

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1024365	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier Kids Health	Street Address, City, State 1216 Sherwood Park Drive, Gainesville, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 10, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the the tour of the laboratory and an interview with the laboratory director, the laboratory failed to implement and established safety procedure to ensure protection from physical, biochemical and biohazardous materials. Findings include: 1. During the laboratory tour it was observed that the laboratory does not have any eyewash equipment for the laboratory. 2. An interview with the laboratory director on 7/10/18 at approximately 03:30 p.m. confirmed the absence of any eyewash equipment in the laboratory.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental</p>

conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and an interview with the laboratory director, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. A review of the Hematology analyzer (Coulter AcT Diff) QC documents revealed the laboratory failed to produce Levy-Jennings QC reports at the time of survey. 2. An interview with the laboratory director on 7/10/18 in the review conference room at approximately 04:00 p.m. confirmed no Levy-Jennings QC reports were available at the time of survey.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the 2017 API (American Proficiency Institute) Proficiency Testing (PT) documents and an interview with the laboratory director, the laboratory director failed to ensure Proficiency Testing results were submitted within the timeframes established by the PT program. Findings include: 1.) A review of the 2017 API PT records revealed Event #2 of the Hematology survey received a score of 0% "Failure to Participate" because results were not submitted to API on a timely basis. 2.) An interview with the laboratory director, at approximately 04:15 pm on July 10, 2018 in the conference room confirmed the laboratory failed to submit PT results before the cut off date.