Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0230875	04/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Chester Pediatrics	4707 Buckingham Ct, Chester, 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 Chester Pediatrics on 04/12/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation and interview, the lab failed to maintain PT documents four of six events reviewed. Record review included all three events in 2020 and 2021. Findings include: 1. Review of the American Proficiency Institute (API) PT and lab records revealed lack of documentation for the following: 2020 Event 1- Lack of original hematology results, 2020 Event 3- Lack of attestation signature by testing personnel and lab director; lack of review of API results, 2021 Event 1- Lack of review of API results,

	2021 Event 3- Lack of attestation signatures by testing personnel and lab director. 2. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and an interview, the laboratory failed to participate in one of three Complete Blood Count (CBC) events reviewed. Record review included all three events in 2021. Findings include: 1. Review of the CASPER 0155D Individual Laboratory Profile Report and the American Proficiency Institute (API) PT records for the third event in 2021 revealed the laboratory received a score of 0%. 2021 Event 3- 0%- for the CBC module (Notation by API-failure to participate). 2. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
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 the review of lab temperature records, performance verification records, lack of documentation, manufacturer operator's manual, maintenance records, policy and procedures (P&P), and quality assurance (QA) records, and interview, the lab failed to: 1. monitor and document room temperatures for 182 of 365 days reviewed in the year 2021. Refer to D5411. 2. verify the reference (normal) ranges for Complete Blood Cell counts (CBC). Refer to D5421. 3. follow manufacturer's instructions of performing weekly maintenance for the Cell-Dyn Emerald hematology analyzer. Refer to D5429 and 4. ensure the current quality assurance plan identified and addressed analytic issues in the subspecialty of hematology. Refer to D5791.
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 the review of lab temperature records, lack of documentation, manufacturer requirements and interview, the lab failed to monitor and document room temperatures for 182 of 365 days reviewed in the year 2021. Findings include: 1. Review of lab temperature records revealed lack of documentation of room temperature recordings for the following in 2021: January- 8 days, February- 2 days, March - 7 days, April- 9 days, May-14 days, June- 26 days, July- 25 days, August- 26 days, September- 23 days, October- 22 days and November- 20 days. Total of 182 of 365 days reviewed. 2. Review of the Cell Dyn Emerald operator's guide revealed the required environment temperature range of 18-32 degrees Celsius. Review of the package insert for the Cell Dyn 18 Plus controls revealed the following statement, "1. Remove vials of controls from the refrigerator and warm to RT (18-30 degrees Celsius) for 15 minutes before use." 3. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification records, lack of documentation, and interview, the laboratory failed to verify the reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the hematology analyzer prior to reporting patient results from 06/30/21 and up to 04/12/22. Findings include: 1. Review of the Abbott Cell Dyn Emerald (installed 06/30/21) hematology analyzer's performance verification documentation revealed lack of documentation of verification of the reference (normal) ranges for CBCs during or after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reference (normal) ranges for the above-specified instrument prior to patient testing. The laboratory provided no documentation for review. 2. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on the review of manufacturer operator's manual, maintenance records, lack of documentation and interview, the lab failed to follow manufacturer's instructions of performing weekly maintenance for the Cell-Dyn Emerald hematology analyzer for 31 of 52 weeks in 2020 and eight of 52 weeks in 2021. Findings include: 1. Review of the Cell-Dyn Emerald operator's manual (Revision date March 2019) revealed the following statement, "Section 9, Weekly Maintenance, Bleach Cleaning- Bleach cleaning the system with a bleach solution is performed weekly and as needed if instrument use conditions cause frequent rejection of measured or quality control material out of range issues." 2. Review of the Cell-Dyn Emerald event logs indicating performance of maintenance procedures for 2020 and 2021 revealed lacked of documentation of the performance of the weekly bleach cleaning procedures for the following weeks: February 9-15, 16-22 and 23-29, 2020, March 8-14, 15-21, 2020, March 29- April 4, 2020, April 5-11 and 19-25, 2020, May 3-9, 10-16, and 17-23, 2020, May 31-June 6, 2020, June 14-20 and 21-27, 2020, June 28-July 4, 2020, July 12-18 and 19-25, 2020, July 26-August 1, 2020, August 2-8, 9-15 and 23-29, 2020, September 6-12, 13-19 and 20-26, 2020, October 11-17, 2020, November 1-7, 15-21 and 22-29, 2020, November 29-December 5, 2020, December 6-12 and 20-26, 2020. Total 31 weeks. January 3-9, 2020, February 7-13, 2021, May 16-22, 2021, July 18-24, 2021, November 14-20, 2021, November 28-December 4, 2021, December 5-11 and 19-25, 2021. Total eight weeks. 3. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
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 proficiency testing records, temperature records, instrument installation records, maintenance records, testing personnel (TP) records, policy and procedures (P&P), and quality assurance (QA) records, the current quality assurance plan failed to identify and address analytic issues in the subspecialty of hematology from 01/01/20 and up to the date of survey on 04/12/22. Findings include: 1. Review of proficiency testing records, temperature records, instrument installation records, instrument maintenance records and TP records revealed the following: - Lack of maintenance of proficiency testing documents for four of six events (Refer to D2015), - Lack of room temperature documentation for 182 of 365 days in 2021 (Refer to D5411), - Lack of verification of reference (normal) range for the hematology analyzer (Refer to D5421), - Lack of documentation of weekly maintenance for the Cell-Dyn Emerald analyzer (Refer to D5429), - Lack of annual competency assessments for 2021 (Refer to D6054), and - Lack of semi-annual competency assessment (Refer to D6053). 2. Review of P&P revealed a collective "Quality Assessment Policies" document. The following statements observed within the policies, "Competency (page 2): Competency is evaluated by a 6 step process (to include but not limited to) direct observation of routine patient test performance, including patient prep, assessment of test performance through testing previously

	analyzed specimen, internal blind testing samples or external proficiency testing samples and assessment of problem solving skills." "Information Management (page 6), Documentation: Error/Complaint Management- Remedial action is taken when: 1. Test systems do not meet laboratory established criteria." "Maintenance (page 8): Each equipment item is accompanied by 2) Established maintenance protocol log for Cell Dyn Emerald placed in the instrument binder. Maintenance protocol is reviewed, practiced and documented before patient testing." "Proficiency Testing: Quarterly- Review of result reports for document of: 1. Review 2. Discussion and 3. Corrective Action/Follow Up." 3. Review of the QA records revealed the lab utilized a "Monthly QA Review" checklist. The checklist consisted of one page that identified tasks to be completed in the vertical column (left of page) and each month in a calendar year in a horizontal row (top of page). The tasks to be completed included not limited to: " I. General- Maintenance logs complete, temperature logs complete." II. Personnel Competency Assessment- Yearly Competency Reviews. III. Proficiency Testing- Copies of test results retained, operator's initials, report reviewed in duplicate." The checklists provided a check mark (task completed) or hand-written NA (not applicable) in the column of each task completed corresponding with each month for a calendar year. Review of the checklists revealed the following: 2020 year- a check mark for maintenance logs complete and temperature logs complete for all 12 months. A check mark for Proficiency Testing for the months of March, July and November. The lab director signed the bottom of the page (no date) of the QA checklist. 2021 year- January-April- a check mark for maintenance logs complete and temperature logs complete and yearly competency reviews. A check mark for Proficiency Testing for March. The checklist lacked documentation of completion (left blank) for the months of May-November. The lab director signed the bottom of the page (no date) of the QA checklist. The checklists lacked documentation of identification and review of the above-mentioned system issues. In addition, the checklist lacked documentation of remedial or corrective actions for above-mentioned system issues. No other documentation of remedial actions or corrective actions available for review upon request. 4. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the review of performance verification documents, lack of documentation, and interview, the lab director failed to review and approve the accuracy, precision, reportable range documentation for the hematology analyzer installed on 06/30/21 and up to the date of survey on 04/12/22. Findings include: 1. Review of the performance verification documents for the Abbott Cell Dyn Emerald hematology analyzer revealed instrument installation on 06/30/21 and patient use on 07/01/21. The documents lacked the lab director signature of review and approval of the accuracy, precision and reportable range studies. The reference range (normal value)

	verification was not available for review (See D5421). 2. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of proficiency testing records, temperature records, instrument installation records, maintenance records, testing personnel (TP) records, policy and procedures (P&P), and quality assurance (QA) records, the lab director failed to ensure the current quality assurance plan identified and addressed analytic issues in the subspecialty of hematology from 01/01/20 and up to the date of survey on 04/12 /22. Refer to D5791.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP and the technical consultant (TC), the TC failed to perform and document the semi-annual competency assessment for one of one TP in 2021. Findings include: 1. Review of the CMS-209 form revealed the lab director performs the duties of TC. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of a semi-annual competency assessment for TP F. See attached TP code sheet. 3. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP and the technical consultant (TC), the TC failed to perform and document the

	annual competency assessments for five of five TP in 2021. Findings include: 1. Review of the CMS-209 form revealed the lab director performs the duties of TC and 5 TP performing patient testing in 2020 and 2021. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of the annual competency assessments for the following: TP A- 2021, TP B- 2021, TP C- 2021, TP D- 2021, TP E- 2021, See attached TP code sheet. 3. An exit interview with the testing personnel and lab director on 04/12/22 at 1810 confirmed the findings.