Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226364	02/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Chesterfield Pediatrics Pc	5955 Harbour Park Drive, Midlothian, 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 Chesterfield Pediatrics on February 6, 2019 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:
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: **Repeat Deficiency. Based on the review of proficiency testing (PT) records, quality control (QC) records, and interviews with the primary testing personnel (TP) and lab director, the lab failed to maintain PT records for six (6) of the 6 PT events reviewed for 2017 and 2018. Findings include: 1. The inspector requested to review the American Proficiency Institute (API) hematology PT records for 2017 and 2018 calendar year events. The primary TP presented API results for the 2nd event in 2018. In an interview with the primary TP at approximately 9:45 AM, she/he stated that they were a new TP and that she/he did not know where the other records were located. 2. During the review of QC records, the inspector located the results for the 2017 Event 3 and 2018 Event 3; however, there was no documentation of review by staff or the

	lab director. The laboratory did not have the following hematology PT records: 2017 Event 1- Attestation statement, original and submitted PT results, API results. 2017 Event 2- Attestation statement, original and submitted PT results, API results. 2017 Event 3- Attestation statement and original and submitted PT results. 2018 Event 1- Attestation statement, original and submitted PT results, API results. 2018 Event 2- Attestation statement and original and submitted PT results. 2018 Event 3- Attestation statement and original and submitted PT results. 3. An interview with the lab director at approximately 3:45 PM confirmed the above-specified findings.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the review of proficiency testing PT) scores for the second and third events in 2018, the CASPER 0153D Unsuccessful PT report and an interview with the lab director, the laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the Red Blood Cell Count (RBC) and Hematocrit (HCT) parameters, resulting in unsuccessful performance (Cross Reference D2130).
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the review the American Proficiency Institute (API) proficiency testing (PT) scores for the third events in 2018, the CASPER 0155D Individual Laboratory Profile report and an interview with the lab director, the laboratory failed to achieve an overall score of at least 80% for the third Hematology PT event in 2018. Findings include: 1. Review of the API hematology PT scores and the CASPER 0155D Individual Laboratory Profile report revealed that the laboratory received an overall score of 65% for the 3rd event in 2018. White Blood Cell (WBC) Differential (Diff)- 33% Red Blood Cell (RBC) count- 0% Hematocrit (HCT)- 60% The individual scores

	above resulted in the overall unsatisfactory performance for the above listed event. 2. An interview with the lab director at approximately 3:45 PM confirmed the above-specified findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review the American Proficiency Institute (API) proficiency testing (PT) scores for the second and third events in 2018, the CASPER 0153D Unsuccessful PT report and an interview with the lab director, the laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the Red Blood Cell Count (RBC) and Hematocrit (HCT) parameters, resulting in unsuccessful performance. Findings include: 1. Review of the API hematology PT scores and the CASPER 0153D Unsuccessful PT report revealed the following scores: 2018 2nd event RBC - 60% HCT- 60% 2018 3rd event RBC - 0% HCT- 60% The laboratory has received an unsuccessful API PT score for the above listed analytes. 2. An interview with the lab director at approximately 3:45 PM confirmed the findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, and interview, the laboratory failed to retain the "Cell Dyn 18 Plus control " manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for seven (7) of nine (9) lot numbers utilized from March 1, 2017 and up to the date of survey on February 6, 2019. Findings include: 1. Review of the laboratory's end of the lot instrument printouts from March 1, 2017 and up to the date of survey on February 6, 2019 revealed the laboratory received and utilized 9 lot numbers of the "Cell Dyn 18 Plus control ". The following QC lot numbers had no documentation of acceptable ranges or manufacturer's package inserts: 6354, 7184, 7268, 8071, 8155, 8239 and 8323. 2. An interview with the lab director at approximately 3:45 PM 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: **Repeat Deficiencies** Based on the review of policy and procedures (P&P), operator's manual, calibration records, quality control (QC) records, instrument data log, electronic medical records (EMR) and an interview with the laboratory director, the laboratory failed to 1) follow the established policy and manufacturer's instructions for performing the calibration in 2017 and 2018 (Cross Reference D5437); and 2) follow the established policy for performing QC procedures each day of patient testing (Cross Reference D5447).
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: ** Repeat Deficiency.** Based on the review of policy and procedures (P&P), operator's manual, calibration records, and an interview with the laboratory director, the laboratory failed to follow the established policy and manufacturer's instructions for performing the calibration verification procedures on the Abbott Cell Dyn Emerald hematology analyzer every six months in 2017 and 2018. Findings include: 1. Review of the P&P "Plan of Action for Quality Assurance policy", signed by the lab director in 2016 and 2018 (not date provided) revealed the following statement: " 5. Calibration of Emerald will be done semi-annually or after quality control data indicates as documented in cell-dyne manual. Calibration is also done following any maintenance." Review of the manufacturer operator's manual for the Abbott Cell Dyn Emerald analyzer revealed the following statements: "Section 6- When to Calibrate-Criteria should be established for calibration verification. Calibration verification criteria include: When indicated by Quality Control data, after major maintenance and service procedures, at least every 6 months and as directed by the regulatory agencies governing the laboratory." 2. Review of calibration verification documents revealed procedures performed on September 14, 2017 and July 17, 2018. There was no other calibration documentation available for review. 3. An interview with the lab director at approximately 3:45 PM confirmed the findings.
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: ** Repeat Deficiency** Based on the review of policy and procedures (P&P), quality control (QC) records, instrument data log, electronic medical records (EMR) and interview with the laboratory director, the laboratory failed to follow the established policy for performing QC procedures each day of patient testing on May 1 and 3, 2018 and October 2-16, 2017, while reporting a total of thirteen (13) patients. Dates of record review included March 1, 2017 and up to the date of survey on February 6, 2019. Findings include: 1. Review of the P&P "Plan of Action for Quality Assurance policy", signed by the lab director in 2018 (no date provided) revealed the following statement: "2. Cell-dyne Emerald will have quality control done each morning of operation. If controls are not within prescribed limits, Emerald is shut down until maintenance is performed and controls are re-run in accepted limits." 2. Review of the daily QC records from March 1, 2017 and up to the date of survey on February 6, 2019 revealed the following dates in which there was no documentation of daily QC procedure according to the established policy: October 2-17, 2017 and May 1 and 3, 2018. 3. Review of the instrument data log and EMR patient data revealed the following patients resulted that did not have documentation of daily QC procedures: October 4, 2017- Accession number 2468, 1607, and 4871, October 5, 2017- Accession number 6309 and 268, October 6, 2017- Accession number 1171, October 12, 2017- Accession number 901, 2671 and 1113, October 16, 2017- Accession number 5395 and 5914, May 1, 2018- Accession number 5122 and May 3, 2018- Accession number 5217. Total of 13 patients. 4. An interview with the laboratory director at approximately 3:45 PM confirmed the above-specified 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: **Repeat Deficiency** Based on the review of policy and procedures (P&P), quality control (QC) records, calibration records, and an interview with the laboratory director, the current quality assurance policy failed to identify and address failures in the analytic phase for the hematology specialty at the date of survey. Findings include: 1. Review of the P&P "Plan of Action for Quality Assurance policy", signed by the lab director in 2016 and 2018 (not date provided) revealed the following statements: "2. Cell-dyne Emerald will have quality control done each morning of operation. If controls are not within prescribed limits, Emerald is shut down until maintenance is performed and controls are re-run in accepted limits." "3. Monthly quality control report will be uploaded to abbott eqc the first week of the month. Results will be reviewed by the lab director when received." "5. Calibration of Emerald will be done semi-annually or after quality control data indicates as documented in cell-dyne manual. Calibration is also done following any maintenance." 2. The laboratory did not have documentation of performing the daily Cell Dyn 18 Plus QC procedures on October 2-17, 2017 and May 1 and 3, 2018 (Cross Reference D5447). 3. There was no documentation of the Abbott Cell Dyn

	eQC reports for the following lot numbers: 6354, 7100, 7184, 7268, 7352, 8071, 8155, 8239 and 8323. Each lot number includes low, normal and high range values. 4. The laboratory did not follow the established policy for performing the semi-annual calibration for the hematology instrument in 2017 and 2018 (Cross Reference D5437). 5. An interview with the lab director at approximately 3:45 PM confirmed the findings.
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 the review of policy and procedures (P&P), proficiency testing (TP) records, quality control (QC) records, instrument data log, electronic medical records (EMR), calibration verification records, the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), and interviews with the primary TP and lab director, the lab director failed to 1) follow the established policy for reviewing PT results (Cross Reference D6018); 2) follow the established policy for performing and documenting corrective actions for two (2) of 6 PT events (Cross Reference D6019); 3) ensure that staff followed the established policy for a) performing QC procedures each day of patient testing on May 1 and 3, 2018 and October 2-16, 2017 and b) performing calibration verification procedures (Cross Reference D6020); 4) ensure the current quality assurance policy could identify and address failures in the analytic phase for the hematology specialty (Cross Reference D6021); 5) provide documentation of the highest level of education and initial training and competency assessments for four (4) of 4 new TP performing patient testing (Cross Reference D6029); and 6) follow the established policy for performing training on TP on a semi-annual basis for six (6) of seven (7) TP performing patient testing (Cross Reference D6030).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), proficiency testing (TP) records and interview, the laboratory director failed to follow the established policy for reviewing PT results for six (6) of 6 PT events (Cross Reference D2015). Findings include: 1. Review of the P&P "Proficiency Testing Protocol" (signed by the lab director February 11, 2015) revealed the following statement: "Upon receipt of the results the nursing supervisor as well as the lab director will review them and the lab director will sign off on them." 2. Review of PT records revealed lack of

	documentation of the American Proficiency Institute (API) results and review by staff and the lab director as defined by the policy. 3. An interview with the lab director at approximately 3:45 PM confirmed the findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), proficiency testing (TP) records and interview, the laboratory director failed to follow the established policy for performing and documenting corrective actions for two (2) of 6 PT events (Cross Reference D2122 and D2130). Findings include: 1. Review of the P&P "Proficiency Testing Protocol" (signed by the lab director February 11, 2015) revealed the following statement: "Upon receipt of the results the nursing supervisor as well as the lab director will review them and the lab director will sign off on them. If there are any values that are less than 80% troubleshooting needs to be done to ensure that the machine is working properly. Patients whose results may have been inaccurate due to machine failure will be contacted for retesting." 2. Review of PT records revealed lack of documentation of troubleshooting procedures for the second and third events in 2018 by the lab director or staff as defined by the policy. 3. An interview with the lab director at approximately 3:45 PM confirmed the findings.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: **Repeat Deficiency** Based on the review of policy and procedures (P&P), quality control (QC) records, instrument data log, electronic medical records (EMR) and interview with the laboratory director, the laboratory director failed to ensure that staff followed the established policy for 1) performing QC procedures each day of patient testing on May 1 and 3, 2018 and October 2-16, 2017, while reporting a total of thirteen (13) patients (Cross Reference D5447) and 2) performing calibration verification procedures (Cross Reference D5437).
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: **Repeat Deficiency** Based on the review of policy and procedures (P&P), quality control (QC) records, calibration records, and an interview with the laboratory director, the laboratory director failed to ensure the current quality assurance policy could identify and address failures in the analytic phase for the hematology specialty (Cross Reference 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: **Repeat Deficiency** Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), and interviews with the primary testing personnel (TP) and laboratory director, the laboratory director failed to provide documentation of initial training and competency assessments for four (4) of 4 new TP performing patient testing with the Abbott Cell Dyn Emerald hematology analyzer at the date of survey. Findings include: 1. Review of the CLIA CMS 209 form and an interview with the primary TP at approximately 10:30 AM revealed that there were four (4) new TP in 2018. (See attached TP code sheet) There was no documentation of the highest level of education and initial training and competency assessments by the lab director for TP A, B, C, and D for the Abbott Cell Dyn Emerald hematology analyzer (Cross Reference D6065). 2. An interview with the lab director at approximately 3:45 PM confirmed the findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: **Repeat Deficiency** Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), and an interviews with the primary testing personnel (TP) and laboratory director, the laboratory director failed to follow the established policy for performing training on testing personnel (TP) on a semi-annual basis for six (6) of seven (7) TP performing patient testing at the date of survey. Findings include: 1. Review of the CLIA CMS 209 form and an interview with the primary TP at approximately 10:30 AM revealed that there were four (4) new TP in 2018 and that three (3) different TP performed patient testing for the calendar year 2017 and up into 2018. (See attached TP code sheet) There was no documentation of competency assessments or the semi-annual training by the lab director for TP A, B, C, E, F and G. 2. Review of the P&P "Plan of Action for Quality Assurance policy", signed by the lab director in 2016 and 2018 (not date provided) revealed the following statement: "6. Training of all testing personnel will be done on a semi-annual schedule by both the lab director and nursing supervisor." 3. An interview with the lab director at approximately 3:45 PM confirmed the findings.
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), and interviews with the primary testing personnel (TP) and lab director, the laboratory failed to provide documentation of the highest level of education for four (4) of 4 TP performing patient testing at the date of survey on February 6, 2019. (Refer to D 6065).
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), and interviews with the primary testing personnel (TP) and lab director, the laboratory failed to provide documentation of the highest level of education for four (4) of 4 TP performing patient testing at the date of survey on February 6, 2019. Findings include: 1. Review of the CLIA CMS-209 form revealed that there are 4 new TP performing patient testing (See TP Code Sheet). An interview with the primary TP at approximately 10:30 AM revealed that the all 4 TP did not have documentation of the highest level of education available for review at the date of survey. 2. An interview with the lab director at approximately 3:45 PM confirmed the findings.