

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2156570	(X3) Date Survey Completed 10/13/2020
Name of Provider or Supplier Hope Primary & Urgent Care	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/13/2020, the laboratory failed to perform at least two levels of quality control samples on two of five days of Complete Blood Count (CBC) testing reviewed on the Sysmex Pochi Hematology instrument. Findings include: 1. One patient CBC was tested on 07/03/2020 according to the In-house CBC log. Review of quality control data failed to reveal quality control results. 2. One patient CBC was tested on 09/03/2020 according to the In-house CBC log. Review of quality control data failed to reveal quality control results. Interview with the Technical Consultant at 3:00 PM on 10/13/2020, revealed the facility failed to have a system in place to ensure at least two levels of quality control samples were tested prior to testing patient samples.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES 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>

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 10/13/2020, the Technical Consultant failed to perform and document annual competency using the 6 mandated competency assessment requirements for one testing personnel responsible for moderate complex testing from 10/15/2018 to 10/12/2020. Findings include: 1. Record review failed to reveal competency assessments for Testing Personnel #1 listed on the CMS 209 for direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples and problem solving skills. Interview with the Technical Consultant at 3:00 PM on 10/13/2020, revealed the facility failed to have a system in place to ensure competency was performed using the six (6) mandated competency assessment requirements for testing personnel performing Complete Blood Counts on the Sysmex Pochi-100 hematology instrument.