Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0691478	(X3) Date Survey Completed 02/05/2020
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview on 02/05/2020, the laboratory failed to monitor and document room temperature and humidity from 01/16/2019 to 02/04 /2020 as required by the manufacturer for operation of the Sysmex XN-330 Hematology analyzer on each day of patient testing. Findings include: 1. Review of the Operator's Manual for the Sysmex XN-330 hematology analyzer revealed under Performance Specifications, room temperature for operation is 15 - 35 degrees Centigrade. 2. Review of the Operator's Manual for the Sysmex XN-330 hematology analyzer revealed under Performance Specifications, humidity temperature for operation is 20 - 85%. 3. The laboratory failed to provide documentation of room temperature and humidity recordings from 01/16/2019 when the Sysmex XN-330 was installed to 02/04/2020. 4. Testing personnel acknowledged in an interview at 12:30 PM on 02/05/2020, the laboratory failed to have a system in place to ensure manufacturer performance specifications of room temperature and humidity readings were documented each day of patient testing.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of Hematology proficiency testing results from Wisconsin State Laboratory Hygiene (WSLH) testing agency and staff interview on 02/04/2020, the laboratory director failed to ensure proficiency testing results were reviewed by staff for five of six testing events in 2018 and six of six testing events in 2019. Findings include: 1. There was no evidence of review of hematology proficiency testing results from WSLH for three testing events in 2018. 2. There was no evidence of review of hematology proficiency testing results from WSLH for two testing events in 2019. 3. There was no evidence of review of urine culture proficiency testing results from WSLH for three testing events in 2018. 4. There was no evidence of review of urine culture proficiency testing results from WSLH for three testing events in 2019. 5. Testing personnel acknowledged in an interview at 11:00 AM on 02/05/2020, the laboratory director failed to have a system in place to ensure proficiency testing results received from WSLH were reviewed by appropriate staff to evaluate the laboratory's performance.