

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2137771	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Children's Clinic Of Fredericksburg, The	Street Address, City, State 4532 Plank Road, Fredericksburg, 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 announced CLIA recertification survey was conducted at The Children's Clinic of Fredericksburg on July 23, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations Specific deficiencies cited are as follows and includes the Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6000 -42 CFR. 493.1403 Laboratory Director, D6063 -42 CFR. 493.1421 Testing personnel qualifications.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: A. Based on a review of proficiency testing (PT) documentation, lack of documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for three (3) of 3 Hematology/Coagulation events; and failed to document evaluation review for two (2) of 3 Hematology/Coagulation events reviewed from January 2023 until the date of the survey on July 23, 2024. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation, a total of 5 events (2023</p>

Events 1-3 and 2024 Event 1-2), revealed the laboratory failed to retain signed result review documentation and attestation statements for the following three events: 2023 API Hematology/Coagulation-2nd Event-a lack of result review and attestation signatures by the LD and TP; 2024 API Hematology/Coagulation-1st Event-a lack of result review and attestation signatures by the LD and TP. 2024 API Hematology /Coagulation-2nd Event-a lack of attestation signature by the LD. Evaluation pending with PT agency. The surveyor requested to review the PT results reviews and attestation documentation for the events listed above. The laboratory provided no documentation for review. 2. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024 at 1:00 PM, the above findings were confirmed. B. Based on a review of proficiency testing (PT) documentation, lack of documentation, and an interview, the laboratory failed to retain the hematology analyzer printed results for one (1) of five (5) Hematology/Coagulation events reviewed from January 2023 until the date of the survey on July 23, 2024. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation, a total of 5 events (2023 Events 1-3, 2024 Event 1-2), revealed the laboratory failed to retain the Sysmex XP-300 hematology analyzer printed results for 2023 API Event 2. The surveyor requested to review the analyzer printed records for 2023 API Event 2. The laboratory provided no documentation for review. 2. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024 at 1:00 PM, the above findings were confirmed.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on a review of the laboratory's policies/procedures, instrument operation's manual, temperature logs, quality control documentation, patient reports, Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), lack of documentation and interviews, the laboratory failed to follow the laboratory director approved POC dated 01/06/2023 to monitor, evaluate and correct the analytic system by failing to: 1. monitor and document the laboratory's room temperature and relative humidity for nine of two-hundred thirty-five days reviewed from December 1, 2024 until July 23, 2024 (see D5411) REPEAT DEFICIENCY; 2. perform and document daily quality control materials on the hematology analyzer for seven days from December 1, 2024 until July 23, 2024 (see D5447) REPEAT DEFICIENCY; 3. follow their established quality control policy and document corrective actions for "out of range" Hematology QC for three (3) of thirty-one (31) days reviewed in March 2024 (see D5481); and 4. ensure the laboratory director approved plan of correction was followed and current quality assurance plan identified and addressed analytic issues in the subspecialty of hematology (see D5791) REPEAT DEFICIENCY.

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 a review of the laboratory's temperature and humidity records, manufacturer requirements, plan of correction (dated 01/06/2023), lack of documentation, and interview, the laboratory failed to follow the laboratory director approved plan of correction to monitor and document the room temperatures and relative humidity for nine (9) of two-hundred thirty-five (235) days reviewed from December 1, 2023 until July 23, 2024. REPEAT DEFICIENCY The findings include: 1. Review of the laboratory "Environment Log" records revealed a lack of documentation of room temperature and relative humidity recordings for the following days from December 1, 2023 until July 23 2024: 12/03/2024, 12/05/2024, 12/28/2024, 02/01/2024, 04/15 /2024, 04/19/2024, 05/25/2024, 05/30/2024 and 06/09/2024. A total of 9 of 235 days reviewed. The surveyor requested to review documentation of the room temperature and relative humidity for the above listed 9 days. The laboratory provided no documentation to review. 2. Review of the Sysmex XP-300 Hematology Instrument operator's guide revealed the required environment temperature range of 59-90 degrees Fahrenheit and humidity range of 10-90%. 3. Review of the laboratory's plan of correction (dated 01/06/2023) revealed the following statements, "2. Room temperature and humidity will be recorded daily on the Environmental Log by lab staff. 3. Lab supervisor will use a checklist to ensure that all staff, before working in the lab understand how to monitor the lab temperature and humidity...the Lab supervisor will monitor the daily log entries for compliance...The Lab Supervisor will provide a weekly log compliance report to the Lab Coordinator for review. 4. The Lab Coordinator will monitor the weekly Environmental Log report from the Lab Supervisor. 5. The completed lab Environmental Log will get submitted to the Laboratory Director monthly for review and signature confirming compliance." The surveyor requested to review the "Weekly log compliance report" from January 2023 until June 2024. The laboratory provided documentation of the "Weekly log compliance report" for the months of January 2023 until July 2023. In an interview with the Operations Manager (OM) on July 23, 2024, the OM stated the laboratory was unable to find the above referenced logs for August 2023 until June 2024. 4. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024 at 1:00 PM, the above findings were confirmed.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control records (QC), laboratory policies and procedures, patient testing records, laboratory director approved Plan of Correction (dated 01/06

/2023), lack of documentation, and interview, the lab failed to follow their established policy and perform daily QC procedures for the Sysmex XP-300 hematology analyzer for seven (7) of 234 days from December 1, 2023 until July 23, 2024 while reporting twenty-four (24) patients. REPEAT DEFICIENCY The findings include: 1. Review of the daily Sysmex XP-300 QC records and patient testing records from December 1, 2023 until July 23, 2024, a total of two-hundred thirty-four (234) days, revealed a lack of documentation of QC procedures for the following dates and patients reported: 04/07/2024 - 1 patient reported; 04/12/2024 - 10 patients reported; 04/15/2024 - 3 patients reported; 06/04/2024 - 3 patients reported; 06/06/2024 - 2 patients reported; 06/07/2024 - 1 patient reported; 06/12/2024 - 4 patients reported. A total of 7 days with no QC performed and 24 patients reported. The surveyor requested to review the QC documentation for the above listed dates. The laboratory provided no documentation to review. 2. Review of the laboratory's policies and procedures revealed a policy, "Reagents, Controls, PT Testing Kit, etc", which stated "Quality Control low, normal and high are to be run daily." 3. Review of the laboratory's plan of correction (dated 01/06/2023) revealed the following statements, "1. Lab Supervisor... will ensure that at least once a day patient specimens are assayed or examined perform the following for each quantitative procedure, include two control materials of different concentrations. 2. Lab supervisor...will audit the daily QC for compliance, provide a weekly report to Lab Coordinator for review. 3. The Lab Coordinator will monitor the weekly report from the Lab Supervisor. 4. The completed lab log will get submitted to the Laboratory Director monthly for review and signature confirming compliance." The surveyor requested to review the "Weekly log compliance report" from January 2023 until June 2024. The laboratory provided documentation of the "Weekly log compliance report" for the months of January 2023 until July 2023. In an interview with the Operations Manager (OM) on July 23, 2024, the OM stated the laboratory was unable to find the above referenced logs for August 2023 until June 2024. 4. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024 at 1:00 PM, the above findings were confirmed.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies and procedures, Hematology Quality Control (QC) records, patient records, lack of documentation and an interview, the laboratory failed to follow their established quality control policy and document corrective actions for "out of range" Hematology QC for three (3) of thirty-one (31) days reviewed in March 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Control", with the following statements, "Any outliers (i.e., controls that are outside acceptable limits) are

addressed and corrected before patient samples are tested. All quality control results are recorded. If a control result does not fall within an acceptable range it is recorded along with the value eventually accepted. Any repeat runs of controls or any corrective actions taken to bring controls into range are documented." 2. Review of the laboratory QC records for the Sysmex XP-300 from December 2023 until July 23, 2024 revealed the following days in March 2024 when the Sysmex XP-300 Eight Check-3WP Xtra QC (lot# 4051071, exp 05/29/2024) was out of range with a lack of documentation of repeat analysis or corrective actions performed: 03/21/2024 Sysmex QC low -Mean Corpuscular Volume (MCV) and Mean Corpuscular Hemoglobin=low. 03/21/2024 Sysmex QC high -White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet (PLT)=high and MCV=low. 03/21/2024 Sysmex QC normal -RBC, HGB=high and MCV=low. 03/26/2024 Sysmex QC low -RBC, HGB, HCT, MCV, MCH=low. 03/29/2024 Sysmex QC high -WBC, RBC, PLT=high and MCV=low. 3 of 31 days without repeat analysis and corrective actions documented. The surveyor requested to review documentation of the QC repeat analysis and corrective actions taken for the above listed out of range QC. The laboratory provided no documentation for review. 3. Review of the patient records for March 2024 revealed the following number of patients were tested: March 21, 2024-3 patients, March 26, 2024-5 patients, March 29, 2024-3 patients. A total of 11 patients tested. 4. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024 at 1:00 PM, the above findings were confirmed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's policies and procedures, laboratory director approved plan of correction (dated 01/06/2024), quality control (QC) records, patient records, temperature and humidity records and interviews, the laboratory failed to follow their approved Plan of Correction (POC) and established Quality Assurance (QA) plan to identify and address analytic issues within the specialty of hematology (Cross Reference D5411 and D5447) from January 2023 until July 23, 2024.
REPEAT DEFICIENCY The findings include: 1. Review of the laboratory's "Quality Assessment (QA)", policies and procedures, quality control (QC) records, patient records, instrument maintenance records and temperature and humidity records revealed the following analytic issues: -lack of monitoring and documentation of the laboratory's room temperature and relative humidity (see D5411), -lack of documentation of quality control performed on the Sysmex XP-300 hematology analyzer for seven days (see D5447). 2. Review of the QA plan revealed the following statements "Review all daily logs monthly which includes room temperature, refrigerator, room humidity and ensure temperatures were within the normal range according to the QC plan and appropriate corrective actions were taken for any temperatures that were out of range. Review and sign daily quality controls (low, normal high) to ensure flags were not shown and has passed accordingly...Ensure the laboratory director has signed all logs including but not limited to: Daily temperature logs, QC daily reports, Weekly and Monthly Maintenance, Bi-annually calibration reports, proficiency test attestations and results, Corrective actions and testing

personnel evaluations and training." 3. Review of available QA records from January 2023 until July 2024 revealed a lack of documentation of the following: -Laboratory Director review (LD) of the daily temperature logs, and Sysmex Daily, Weekly and Monthly Maintenance from August 2023 until July 2023; -LD review of the Sysmex daily QC for May 2024 and June 2024; -LD review of proficiency test attestations and results (see D2015). -LD review of Sysmex Insight peer reports from January 2023 until July 2024; and -The corrective actions taken and LD review when temperatures /humidity documentation and QC documentation was not completed (see D5411 and D5447). The surveyor requested to review the above listed documentation from August 2023 until July 2024. The laboratory provided no documentation for review.

4. Review of the laboratory's approved POC (dated 01/06/2023) revealed the following statements, " ...2. Lab supervisor will perform audits to ensure that all lab staff perform and document the daily, weekly, and monthly logs and provide a weekly report to the Lab Coordinator for review. 3. The Lab Coordinator will monitor the logs audit reports from the Lab Supervisor and submit monthly performance reports to the Lab Director for review and signature." 5. Review of the available log audit reports from January 2023 until the date of survey on July 23, 2024, revealed a lack of documentation of the weekly log audit reports from August 2023 until July 23, 2024. The surveyor requested to review the weekly log audit reports from August 2023 until July 2024. The laboratory provided no documentation for review. 6. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024, at 1:00 PM, the above findings were confirmed.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of the laboratory's policies and procedures, proficiency testing (PT) records, temperature and humidity records, quality control (QC) documents, patient records, quality assessment (QA) documents, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interviews, the laboratory director failed to ensure: 1. PT attestations were signed, evaluations were reviewed and original documents were retained (see D2015 A & B); 2. Quality Control (QC) policies and procedures were maintained for the non-waived Complete Blood Cell counts performed on the Sysmex XP-300 Hematology Analyzer for fourteen days from December 2023 until July 23, 2024 (see D6022); 3. the approved Plan of Correction (dated 01/06/2023) was followed and the established quality assessment plan identified and addressed analytic issues within the specialties of hematology from January 2023 until July 23, 2024 (See D6022); 4. the laboratory's established policy to perform and document training/competency assessments prior to performing patient testing was followed for two of two new TP (see D6029).

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, quality control (QC) documentation, patient records, Environment logs", quality assessment documentation (QA), lack of documentation and interview, the laboratory director failed to ensure the current QC procedures were maintained for the Sysmex XP-300 analyzer; and QA reviews identified and corrected analytic issues within the specialty of hematology from January 2023 until July 23, 2024. Refer to D5411, D5447 and D5791.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) 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 of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116) form, testing personnel (TP) records, the laboratory's policies and procedures, lack of documentation and interviews, the laboratory director failed to follow the laboratory's established policy to ensure two of two new TP had documented training/competency assessments prior to performing patient testing procedures utilizing the Sysmex XP-300 for Complete Blood Cell (CBC) counts as of the date of survey on July 23, 2024. The findings include: 1. Review of the CLIA CMS-2567 form revealed the laboratory performs moderate complexity CBC testing on the Sysmex XP-300 Hematology analyzer. 2. Review of CLIA CMS-209 form revealed TP A and TP B listed as performing patient testing utilizing the Sysmex XP-300 hematology analyzer (See attached TP Code Sheet). 3. Review of TP records and an interview with the Operations Manager on July 23, 2024 at 10:20 AM revealed TP A was hired/began patient testing utilizing the Sysmex XP-300 on 4/16/2024 and TP B was hired/began patient testing utilizing the Sysmex XP-300 on 6/7/2024. Further review of the TP A and TP B's personnel records revealed a lack of documentation of the training/initial competency of TP A and TP B. The surveyor requested to review training/initial competency assessment documents for TP A and TP B. The laboratory provided no documentation for review. 4. Review of the laboratory's policies and procedures revealed a "Quality Control Plan", with the following statements, "TESTING PERSONNEL-Train and evaluate testing personnel upon hire and document successful demonstration of competency according to the laboratory policy and regulations. Routinely evaluate the performance of the testing personnel, first when hire, 3 months from hire, 6 months from hire, a year from hire and yearly

thereafter. A total of 3 times per the first year of hire." 5. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024, at 1:00 PM, the above findings were confirmed.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116) form, testing personnel records, lack of documentation, and interview, the laboratory failed to retain documentation of the education qualifications for one of three new testing personnel responsible for reporting moderate complexity patient test results during the review timeframe of January 2023 until the date of the inspection on July 23, 2024. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116) form, personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of education qualifications for one (1) of three (3) testing personnel (TP) responsible for hematology testing during the review timeframe of January 2023 until the date of the survey on July 23, 2024. The findings include: 1. Review of the CLIA CMS-116 form revealed the laboratory performs moderate complexity testing on the Sysmex XP-300 Hematology analyzer. 2. Review of the CMS 209 form revealed that the laboratory director identified 3 personnel as responsible and qualified to perform moderate complexity hematology Complete Blood Cell Count patient testing. 3. Review of the available laboratory personnel records for evaluation of education documentation revealed a lack of documentation of the education for TP C. (See Personnel Code Sheet.) The surveyor requested to review an official transcript or diploma documenting of education for TP C. The laboratory provided no documentation for

review. 4. In an exit interview with the Laboratory Director and Operations Administrator on July 23, 2024, at 1:00 PM, the above findings were confirmed.