Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0962601	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Primary Plus Kid Care	1350 Medical Park Drive, Maysville, 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 staff interview and record review, the laboratory failed to monitor and document the humidity of the laboratory where the ACT-Diff analyzer testing was performed. Humidity of the laboratory was not recorded from November 16, 2016 through November 26, 2018. Findings include: The Manufacturer's Operations Manual for the ACT-Diff analyzer lists an operating range for humidity for the analyzer to be between twenty percent (20%) and eighty-five percent (85 %). Review of the Maintenance Log, on 11/27/18 at 11:50 AM, revealed no documented evidence the humidity of the laboratory where the ACT-Diff analyzer testing was performed had been monitored from November 16, 2016 through November 26, 2018. Testing personnel acknowledged in an interview on 11/27/18 at 11:50 AM, the laboratory failed to have a system in place to ensure the humidity of the laboratory was monitored and documented daily.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

	the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on staff interview, and record review, the laboratory failed to ensure there was a system in place to ensure data entered manually into the electronic medical record was checked for clerical errors. Findings include: Record review revealed the laboratory did not have a system in place for detecting clerical errors entered manually into the electronic medical record from 11/16/16 through 11/26/18. Staff acknowledged in an interview, on 11/27/18 at 1:00 PM, there was no system in place from 11/16/16 through 11/26/18 to check for clerical errors introduced into the electronic medical record due to manual entry.
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 staff interview and record review, of the Hematology proficiency testing results from WSLH Testing Agency, the Laboratory Director failed to ensure proficiency testing results were reviewed by the Medical Director or Testing Staff staff for the complete year of 2017 and 2018. Findings Include: Record review on 11 /27/18 at 12:18 PM, revealed the final results of the hematology proficiency for 2017 and 2018 were not reviewed by the Testing Staff or the Medical Director. Staff acknowledged in an interview, on 11/27/18 at 12:18 PM, there was no system in place to ensure the results from the hematology proficiency testing were reviewed by the Medical Director or Testing Staff from 11/16/16 through 11/26/18.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. This STANDARD is not met as evidenced by: Based on staff interview and record review, the Technical Consultant failed to perform and document Annual Competency using the six (6) mandated Competency Assessment requirements for testing personal. Competency Assessment was

	performed using zero (0) of six (6) methods of assessment for four (4) out of four (4) employees from November 16, 2016 through November 26, 2018. Findings include: Record review on 11/27/18, revealed there was no documented Competency Assessments between November 16, 2016 and November 26, 2018, for four (4) employees that included the following: 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 staff on 11/27/18 at 10:14 AM, revealed the facility failed to have a system in place between November 16, 2016 and November 26, 2018 to ensure competency was performed using all Six (6) mandated Competency Assessment requirements from November 16, 2016 through November 26, 2018.