

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2127956	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Community Health Centers Of Western Kentucky, Inc	Street Address, City, State 10220 Dixie Beeline Hwy, Guthrie, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 11/29/2018, the laboratory failed to monitor and document external humidity and room temperature for the performance of Complete Blood Counts (CBCs) on the Sysmex XP-300 Hematology analyzer from 08/02/2017 through 11/28/2018. Findings include: Review of the Sysmex Operator's Manual revealed the specifications for operating environment to be 15 to 30 degrees Centigrade for ambient temperature and 30% to 85% for relative humidity. The laboratory failed to provide documentation of room temperature and humidity from the date of the last survey performed 08/02/2017. The laboratory director revealed in an interview at 11:15 AM on 11/29/2018, the laboratory failed to have a system in place to ensure room temperature and humidity readings were recorded daily.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where</p>

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and staff interview on 11/29/2018, the laboratory failed to ensure patient test reports include at least two identifiers for positive patient identification on six of six Complete Blood Count (CBC) test reports. Findings, include: A CBC was reported on Patient #1 on 01/04/2018. The report failed to include two patient identifiers. A CBC was reported on Patient #2 on 03/19/2018. The report failed to include two patient identifiers. A CBC was reported on Patient #3 on 05/02/2018. The report failed to include two patient identifiers. A CBC was reported on Patient #4 on 07/13/2018. The report failed to include two patient identifiers. A CBC was reported on Patient #5 on 08/10/2018. The report failed to include two patient identifiers. A CBC was reported on Patient #6 on 10/11/2018. The report failed to include two patient identifiers. The Laboratory Director revealed in an interview at 11:15 AM on 11/29/2018, the laboratory failed to have a system in place to ensure at least two patient identifiers were on CBC test reports for positive patient identification.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on staff interview and record review on 11/29/2018, the laboratory failed to ensure normal values were available to the authorized person for five of six patient Complete Blood Count (CBC) test reports. Findings include: A CBC was reported on Patient #1 on 01/04/2018. The report failed to include normal values for each analyte. A CBC was reported on Patient #3 on 05/02/2018. The report failed to include normal values for each analyte. A CBC was reported on Patient #4 on 07/13/2018. The report failed to include normal values for each analyte. A CBC was reported on Patient #5 on 08/10/2018. The report failed to include normal values for each analyte. A CBC was reported on Patient #6 on 10/11/2018. The report failed to include normal values for each analyte. An interview with the Laboratory Director at 11:15 AM on 11/29/2018, revealed the laboratory failed to have a system in place to ensure normal values were on patient CBC test reports.