Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2151724	08/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Children's Heart Institute	171 Elden Street, Suite 200, Herndon, VA	

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	An unannounced, off-site CLIA complaint survey was conducted at Children's Heart Institute on July 27, 2020 to August 24, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, verification of accuracy records, and an interview, the laboratory failed to perform four (4) of four (4) verification of accuracy evaluations for flow cytometry testing in calendar year 2018 and 2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy for twice annual accuracy verification policy for flow cytometry testing, "SOP QAL 29 Alternative Proficiency Testing", which stated, "1. Alternative Proficiency Testing (APT) is performed because CAP (College of American Pathologists) does not cover all the targets being tested. 2. For APT a donor is selected and tested between multiple technologists/technicians within the same site or across different sites." 2. Review of the laboratory's twice annual verification of accuracy documentation for calendar year 2018 and 2019 revealed a lack of documentation of flow cytometry twice annual verification of accuracy for calendar year 2018 and 2019. The surveyor requested documentation of verification of accuracy documentation for 2018 and 2019. The laboratory provided no additional documentation for review. 3. In an exit interview with the current Laboratory Director (LD) on August 24, 2020 at approximately 11:50 AM, the above findings were confirmed.
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 a review the laboratory's competency policy, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interview, the laboratory director (LD) failed to follow the laboratory's competency policy and ensure an initial competency assessment was performed for one (1) of one (1) TP prior to testing and reporting patient results using the Thermo Fisher Attune NxT flow cytometer. Dates of record review include November 1, 2018 up to February 22, 2020. Findings include: 1. Review of the laboratory's competency policy, "SOP QAL 25" revealed a statement "...3. Competency is assessed at the following frequency: a. During the first year of an individual's duties, competency is assessed before signing off and six months after signing off training. b. After an individual has completed two competencies and performed testing for one year, the competency is assessed at once year on the dare of sign off." 2. Review of the laboratory's CLIA CMS-209 Form revealed 1 TP identified as performing patient testing using the the Thermo Fisher Attune NxT flow cytometer. 3. Review of the available laboratory personnel records revealed a training record completed on November 15, 2018 and a lack of documentation of initial competency assessment for TP A prior to use of the Attune flow cytometer. The inspector requested to review documentation of the initial competency assessment for TP A. The laboratory provided no documentation for review. See Personnel Code Sheet attached. 4. An interview with former Laboratory Director and former Technical Supervisor on August 18, 2020 at approximately 9:50 AM confirmed the findings.
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 a review of the laboratory's competency policy, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interview, the Technical Supervisor (TS) failed to follow the laboratory's competency policy and perform the semi-annual competency assessment for one (1) of one (1) TP. Dates of record review include November 1, 2018 up to February 22, 2020. Findings include: 1. Review of the laboratory's competency policy, "SOP QAL 25" revealed a statement "...3. Competency is assessed at the following frequency: a. During the first year of an individual's duties, competency is assessed before signing off and six months after signing off training. b. After an individual has completed two competencies and performed testing for one year, the competency is assessed at once year on the dare of sign off." 2. Review of the laboratory's CLIA CMS-209 Form and laboratory training documents revealed 1 TP

	identified as performing patient testing with training completed on November 15, 2018. 3. Review of the available laboratory personnel records revealed a training record completed on November 15, 2018 and a lack of documentation of a semi-annual competency assessment for TP A. The inspector requested to review documentation of the semi-annual competency assessment for TP A. The laboratory provided no documentation for review. See Personnel Code Sheet attached. 4. An interview with former Laboratory Director and former Technical Supervisor on August 18, 2020 at approximately 9:50 AM confirmed the findings.
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 a review the laboratory's competency policy, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interview, the Technical Supervisor (TS) failed follow the laboratory's competency policy and perform the annual competency assessment for one (1) of one (1) TP. Dates of record review include November 1, 2018 up to February 22, 2020. Findings include: 1. Review of the laboratory's competency policy, "SOP QAL 25" revealed a statement "...3. Competency is assessed at the following frequency: a. During the first year of an individual's duties, competency is assessed before signing off and six months after signing off training. b. After an individual has completed two competencies and performed testing for one year, the competency is assessed at once year on the dare of sign off." 2. Review of the laboratory's CLIA CMS-209 Form and laboratory training documents revealed 1 TP identified as performing patient testing with training completed on November 15, 2018. 3. Review of the available laboratory personnel records revealed a training record completed on November 15, 2018 and a lack of documentation of an annual competency assessment for TP A for 2019. The inspector requested to review documentation of the annual competency assessment for TP A. The laboratory provided no documentation for review. (See Personnel Code Sheet attached.) 3. An interview with former Laboratory Director and former Technical Supervisor on August 18, 2020 at approximately 9:50 AM confirmed the findings.