Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	49D0998730	09/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lakeview Pediatrics And Family Medicine	3060 Godwin Boulevard, Suffolk, 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 Lakeview Pediatrics and Family Medicine on September 14, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes two Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems D6000 -42 CFR. 493.1403 Laboratory Director
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, PT Corrective Action Forms, and interviews, the laboratory failed to document remedial action taken for two (2) of three (3) hematology PT events reviewed for calendar year 2021. Findings include: 1. Review of the laboratory's 2021 American Proficiency Institute (API) Hematology modules' test result documentation (2021 Events 1-3) a total of 3 events, revealed no evidence of remedial action for the following 2 unsatisfactory events: 2021 API 2nd Event- 67% White Blood Cell Differential, 40 % Granulocytes, 60% Lymphocytes; 2021 API 3rd Event- 60% Lymphcytes (resulting in unsuccessful performance). 2. Review of the laboratory's 2021 PT corrective action records

	revealed incomplete corrective form documentation for the events listed above. The inspector inquired regarding the incomplete corrective action forms and lack of lab director evaluation. The clinical coordinator stated on 9/14/22 at approximately 1 PM, "We borrowed those corrective action forms from one of our other offices and the staff knew we needed to address the unsatisfactory PT but I agree that the evaluations were not thoroughly completed. They did not complete the corrective action with the director." 3. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above 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, lack of documentation, and interviews, the laboratory failed to retain manufacturer's assay package inserts for seven (7) of 7 hematology QC lot numbers utilized for evaluating the precision /accuracy of the Complete Blood Count (CBC) analyzer in the twenty-one months reviewed (January 2021 to September 14, 2022). Findings include: 1. Review of the laboratory's Abbott Emerald analyzer QC records revealed the following 7 Cell Dyn Plus QC lot numbers (#) placed in use to evaluate precision/accuracy for CBC patient testing from January 2021 through the date of the survey on 9/14/22: #0293 #0349 #1067 #1151 #1319 #2122 #2206 2. The inspector requested to review the Abbott assay information sheets for the 7 QC lot numbers outlined above. The documentation was not available for review. The clinical coordinator stated on 9/14/22 at approximately 11 AM, "I have the Abbott package insert for the calibrators we used last week but it looks like did not keep the QC package inserts." 3. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above findings.
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 proficiency testing (PT) records and an interview, the laboratory failed to perform twice annual accuracy verification for Lymphocyte Percent (LYMPH %) hematology patient testing in calendar year 2021. (Cross Reference D2128.) Findings include: 1. Review of the laboratory's 2021 American Proficiency Institute (API) PT results (Events 1-3) revealed that the laboratory received unsatisfactory LYMPH % scores of sixty percent (60%) on the following two (2) hematology events: 2021 2nd Event, 2021 3rd Event. The laboratory's LYMPH % scores resulted in an Unsuccessful Long-Term Performance rating from API in calendar year 2021. 2. The inspector requested to review documentation of accuracy

	verification during the timeframe of the events outlined above. No records were available for review. 3. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above 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 a review of the laboratory's Centers for Medicare and Medicaid Services CLIA Application Form, procedures, 2020 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), manufacturer's operations manual, instrument maintenance logs, hematology calibration records, patient test logs, lack of documentation, and interviews, the laboratory failed to: 1. ensure an Abbott iSTAT chemistry procedure was written and approved by the laboratory director (LD) while utilizing the analyzer to report Sodium, Potassium, Chloride, Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, and Creatinine and adherence to an established LD approved corrective action plan for hematology calibration procedures during the review timeframe of January 2021 to the date of the inspection on September 14, 2022. Cross Reference-D5401; 2. document performance of required twice annual hematology instrument preventative maintenance from January 2021 through the date of the inspection on 9 /14/22. Cross Reference- D5429; 3. document calibration procedures every six months for Complete Blood Count patient testing according to their written procedure in calendar year 2021 and up to the date of the inspection on 9/14/22. *NOTE: THIS IS A REPEAT DEFICIENCY* Cross Reference- D5437.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's Centers for Medicare and Medicaid Services CLIA Application Form (CMS 116), procedure manual, lack of documentation, patient test logs, and an interview, the laboratory failed to ensure an Abbott iSTAT chemistry procedure was written and approved by the laboratory director (LD) while utilizing the analyzer to report patient Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), and Creatinine (Creat) results during the review timeframe of January 2021 to the date of the inspection on September 14, 2022. Findings include: 1. A review of the laboratory's CMS 116 form with the clinical coordinator on 9/14/22 at approximately

	10:00 AM revealed that the LD identified performance of non-waived chemistry Chem 8 panels (Na, K, Cl, TCO2, iCa, Glu, BUN, Creat) utilizing Abbott iSTAT chemistry analyzer (Serial Number 404261). 2. Review of the LD approved procedure manual revealed no policy or procedure for the iSTAT Chem 8 testing outlined above. The inspector requested to review the iSTAT Chem 8 procedure. No procedure was available for review. 3. Review of the laboratory information system patient iSTAT logs revealed five hundred eighty four (584) patient Chem 8 panels were analyzed during the review timeframe of January 2021 to the date of the inspection, 9/14/22. 4. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above findings. B. Based on review of procedures, 2020 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), hematology calibration records, lack of documentation, and an interview, the laboratory failed to follow an established laboratory director (LD) approved corrective action procedure to ensure performance of calibration procedures every six months for Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2021 and up to the date of the inspection on September 14, 2022. Findings include: 1. Review of the laboratory's procedures revealed the following two protocols: Quality Assurance protocol section (CBC Calibration) that stated "calibration frequency for Abbott Emerald is at least once every six months"; CMS-2567 POC (LD signed/approved 12/9/20) which outlined a corrective action plan for documentation of every six month hematology analyzer calibration steps: "A new schedule has been instituted with new calibration dates for every 6 months. This schedule was made and put in place on November 11, 2020. The LD and TC will ensure that all calibrations are completed in a timely manner. The LD has been given the new schedule to ensure calibrations are completed." 2. Review of the Emerald hematology instrument calibration documentation from January 2021 to the date of the inspection on 9/14/22, a total of twenty-one (21) months, revealed one calibration recorded on 9/8/22. 3. The inspector requested to review additional calibration records for the Emerald analyzer during the 21 month review timeframe outlined above. No additional calibration documentation was available for review. Cross Reference 5437. 4. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above 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 a review of procedures, manufacturer's operations manual, instrument maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required twice annual hematology instrument preventative maintenance from January 2021 through the date of the inspection on September 14, 2022. Findings include: 1. Review of the laboratory's procedure manual revealed a policy (Emerald Cell-Dyn Maintenance) that stated: "Every 6 months grease pistons". 2. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions "perform the Lubricating Syringe Pistons procedure twice annually". 3. Review of the laboratory's Emerald hematology daily/monthly logs from January 2021 to the date of the survey, 9/14/22, revealed no "Lubricating Syringe Pistons" maintenance documentation. 4. The inspector requested to review documentation of

	the twice annual maintenance during the 21 months outlined above. The clinical coordinator stated on 9/14/22 at approximately 11:30 AM, "I am not sure if this maintenance was done. I can reach out to the preventative maintenance contractor to ask if it was done at least on yearly preventative maintenance checks. Our technical consultant is no longer employed but would have made sure this was done." 5. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above findings.
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: Based on review of policies and procedures, hematology calibration records, lack of documentation, and interviews, the laboratory failed to document calibration procedures every six months for Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2021 and up to the date of the inspection on September 14, 2022. *REPEAT DEFICIENCY* Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance protocol section (CBC Calibration) that stated "calibration frequency for Abbott Emerald is at least once every six months". 2. Review of the Emerald hematology instrument calibration documentation from January 2021 to the date of the inspection on 9/14/22, a total of twenty-one (21) months, revealed one calibration recorded on 9/8/22. 3. The inspector requested to review additional calibration records for the Emerald analyzer during the 21 month review timeframe outlined above. No additional calibration documentation was available for review. The clinical coordinator stated on 9/14/22 at approximately 1:30 PM, "Our technical consultant lab technologist retired in 2021 and we have tried to have one of our other lab techs to help the lab director keep up with the calibration schedules. I cannot locate any other calibration records." 4. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above 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 a review of procedures, quality control (QC) records, and an interview, the laboratory failed to document evaluation of statistical analysis to identify possible shifts/trends for Complete Blood Count (CBC) QC materials used to verify the accuracy of the Abbott Emerald hematology analyzer for twenty-one (21) of 21 months reviewed (timeframe: January 2021 to date of inspection September 14, 2022). Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance Policy that stated "At the end of each month, the monthly hematology LJ QC will be printed, reviewed, and signed by the technical consultant /lab director." 2. Review of the Emerald hematology instrument's QC records for Cell Dyn Plus QC materials from 1/1/21 to 9/14/22 revealed no documentation/review /verification of QC statistical analysis for the 21 months of review. 3. The inspector requested to review the Levey-jennings (LJ) review for the 21 months outlined above. No documentation was available. The clinical coordinator stated on 9/14/22 at approximately 1:30 PM, "I think our lab tech from one of our larger labs has been coming over to print the LJ QC reports and has been reviewing them for the director. I have left messages with that office to ask for the reports. I am not sure where they are at this time." 4. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above 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 a review of the laboratory's policy and procedure manual, quality assurance (QA)/quality control (QC)/ proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed to: 1. ensure that the policy for monthly QA checklists were maintained during the twenty-one (21) month review timeframe (January 2021 through the date of the survey on September 14, 2022). Cross Reference D6021. 2. identify the QA failures for lack of 21 months of hematology QC Levey jennings statistical analysis documentation, lack of twice annual accuracy verification for CBC analyte Lymphocyte Percent in calendar year 2021, lack of retention of assay package inserts for seven (7) of 7 hematology QC lot numbers, lack of retention of initial/semiannual competency assessment for one new laboratory testing personnel (TP) and annual hematology/chemistry competency evaluations for seven TP in the 21 months reviewed (January 2021 to date of inspection 9/14/22). Cross Reference D6022.
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 a review of the laboratory's policy and procedure manual, quality assurance (QA) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the QA policies were maintained during the twenty-one (21) month review timeframe (January 2021 through the date of the survey on September 14, 2022). Findings include: 1. Review of the laboratory's policy and procedure manual revealed a written and approved QA policy that outlined a monthly QA checklist to evaluate testing personnel, procedure manual updates, quality control, maintenance, proficiency testing documentation, communication, and remedial actions. The QA policy stated "the QA form is to be completed monthly and reviewed by the LD". 2. Review of the laboratory's available QA documentation from January 2021 through the date of the survey on 9/14/22 revealed no monthly QA checklists. The inspector requested to review the QA checklists for the 21 months of review. No records were available for review. The clinical coordinator stated on 9/14/22 at approximately 12:30 PM, "We have all of the QA checklists up through 2020. Our technical consultant laboratory technologist retired in 2021 and she was very good to keep those QA records up to date". 3. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above findings.
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 procedures, quality control (QC) and proficiency testing (PT) records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory laboratory director failed to identify the following quality assurance (QA) failures: 1. lack of twenty-one (21) months of hematology QC Levey jennings statistical analysis documentation per the laboratory's QA policy from January 2021 to date of inspection September 14, 2022. Cross Reference: D5791. 2. lack of twice annual accuracy verification for Complete Blood Cell (CBC) analyte Lymphocyte Percent when PT resulted in unsuccessful performance in calendar year 2021. Cross Reference: D5217. 3. lack of retention of manufacturer's assay package inserts for seven (7) of 7 hematology QC lot numbers utilized for evaluating the precision /accuracy of the CBC analyzer in the 21 months reviewed (timeframe January 2021 to date of inspection 9/14/22). Cross Reference: D3031. 4. lack of retention of initial /semiannual competency assessment documentation for one new laboratory testing personnel from January 3, 2022 up to the inspection date of 9/14/22. Cross Reference: D6053. 5. lack of retention of annual hematology and chemistry competency evaluation documentation for seven testing personnel in calendar year 2021 and up to 9/14/22. Cross Reference: D6054.
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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and interviews, the technical consultant (TC) failed to document performance of semiannual competency assessment for a new laboratory testing personnel (TP A) from January 3, 2022 up to the inspection date of September 14, 2022. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC. The LD identified eight (8) TP responsible for hematology Complete Blood Count (CBC) and chemistry Abbott iSTAT Chem 8 analysis/reporting of patient test results. During the review of the CMS 209 with the clinical coordinator on 9/14/22 at approximately 10:00 AM, the coordinator stated, "We have one new testing personnel since the last inspection. The new staff member's start date was January 3, 2022." 2. Review of the laboratory's TP records revealed no initial training for the new personnel, TP A. The inspector requested to view initial and semiannual competency assessment documentation for TP A. The documentation could not be presented for review. The clinical coordinator stated on 9/14/22 at approximately 12 PM, "I do not have the training or competency assessments. After our technical consultant technologist retired in 2021, we should have had another lab tech from one of our other locations come onsite to do the assessments. I will have to find out if they were completed." 3. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above 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 a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical consultant (TC) failed to perform annual hematology and chemistry competency evaluations for seven (7) of eight (8) testing personnel (TP) in calendar year 2021 and year to date, September 14, 2022. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director also performs the duties of TC. The LD identified 8 TP responsible for patient hematology Complete Blood Count (CBC) and chemistry Abbott iSTAT Chem 8 analysis/reporting of test results during the inspection review timeframe of January 2021 to 9/14/22 (TP A was identified as being a new staff member as of 1/3/22 and TP B - H as long term staff). See Personnel Code Sheet. 2. Review of the laboratory personnel files revealed no annual hematology and chemistry competency assessment documentation for calendar year 2021 or year to date 2022 for TP B - H. The inspector requested to review competency assessments for the 7 TP identified above. No records were available for review. The clinical coordinator stated on 9/14/22 at approximately 12 PM, "I do not have the competency assessments. After our technical consultant technologist retired

	in 2021, we should have had another lab tech from one of our other locations come onsite to do the assessments. I will have to find out if they were completed." 3. An exit interview with the clinical coordinator on 9/14/22 at approximately 2:00 PM confirmed the above findings.