Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2059352	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chattanooga Childrens Clinic	403 Spring Creek Rd, Chattanooga, TN	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: _____ Based on observation around 10:00 a.m. February 22, 2018 (during lab tour) of Glucola stored in reagent refrigerator and interview with the office manager, determined the laboratory failed to establish safety procedures to ensure that biohazardous materials and Glucola for human consumption were not stored in the same refrigerator. The findings include: 1. Observed around 10: 00 a.m. February 22, 2018, many bottles of Glucola used for human consumption stored in reagent refrigerator with materials considered biohazardous materials. 2. An interview at approximately 12:00 p.m. February 22, 2018 with the office manager confirmed there was no procedure to ensure that biohazardous materials and Glucola were not stored in the same refrigerator. _____
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: _____ Based on CMS form-209 "Laboratory Personnel Report", Technical Consultant job responsibilities, competencies for testing

	persons 5 of 5, lack of competencies for Technical Consultant and interview with the office manager and primary laboratory testing person, determined there were no competencies for technical consultant and technical consultant failed to perform competencies on testing personnel as stated in job responsibilities for 2016 and 2017. The findings include: 1. CMS form-209 shows one Technical Consultant and 5 testing persons. 2. Technical Consultant (TC) job responsibilities state: "TC evaluates and documents performance of individuals responsible for testing at 6 months and 12 months in the first year of employment and yearly after". 3. Competencies for 5 of 5 testing persons were performed by primary laboratory testing person who does not qualify as a technical consultant for 2016 and 2017. 4. There were no competencies documentated for technical consultant for 2016 or 2017. 5. Interview at approximately 12:00 p.m. February 22, 2018 with the office manager and primary testing person confirmed there were no competencies documented for technical consultant and competencies for testing persons 5 of 5 were not performed by the technical consultant for the two year period. _____
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: _____ Based on observation of in use Complete Blood Count (CBC) control materials (lacking open date) around 10:00 a.m. February 22, 2018 during lab tour and interview with the primary laboratory testing person and office manager, determined the laboratory failed to document open date and open vial expiration date for CBC control materials in use 2/22/18. The findings include: 1. Observed during lab tour 2/22/18 around 10:00 a.m. in use CBC control materials lacking open date/open vial expiration date. 2. Interview at approximately 12:00 p.m. February 22, 2018 with primary laboratory teseting person and office manager, confirmed there was no open date on in use CBC control materials. _____
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: _____ Based on review of unacceptable CBC quality control (QC) material for level 3 in April 2017, procedure review, lack of corrective action documentation and interview with the office manager and primary testing person, determined the laboratory failed to follow procedure for QC acceptablility prior to reporting patient test results. The findings include: 1. Review of Level 3 QC materials for April 2017 was unacceptable on dates: 4/04/17, 4/06/17, 4/07

	/17, 4/11/17, 4/21/17, 4/24/17, 4/25/17, 4/26/17, 4/27/17 and 4/28/17. 2. Procedure review states that all 3 levels of QC materials are to be within limits each day of patient testing. 3. No corrective action was documented for dates when level 3 CBC QC was unacceptable. 4. Interview at approximately 12:00 p.m. February 22, 2018 with the office manager and primary testing person confirmed that level 3 CBC control material was unacceptable 10 days during April 2017 with no corrective action documented and patient testing being reported. _____
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: _____ Based on review of four patient CBC (complete blood count) reports lacking testing personnel identification and interview with office manager and primary testing person, determined the laboratory failed to include identity of testing person on final reports for 2017 and 2018. The findings include: 1. Review of four patient CBC reports dated 1/26/18, 11/28/17, 8/1/17 and 4 /10/17 lacked testing personnel identification. 2. Interview at approximately 12:30 p. m. February 22, 2018 with the office manager and primary testing person confirmed the laboratory failed to include identity of testing person on final CBC reports reviewed in 2017 and 2018. _____
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: _____ Based on observation around 10:00 a.m. February 22, 2018 (during lab tour) of Glucola stored in reagent refrigerator and interview with the office manager, determined the laboratory director failed to ensure that biohazardous materials and Glucola for human consumption were not stored in the same refrigerator. The findings include: 1. Observed around 10:00 a.m. February 22, 2018, many bottles of Glucola used for human consumption stored in reagent refrigerator with materials considered biohazardous materials. 2. An interview at approximately 12:00 p.m. February 22, 2018 with the office manager confirmed there was no procedure to ensure that biohazardous materials and Glucola were not stored in the same refrigerator. _____