Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1062797	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Childrens Healthcare Of Atlanta At Scottish Rite	1001 Johnson Ferry Road, Ne, Atlanta, 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 February 14, 2019. 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	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 review of the policy and procedure manual (SOP), observation, and staff interview, the laboratory establish and observe safety procedures to ensure protection from physical, biochemical, and biohazardous materials. Findings include: 1. SOP review revealed the laboratory has not established an eyewash policy and procedure. 2. Observation during the laboratory tour revealed there was no eyewash equipment in the laboratory or accompanying exam rooms. .. 3. An interview with Staff #1 (CMS 209) in a medical office on 2/14/19 at approximately 3:00 p.m. confirmed there was no eyewash policy and procedure in the SOP nor was there any eyewash equipment in the laboratory or accompanying exam rooms.
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 review of the laboratory policy and procedure manual (SOP) the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings include: 1. SOP review revealed the laboratory had not established nor implemented a 6-procedure competency procedure to assess testing personnel (TP) competency. 2. An interview with Staff #1 in a medical office on 2/14 /19 at approximately 3:00 p.m. confirmed there was not a 6-procedure competency policy in the SOP.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on policy and procedure manual (SOP) review and staff interview, the laboratory director (LD) failed to specify in writing the responsibilities and duties of each individual involved in any phase of laboratory testing as required. Findings include: 1. SOP review revealed the LD did not establish a duties and responsibilities policy and procedure. 2. An interview with Staff #1 (CMS 209) in a medical office on 2/14/19 at approximately 3:00 p.m. confirmed there was not a duties and responsibilities policy and procedure in the SOP.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure the TP has received proper training and has demonstrated they can perform all testing operations reliably as required. Findings include: 1. TP competency document review revealed Staff #9 (CMS 209) did not have an initial competency performed at this facility in 2018. 2. An interview with Staff #1 (CMS 209) confirmed the aforementioned TP did not have an initial training competency performed at this facility in 2018.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical supervisor (TS) failed to evaluate and document the performance of TP at least semiannually during the first year the individual tests patient specimens. Findings include: 1. TP competency document review revealed the TS did not perform a six-month competency for Staff #2 (CMS 209) in 2017. 2. An interview with Staff #1 (CMS 209) in a medical office on 2/14/19 at approximately 3:00 p.m. confirmed the aforementioned TP did not have a six-month competency performed in 2017.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on testing personnel (TP) competency document review and staff interview, the technical supervisor (TS) failed to evaluate and document TP competency annually as required. Findings include: 1. TP competency document review revealed the TS failed to perform annual competencies for the following: 2017 -- (CMS 209):Staff #1 and Staff#5; 2018 -- (CMS 209) Staff #4 and Staff #5. 2. An interview with Staff #1 (CMS 209) in a medical office on 2/14/19 at approximately 3:00 p.m. confirmed annual competencies were not performed on the aforementioned TP. for 2017 and 2018.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or

	medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview, TP failed to meet the required educational requirements to perform high-complexity testing as required. Findings include: 1. TP document review revealed Staff #5 (CMS 209) is unqualified to perform high-complexity testing due to lack of educational qualifications. 2 An interview with Staff #1 (CMS 209) in a medical office on 2/14/19 at approximately 3:00 p.m. confirmed the aforementioned TP was unqualified to perform high-complexity testing due to lack of educational qualifications. This was also confirmed on 3/7/19 by a phone interview with Staff #1 (CMS 209) at approximately 12:30 p.m. and receipt of further educational documentation for Staff #5 (CMS 209) by email on 3/7/2019..