| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0998730 | 11/17/2020 |
| **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 |
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| **D0000** | An announced on-site CLIA recertification survey was conducted at Lakeview Pediatrics and Family Medicine on November 17, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 11/2/2020 and virtual record review conducted on 11/13/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows: |
| **D2020** | BACTERIOLOGY<br>CFR(s): 493.823(a)<br><br>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for Group A Strep Antigen in one (1) out of three (3) Bacteriology testing events reviewed for calendar year 2019. Findings include: 1. Review of the laboratory's American Proficiency Institute PT records (2019 Events 1-3) revealed Group A Strep Antigen scores of less than 80% for the following Bacteriology event: API 2019 2nd Event = 0% (challenges WST-03, WST-04 scored as unacceptable) 2. In an interview with the technical consultant, on 11/17/20 at approximately 1:30 PM, the above findings were confirmed. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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 |

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| | determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory equipment, a tour, review of manufacturer's package insert instructions, and interviews, the laboratory failed to follow Abbott iSTAT chemistry reagent cartridge storage requirements for three (3) of twelve (12) cartridges on the date of the on-site inspection, November 17, 2020. Findings include: 1. During an entrance interview with the laboratory's office manager and technical consultant (TC) on 11/13/20, the inspector was informed of and noted that the laboratory utilized an Abbott iSTAT point of care chemistry analyzer (Serial Number SN 404261). 2. During a tour of the laboratory on 11/17/20 at approximately 12:30 PM, the inspector noted 12 iSTAT chem8 cartridges stored in the refrigerator (Lot Number H20191, expiration date 1/5/2021). The inspector noted 3 iSTAT cartridges (Lot Number H20191) stored at room temperature on the counter beside the iSTAT point of care instrument. The 3 packages had not been labeled with a room temperature storage expiration date. 3. Review of the iSTAT outer package revealed storage temperature instructions as 2-8 C. The manufacturer's package insert stated: "All iSTAT cartridges should be refrigerated at 2-8 C. Once removed from the refrigerator, cartridges may be stored at room temperature (18-30 C) for up to fourteen days. Once a cartridge has been warmed to room temperature, do not return it to the refrigerator. The manufacturer's labeled expiration date should be crossed out and the temperature expiration date should be written on the cartridge package." 4. The inspector inquired of the technical consultant (TC) regarding the laboratory's protocols for the iSTAT reagent cartridges stored at room temperature. The TC stated, at approximately 1:15 PM: "We store the cartridges in the refrigerator and pull out a few to keep at room temperature. The staff has been trained to write a new expiration date on the packages once they pull them out of the refrigerator. I will need to reiterate this with our staff". 5. In an interview with the TC, on 10/17/20 at approximately 1:30 PM, the above findings were confirmed |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory equipment, performance verification records, patient test logs, lack of documentation, and an interview, the laboratory director (LD) failed to evaluate and verify accuracy, precision, and reportable range for Complete Blood Count (CBC) testing for a newly installed Abbott Emerald hematology instrument prior to reporting patient results from 10/22/20 to the date of the survey on 11/17/20. Findings include: 1. During an entrance interview with the laboratory's office manager and technical consultant (TC) on 11/13/20, the inspector was informed of and noted that an Abbott field service specialist installed a new Emerald analyzer (Serial Number SN 030620-008346) on 10/22/20. 2. Review of the hematology analyzer |

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| | installation documentation revealed no evaluation or verification by the lab director of accuracy, precision, or the CBC reportable range for the Abbott Emerald SN 030620-008346. The inspector requested to review documentation that the laboratory director verified the Abbott Emerald instrument prior to patient testing. No documentation was available for review. 3. Review of the patient accessioning test log revealed that the lab had reported three (3) CBC reports from 10/22/20 to 11/13/20. 4. In an interview with the TC at approximately 1:30 PM, the above findings were confirmed. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policies and procedures, hematology calibration records, 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 2020. Findings include: 1. Review of the laboratory's Quality Assurance (QA) procedures revealed a "CBC Calibration" policy that stated "calibration frequency for Abbott Emerald is at least once every six (6) months". 2. Review of the Emerald hematology instrument calibration documentation from January 2019 to the date of the virtual record review on 11/13/20, a total of twenty-three (23) months, revealed the following calibration records: 6/18/19, 8/5/19, 12/18/19, 2/19/20. The inspector requested to review additional calibration records for the Emerald analyzer in calendar year 2020. No additional calibration documentation was available for review. The technical consultant (TC) stated at, approximately 11:00 AM, "The lab staff did miss the deadline for the calibration in that time period. We replaced that Emerald for a new one in October of 2020. They may have decided to postpone the calibration in August because they were planning to install a new machine". 3. In an interview with the TC on 11/17/20 at approximately 1:30 PM, the above findings were confirmed. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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 |

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| | proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel files, lack of documentation, and an interview, the laboratory director (LD) did not perform annual competency assessments for two (2) of two (2) technical consultants during the twenty-six (26) months reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed that the LD identified two technical consultants (TC). (See Personnel Code Sheet.) 2. Review of the laboratory's available personnel files revealed no competency assessment documentation for TC #1 or TC #2 in calendar year 2019 or 2020. The inspector requested to review competency assessment documentation for the duties of TC. No documentation was not available for review upon request. The office manager stated on 11/13/20 at approximately 10:00 AM, during the virtual record review, that "during the COVID-19 pandemic, we furloughed TC #1 and had to utilize TC #2 (from a different office location) to cover for most of calendar year 2020". We did complete competency assessments for them as testing personnel but not for their performance of consulting duties". 3. In an interview with the TC #1 on 11/17/20, at approximately 1:30 PM, the above findings were confirmed. |