| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D0673684 | 03/01/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Kenwood Pediatrics Drs Idriss | 5301 Westbard Circle Suite #3, Bethesda, MD | |

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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| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record and patient sample log review and interview with the technical consultant (TC), the laboratory did not handle bacteriology PT specimens in the same manner as patient samples. Findings: 1. All patient samples which enter the laboratory are recorded on a patient log. 2. A review of patient logs from January, 2016 to February, 2018 showed that bacteriology PT samples were not documented on the patient log along with patient specimens in 7 of 7 PT events. 3. During an interview on 3/1/18 at 1:15 PM, the TC confirmed that bacteriology PT samples were not listed individually on the patient log in the same manner as patient specimens. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from event 1, 2016 to event 1, 2018 showed that the attestation statements for 4 out of 7 events in Bacteriology were not present at the time of the survey; and 2. Two of 7 PT results summaries which are to be signed and dated by the laboratory director indicating that the results have been reviewed and found to be acceptable were not present at the time of the survey. 3. During an interview on 3/1/18 at 1:15 PM, the TC confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on competency assessment record review and interview with the technical consultant (TC), the laboratory did not establish written policies and procedures for assessing the competency of the TC based on the position responsibilities listed in Subpart M- CFR 493.1413. Findings: 1. A review of competency assessment records showed that at the time of the survey there was no competency assessment available for the TC. 2. During an interview on 3/1/18 at 1:15 PM, the TC confirmed that the laboratory director had not performed a competency assessment on the TC. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the standard operating procedure manual (SOPM) and interview |

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| | with the technical consultant (TC), the laboratory's written policies and procedures did not reflect the actual practice of the laboratory. Findings: 1. The laboratory's SOPM was reviewed. Under the procedure, "Laboratory Quality Assurance Plan," under the section, "Monitoring of Aspects of Care," subsection "Patient Test Management," it states, "Panic values are posted next to the Hematology Analyzer and are immediately reported to Dr. Idriss for further action." The TC stated during an interview that there was no hematology analyzer, and that they had "borrowed the procedure from another lab" and "must have forgotten to take that part out"; and 2. The procedure also states that, "All specimens that are sent to outside laboratories for the testing must be documented in the 'Specimen Send Out Log.'" The TC stated during an interview that the laboratory did not have a send out log and during an interview, laboratory staff stated that patients who require additional testing are "sent to have the test done elsewhere." 3. Under the subsection, "Quality Control," the procedure refers the reader to another procedure, "Laboratory Quality Control Acceptance Criteria and Protocol for Unacceptable Quality Control Results." The TC stated during an interview that the SOPM did not include the quality control procedure referred to; and 4. Under, "Daily Temperature," it states that "the temperature of the refrigerator is recorded daily on the Temperature Log," but the SOPM did not include a procedure for downloading temperature data from the digital thermometers used in the laboratory refrigerators, or list normal temperature ranges or how to interpret the data collected from the digital thermometers. 5. The subsection, "Proficiency Testing" states that "records of all Proficiency Testing results, as well as any corrective action, are maintained for two years." Not all proficiency testing documents were present at the time of the survey, See D3037. 6. The subsection, "Communication/Complaints /Corrective Action," states that "there will be quarterly Quality Assurance Committee Meetings." The TC stated during an interview that meetings are not held quarterly. 7. The procedure, "Urine Culture Procedure" instructs the reader to "sterilize inoculating loop in flame of burner" before inoculating agar plate with urine. The laboratory director (LD) stated during an interview that the laboratory uses disposable sterile inoculating loops and does not have a burner. 8. The procedure, "Throat Culture Procedure" states that "the Taxo A discs are checked weekly with positive and negative controls," however a review of "Quality Control for Tax A" logs showed that controls were not run weekly; and 9. The procedure states that "known Group A Strep strains can be bought from our medical supplier" and that "the ATCC number of the control organism is recorded in the laboratory logbook. A negative culture is also obtained and run each week." The procedure did not state how to obtain the "negative culture" or how to record its source. 10. The subsection, "Culti-Loops" describes how to perform quality control with loops coated in control organism. During a tour of the laboratory at 10:30 AM, it was observed that there were quality control swabs containing Strep. pyogenes, group A in the laboratory refrigerator but no "Culti-Loops." 11. During an interview on 3/1/18 at 1:15 PM, the TC confirmed that the SOPM did not accurately reflect the actual practice of the laboratory. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor observation and interview with the technical consultant (TC), the laboratory did not ensure the accuracy of the thermometers used in the laboratory. Findings: 1. The laboratory monitors the temperature of the laboratory refrigerator, microbiology incubator, and room on a daily basis. 2. The laboratory did not have a certificate of calibration for the incubator and room temperature thermometers. During the survey at approximately 12:30 PM the TC stated that they are checked using a "thermometer that is not NIST." 3. The laboratory did not have a procedure to check the incubator and room temperature thermometers' accuracy and did not check the accuracy of the thermometers in a scientific way. 4. The refrigerator temperature is taken using a digital thermometer which had a current certificate of calibration. During an interview between 11:00 AM and 12:00 PM, laboratory staff stated that the digital thermometer is plugged into the computer and the temperature readings stored on the device are downloaded. The temperature readings are printed in graph form, once a month. 5. There are no temperature ranges listed on the resulting print out and no way to determine if the refrigerator temperatures are out of range. 6. The laboratory did not have a procedure for how to download temperature readings from the digital thermometer, or a procedure specifying the acceptable temperature range for the refrigerator, microbiology incubator, or room temperature, and what corrective action to take if temperatures were out of range. 7. During an interview on 3/1/18 at 1: 15 PM, the TC confirmed that the laboratory did not ensure the accuracy of the thermometers used in the laboratory. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) record review and interview with the laboratory director (LD), the laboratory did not establish or verify the criteria for acceptability of all control materials. Findings: 1. The laboratory's records of Taxo A disc (bacitracin) QC were reviewed. QC is run approximately every 2 weeks. The "Quality Control for Tax A" worksheets showed that the lot number and expiration date of the Taxo A discs and the "control gp A Strep" were recorded, but the negative control which was listed as, "Pt non gp A Strep" had no lot number or expiration date documented. 2. During an interview at 12:15 PM the LD stated that he uses a patient which has previously tested negative as the negative control. 3. No identifying information was documented as to the source of the laboratory's negative control; and 4. The package |

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| | insert for the Taxo A discs states, "At the time of use, check performance with pure cultures of stable control organisms producing known, desired reactions." 5. During an interview on 3/1/18 at 12:15 PM, the LD confirmed that the laboratory did not establish or verify the criteria for the negative control used to test Taxo A discs. |
| **D6011** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(2)<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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.<br><br>This STANDARD is not met as evidenced by:<br>Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 02/3/2016 for not ensuring that employees are protected from physical, chemical, and biologic hazards. The plan of correction stated that this would be corrected. Based on surveyor observation and interview with laboratory staff on the day of the survey, the laboratory director (LD) did not ensure that environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biologic hazards. Findings: 1. A storage room in the doctor's office contained a coffee maker, microwave, pretzels, crackers, candy, and a refrigerator containing employee lunches. 2. At 10:30 AM, the LD was in the storage room and offered to make a cup of tea for the surveyor and at 12:00 PM it was observed that the storage room also contained a biohazard waste box, under the counter below the microwave; and 3. The biohazard waste box was in close proximity to food and drink and did not ensure a safe environment for food storage and consumption. 4. At the time of the survey the laboratory staff removed the biohazard waste box from the storage area. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality assurance (QA) plan and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the QA plan was maintained to identify failures and corrective actions taken when failures are identified. Findings: 1. Record review showed that proficiency testing (PT) specimens were not logged on the patient logs like patient specimens (see D2006), PT records were incomplete (see D3037), the procedure manual did not accurately reflect the current practice of the laboratory (see D5403), temperature logs did not include normal ranges (see D5413), and Taxo A quality control (QC) records did not include |

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| | the source of the negative control (see D5469). 2. Procedure manual review showed that the procedure, "Laboratory Quality Assurance Plan," subsection, "Quality Assurance Activities of the Technical Supervisor" states that "The technical supervisor will monitor the quality control records, test results, temperature logs, and proficiency test results on a quarterly basis." A review of the procedure manual, QC records, laboratory logs, temperature logs, and PT worksheets showed that the QA reviews performed by the TC did not identify errors in quality. 3. During an interview on 3/1/18 at 1:15 PM, the TC confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality assurance (QA) plan and interview with the technical consultant (TC), the TC did not ensure that acceptable levels of analytic performance were maintained for bacteriology testing. Cross refer to Tag D6022. |