

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D2156570	<b>(X3) Date Survey Completed</b>  05/24/2023
<b>Name of Provider or Supplier</b>  Hope Primary & Urgent Care	<b>Street Address, City, State</b>  2157 South Hwy 27, Stearns, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was initiated on 05/24/2023 and concluded on 05/24/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document reviews and interview with the Technical Consultant (TC), the laboratory failed to review graded proficiency testing (PT) results for 3 of 6 PT events in hematology from 2021 and 2022. Findings included: Review of the graded reports for 2022-A, 2022-B, 2022-C from the American Academy of Family Physicians (AAFP), revealed the graded PT reports were not signed or noted as having been reviewed by the laboratory Director and/or their designee. During an interview on 05/24/2023 at 12:45 PM, the Technical Consultant confirmed the PT reports were not signed or otherwise noted as being reviewed by the laboratory Director and/or their designee.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on policy review, document reviews, and interview, the laboratory failed to ensure competency assessments included the six mandated criteria for 4 of 4 testing personnel (TP) reviewed. Findings included: Review of a policy titled, "Quality Assurance Plan for Laboratory," last revised 06/30/2022, indicated, "Each employee working in the laboratory must complete a training program along with proficiency testing prior to performing laboratory procedures." The policy did not address the frequency, method, or criteria for personnel competency assessments. A review of the competency evaluations for TP #1 dated 10/22/2022 and 02/03/2023, TP #2 dated 09/15/2022, TP #3 dated 01/09/2023, and TP #4 dated 03/16/2022 and 07/08/2022, did not address the following six mandated competency assessment requirements: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. - Monitoring the recording and reporting of test results. - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. - Direct observation of performance of instrument maintenance. - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. - Assessment of problem-solving skills. In an interview on 05/24/2023 at 11:10 AM, the Technical Consultant stated there was no formal written policy on the frequency of competency assessments or how the competency assessments should be performed.