Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0321388	03/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
East Louisville Pediatrics Psc	4171 Westport Rd, Louisville, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the staff on 03/26/2018, the laboratory failed to perform and document quality assessment from 03/23/2018 through 03/25 /2018 as outlined in their Quality Assessment Policy. Findings include: Review of the policy and procedure manual revealed the quality assessment plan entitled "Quality Assurance Plan" stated the frequency of review would be at least annually. There was no documentation of monitoring or assessing the pre-analytical, analytical, and post-analytical phases of patient testing. The staff acknowledged in an interview on 03/26 /2018 at 09:59am, that the quality assurance plan oulined in their procedure manual was not followed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and staff interview on 03/26/2018, the laboratory failed to

	follow manufacturer's instructions for daily operating procedures on the Cell-Dyn Emerald Hematology instrument from March 23, 2016 through March 25, 2018. Findings include: Review of manufacturer's Daily Operation Procedures states rinse cycles and background counts are performed with each daily power-up. Background counts must fall within manufacturer's limits and a copy of the counts must be retained for documentation. Review of hematology records failed to reveal background counts were performed and documented each day of patient testing. Testing personnel acknowledged in an interview at 11:33am on 03/26/2018, the laboratory failed to have a system in place to ensure that the background counts were performed and retained with each day of testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview on 03/26/2018, the laboratory failed to check each batch of strep selective agar (SSA) used for identification of B-streptococcus using quality control organisms to check for sterility, ability to support growth, and the selection or inhibition of organisms prior to patient testing from March 23, 2016 through March 26, 2018. Findings include: The laboratory failed to retain quality control documentation of media checks prior to patient testing. Interview with the staff on 03/26/2018 at 10:37am revealed the laboratory failed to have a system in place to ensure quality control organisms were used to check all media for ability to support growth and produce a specific biochemical response prior to patient testing.
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 record review and staff interview on 03/27/2018, the laboratory failed to ensure normal values were available to the authorized person for six of six patient Complete Blood Cell (CBC) test reports. Findings include: A CBC was reported on Patient #1 on 01/17/2017. The report failed to include reference ranges for each analyte. A CBC was reported on Patient #2 on 05/15/2017. The report failed to include reference ranges for each analyte. A CBC was reported on Patient #3 on 06/14/2017. The report failed to include reference ranges for each analyte. A CBC was reported on Patient #4 on 07/10/2017. The report failed to include reference ranges for each analyte. A CBC was reported on Patient #5 on 08/22/2017. The report failed to

	include reference ranges for each analyte. A CBC was reported on Patient #6 on 09/27 /2017. The report failed to include reference ranges for each analyte. An interview with the staff at 11:27am on 03/26/2018 determined the laboratory failed to establish a system to ensure reference ranges were available for all tests reported.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on surveyor interview with the laboratory personnel and review of laboratory policies on 03/26/2018, the laboratory director failed to ensure the policy and procedure manual include policies for the performance of Complete Blood Cell Counts and the collection and testing of Throat Cultures. The findings include: The laboratory failed to provide a policy for the operations of the Cell-Dyn Emerald hematology instrument, failed to provide procedures for the collection of throat cultures, and failed to provide step-by -step procedures used to identify organisms found in throat cultures. Staff acknowledged in an interview on 03/26/2018 at 10: 18am, the laboratory director failed to have a system in place to ensure policies were established and available to all personnnel prior to patient testing.
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 record review and staff interview on 03/26/2018, the Technical Consultant failed to perform and document annual competency using the six mandated competency assessment requirements. Competency assessment was performed for eight out of eight employees from Jan 1, 2016 through March 26, 2018. Findings include: Record review revealed competency assessments failed to include monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintence records, assessment of testing external proficiency testing samples, and assessing the skills for solving problems. An interview with the office manager at 10:11 am on 03/26/2018, revealed the facility failed to have a system in place to ensure competency was performed using the six mandated competency assessment requirements.