

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0998730	<b>(X3) Date Survey Completed</b> 06/07/2024
<b>Name of Provider or Supplier</b> Lakeview Pediatrics And Family Medicine	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Lakeview Pediatrics and Family Medicine on June 6-7, 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 two Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6000 -42 CFR. 493.1403 Laboratory Director.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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: Based on a review of the laboratory's proficiency testing (PT) documentation, procedures, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for six (6) of 6 Core Chemistry, and 6 of 6 Hematology module PT events during the review timeframe of September 2022 to the date of the inspection June 6, 2024. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) Core Chemistry and Hematology PT documentation, a total of twelve (12) module events (Chemistry 2022 Event 3, 2023 Events 1-3, 2024 Events 1-2, Hematology</p>

2022 Event 3, 2023 Events 1-3, 2024 Events 1-2), revealed no signed attestation statements by the LD or performing TP. The inspector requested to review signed attestations for the 12 events outlined above. No documentation was available. The Quality Manager stated on 6/6/24 at 11 AM, "We made the assignments to ensure that the PT was rotated among the testing personnel but we failed to ensure that they signed the attestations". 2. The inspector noted API instructions on the PT records outlined above: "Signatures Required- For all PT results, an attestation statement must be signed by laboratory director and testing personnel and retained for minimum of two years." Review of the laboratory procedure manual revealed a Proficiency Testing Policy that stated, "the director and testing personnel will sign/date the attestation submission to the proficiency program." 3. An exit interview with the Quality Manager on 6/6/24 at 12:30 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 manufacturer's operations manuals, instrument maintenance logs, policies and procedures, hematology calibration records, lack of documentation, and interview, the laboratory failed to: 1. document performance of semi-annual hematology instrument preventative maintenance per manufacturer's instructions in calendar year 2023 through the date of the inspection on June 6, 2024. \*NOTE: THIS IS A REPEAT DEFICIENCY\* Cross Reference- D5429A; 2. document performance of chemistry instrument preventative maintenance every six months per manufacturer's instructions in calendar year 2023 through the date of the inspection on 6/6/24. Cross Reference- D5429B; 3. document calibration procedures every six months for Complete Blood Count patient testing according to their written procedure in calendar year 2023. \*NOTE: THIS IS A REPEAT DEFICIENCY\* Cross Reference- D5437.

**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:  
A. Based on a review of manufacturer's operations manual, instrument maintenance logs, lack of documentation, and an interview, the laboratory failed to document performance of semi-annual hematology instrument preventative maintenance per manufacturer's instructions in calendar year 2023 through the date of the inspection on June 6, 2024. \*\*REPEAT DEFICIENCY Findings include: 1. Review of the Abbott Emerald Operation's Manual under Section 9 (titled: Preventative Maintenance

Schedule) revealed protocol instructions as, "Semi-Annual Maintenance- perform Lubricating Syringe Pistons procedure every six months per procedure below. Document the maintenance on the maintenance log". 2. Review of the laboratory's hematology maintenance logs for Abbott Emerald (Serial Number 030620-008346) for the timeframe of January 2023 to the date of the survey on 6/6/24, revealed that "Lubricating Syringe Pistons" maintenance was documented as performed once (dated 4/3/23). The inspector noted the maintenance was documented by an Abbott field service technician. 3. The inspector requested to review additional documentation of the semi-annual maintenance after 4/3/23. No additional documentation was available for review. 4. An exit interview with the Quality Manager on 6/6/24 at 12:30 PM confirmed the above findings. B. Based on a review of manufacturer's operations manual, instrument maintenance logs, lack of documentation, and an interview, the laboratory failed to document performance of chemistry instrument preventative maintenance every six months per manufacturer's instructions in calendar year 2023 through the date of the inspection on June 6, 2024. Findings include: 1. Review of the Abbott iSTAT Operation's Manual under section titled: Manufacturer's Quality System Instructions, revealed protocol instructions as: "Thermal Probe- ensure the thermal probe check is performed every six months on each iSTAT handheld analyzer. This verification check may be performed in conjunction with the analyzer software updates. Document in maintenance log." 2. Review of the laboratory's available chemistry maintenance logs for Abbott iSTAT (Serial Number 404261) for the timeframe of January 2023 to the date of the survey on 6/6/24, revealed no documentation of the thermal probe verification outlined above. 3. The inspector requested to review documentation of the every six month maintenance performed in calendar year 2023 and year to date 2024. No documentation was available for review. 4. An exit interview with the Quality Manager on 6/6/24 at 12:30 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 an interview, 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 2023. \*REPEAT DEFICIENCY\* Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance protocol (CBC Calibration) that stated "calibration frequency for Abbott Emerald is at least once every six months". 2. Review of the Emerald hematology instrument (Serial Number 030620-008346) calibration documentation for calendar year 2023 up to the date of the inspection on 6/6/24,

revealed two documented calibration procedures (dated 4/03/23, 4/30/24). 3. The inspector requested to review additional calibration records for the Emerald analyzer during calendar year 2023. No additional calibration documentation was available for review. 4. An exit interview with the Quality Manager on 6/6/24 at 12:30 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 Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), CMS CLIA 116 Database, laboratory personnel files, proficiency testing (PT) records, policies, manufacturer's operations manuals, analyzer maintenance records, and interviews, the laboratory director failed to: 1. provide documentation of education credit hours in laboratory practice commensurate with the moderate complexity director responsibilities during the twenty-one months of review (September 2022 to June 6, 2024) - Cross Reference D6003; 2. to identify the quality assessment failures as they occurred for missed PT attestation documentation, missed twice annual hematology and chemistry instrument maintenance, and missed every six month hematology calibrations during the review timeframe outlined above - Cross Reference D 6021.

**D6003**

**LABORATORY DIRECTOR QUALIFICATIONS**  
CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the

American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in

which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

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), CMS CLIA 116 Database, laboratory personnel files, and an interview, the laboratory director (LD) failed to provide documentation of education credit hours in laboratory practice commensurate with the moderate complexity director responsibilities for the twenty one months of review (September 2022 to June 6, 2024). Findings include: 1. Review of the CMS Form 209 revealed that Personnel A was identified as LD and who also performs the duties of clinical consultant and technical consultant, and that nine testing personnel are responsible for moderate complexity Complete Blood Count (CBC) hematology and iSTAT Chemistry 8 panel patient testing during the review timeframe of September 2022 to 6/6/24. \*See Personnel Code Sheet. 2. Review of the CMS CLIA 116 database revealed Personnel B was identified as the laboratory director. The inspector inquired regarding the date of laboratory director change. The Quality Manager stated that Personnel B "left the position in late 2022". \*See Personnel Code Sheet. 3. Review of the laboratory's employee files revealed that Personnel A's file contained current Medical Doctor license. The inspector requested to review documentation of laboratory training /experience or medical education for laboratory director responsibilities oversight of hematology and chemistry specialities. No documentation was available for review at the time of request. The Quality Manager stated during a follow up interview on 7/7/24 at 2 PM, "I thought that since the LD was also listed as a director at one of our Certificate of Waiver locations, that would be sufficient to qualify as LD for Certificate of Compliance as well." 4. An exit interview with the Quality Manager on 6/6/24 at 12:30 PM and follow up interview on 6/7/25 at 2 PM confirmed the above 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 a review of proficiency testing (PT) records, policies, manufacturer's operations manual, analyzer maintenance records, lack of documentation, and interviews, the laboratory laboratory director failed to identify the following quality assessment (QA) failures as they occurred: 1. lack of retention of PT attestation statements for twelve (12) of 12 hematology and chemistry PT modules during the

review timeframe of September 2022 to June 6, 2024; Cross Reference D2015. 2. lack of documentation for required twice annual hematology and chemistry instrument preventative maintenance during review timeframe outlined above; **\*\*REPEAT DEFICIENCY**, Cross Reference D5429. 3. lack of documentation for required calibration procedures every six months for Complete Blood Count patient testing in calendar year 2023; **\*REPEAT DEFICIENCY\*** Cross Reference- D5437.