (Refer to 2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on interview with the Laboratory Director, on 04/19/2022, and a desk review of proficiency testing results from the Wisconsin State Laboratory of Hygiene (WSLH) and the American Academy of Family Physicians (AAFP) proficiency testing agencies on 04/21/2022, it was determined the laboratory failed to achieve satisfactory overall scores in three out of four consecutive testing events for the analyte Cell ID or White Blood Cell (WBC) Differential. Findings include: 1. Record review of proficiency tests results from WSLH revealed the laboratory failed to achieve satisfactory performance with a score of sixty-eight percent (68%) for the first testing event of 2021. 2. Record review of proficiency tests results from WSLH revealed the laboratory failed to achieve satisfactory performance with a score of forty-eight percent (48%) for the second testing event of 2021. 3. Record review of proficiency tests results from AAFP revealed the laboratory failed to achieve a satisfactory performance with a score of twenty percent (20%) for the first testing event of 2022. 4. Interview with the Laboratory Director, on 4/19/2022 at 12:46 PM, revealed the facility was aware of the failure to achieve satisfactory overall scores in three out of four consecutive testing events for the analyte Cell ID or WBC Differential.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

The Laboratory Director failed to provide direction for successful proficiency testing (PT) participation in three out of five events for Hematology in 2021 and 2022 resulting in non-initial unsuccessful proficiency testing participation. (Refer to 6016)

D6016

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of CMS 0155D Report and Wisconsin State Laboratory of Hygiene (WSLH) and the American Academy of Family Physicians (AAFP) proficiency testing agency unsatisfactory scores on 04/21/2022 for three out of four events for

2021 and 2022, the Laboratory Director failed to provide effective direction over proficiency testing for Cell ID or WBC Differential resulting in non-initial unsuccessful proficiency testing participation.