| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2059958 | 02/09/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Kids Kare Pediatrics | 5019 Portico Way, Midland, TX | |

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** | The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Review of American Proficiency Institute (API) proficiency testing records for 2019 and 2020 (three events per year) and interview of facility personnel found that the laboratory failed to attest to the routine integration of proficiency specimens into the routine workload for six of six proficiency testing events in Hematology. The findings included: 1. Review of the API proficiency testing records for Hematology found no attestation statements for review for the six testing events in 2019 and 2020. 2. Additional Proficiency testing records were requested on February 9, 2021 at 10:40 AM but not provided. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on February 9, 2021 at 11:08 AM confirmed that no other proficiency testing records were available for review. She went on to say that they "might have additional records for review, but they are not organized."She went on to say that they "might have additional records for review, but they are not organized." |
| **D3031** | RETENTION REQUIREMENTS |

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| | CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and procedures, calibration records and interview, the laboratory failed to retain calibration records for the pocH-100i Hematology analyzer for 2 of 2 years reviewed. Findings follow. Review of the laboratory's Record Retention Policy, effective 04/07/2017, stated, "It is the policy of this laboratory that the following records be retained in digital or paper form by the laboratory for two years...6. Calibration reports." Review of calibrations stored on the pocH-100i and printed during the survey showed calibrations were performed on 2/13 /2020, 07/08/2019, 12/13/2018, and 6/13/2018. The Sysmex Calibration System Assay Sheet including target values (reference values) and the calibration report had not been retained for the calibrations performed. Interview with testing personnel #3, on the CMS form 209, on February 9, 2021 at 1045 hours in the office confirmed calibrations records were not retained. |
| **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:<br>Review of American Proficiency Institute (API) proficiency testing records for 2019 and 2020 (three events per year) and interview of facility personnel found that the laboratory failed to retain records for six of six proficiency testing events in Hematology testing for at least two years. The findings included: 1. Review of the API proficiency testing records for Hematology found that the laboratory failed to retain records for each testing event as follows: a. 2019 Hematology/ Coagulation - 1st Event - The laboratory failed to retain instrument printouts, attestation statements and original submission forms. b. 2019 Hematology/ Coagulation - 2nd Event - The laboratory failed to retain instrument printouts and attestation statements. c. 2019 Hematology/ Coagulation - 3rd Event - The laboratory failed to retain instrument printouts, attestation statements and original submission forms. d. 2020 Hematology/ Coagulation - 1st Event - The laboratory failed to retain instrument printouts, attestation statements, performance evaluations and original submission forms. e. 2020 Hematology/ Coagulation - 2nd Event - The laboratory failed to retain instrument printouts and attestation statements. f. 2020 Hematology/ Coagulation - 3rd Event - The laboratory failed to retain instrument printouts, attestation statements and original submission forms. 2. Additional Proficiency testing records were requested on February 9, 2021 at 10:40 AM but not provided. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on February 9, 2021 at 11:08 AM confirmed that no other proficiency testing records were available for review. She went on to say that they "might have additional records for review, but they are not organized." |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d) |

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| | All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Review of American Proficiency Institute (API) proficiency testing records for 2019 and 2020 (three events per year) and interview of facility personnel found that the laboratory failed to review and evaluate results for six of six proficiency testing events in Hematology. The findings included: 1. Review of the API proficiency testing records for Hematology found that the laboratory failed to document the review of proficiency testing results in three of three testing events each year for 2019 and 2020. 2. Additional Proficiency testing records were requested on February 9, 2021 at 10:40 AM but not provided. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on February 9, 2021 at 11:08 AM confirmed that no other proficiency testing records were available for review. She went on to say that they "might have additional records for review, but they are not organized." |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions, laboratory's temperature charts, surveyor observation, and interview, the laboratory failed to accurately document the room temperature of the laboratory. Findings follow. Review of the pocH-100i Hematology analyzer Instructions for Use Manual, revision December 2014, under 1.2.1 Performance characteristic specifications on page 1-6 stated Ambient Temperature requirements of "15-30 degrees Celsius (ideal operating temperature at 23 degrees Celsius) (59-86 degrees Fahrenheit)." Random review of the Temperature Recording Form for [the] Refrigerator- Celsius showed the room temperature recorded was 70 degrees Fahrenheit every day from 11/03/2020 - 02/09/2021, including the pm slot the morning of the survey on February 9, 2021. Surveyor observed on February 9, 2021 at 0950 hours in the laboratory the room temperature was 72.7 degrees Fahrenheit. Interview with testing personnel #3, on the CMS form 209, on February 9, 2021 at 0950 in the laboratory confirmed 70 degrees was recorded every day for the room temperature and the pm slot for the day had been prerecorded for 70 degrees. Interview with testing personnel #1, on the CMS form 209, on February 9, 2021 at 1025 hours in the office confirmed staff was using the thermostat setting for the documentation of the room temperature instead of using the thermometer. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory |

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| | must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions and interview, the laboratory failed to document the maintenance performed on the pocH-100i Hematology analyzer. Findings follow. Review of the pocH-100i Hematology analyzer Instructions for Use Manual, revision December 2014, under chapter 4 Cleaning and Maintenance listed various cleaning and maintenance tasks. Chapter 4.1.2 Check instrument status described the CellClean procedure on page 4-2 that stated, "to ensure proper functioning of the instrument, periodical cleaning and servicing is necessary." Chapter 4.1.4 Clean transducer on page 4-4 stated, "a message will appear when either the counter value exceeds 150 or 2 weeks have passed since the last cleaning of the transducer." Chapter 4.1.5 Clean waste chamber on page 4-5 stated, "a message will appear if either the counter value exceeds 1500 or 3 months have passed since the last clean waste chamber." Maintenance logs were requested but not provided on February 9, 2021 at 1155 hours in the office. Interview with testing personnel #3, on the CMS form 209, on February 9, 2021 at 1155 hours in the office acknowledged they do not have a maintenance log, the instrument lets them know when to do the waste chamber and transducer cleaning. |
| **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 the laboratory's policy and procedures, calibration records, and interview, the laboratory failed to perform calibrations at least every 6 months on the pocH-100i Hematology analyzer. Findings follow. Review of the Instrument Calibration and Calibration Verification Policy, effective 04/07/2017, stated, "It is policy of this laboratory that all instruments of moderate complexity be calibrated according to the following guidelines: ...2. Every six months even if the manufacturer states it does not need to be calibrated that often..." Review of calibrations stored on the pocH-100i (see D3031) and printed during the survey showed calibrations were performed on 2/13/2020, 07/08/2019, 12/13/2018, and 6/13/2018. No calibrations had been performed since 2/13/2021 (1 year had elapsed, equivalent to 2 missed calibrations). Interview with testing personnel #1, on the CMS form 209, on February 9, 2021 at 1030 hours in the office confirmed calibrations had not been performed since 02/13/2020. Interview with testing personnel #3 at 0915 hours in the office confirmed the technical consultant left in the summer of 2020 and would run samples periodically on the analyzer. |

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| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedures, quality control records, and interview, the laboratory failed to print the Levy-Jennings graphs and statistical data to monitor over time the accuracy and precision of the test system using the pocH-100i Hematology analyzer. Findings follow. Review of the laboratory's policy and procedure stated, "The technical consultant will also review all QC monthly to look for shifts, trends..." Review of Levy-Jennings graphs showed they were printed up to 07/26/2019. No other means to evaluate accuracy and precision over time were performed. Interview with testing personnel #3, on the CMS form 209, on February 9, 2021 at 1130 hours in the office acknowledged they were told not to print the Levy Jennings, and confirmed the Technical Consultant would print them monthly, but only had graphs up until July 26, 2019. Interview with testing personnel #3 at 0915 hours in the office confirmed the technical consultant left in the summer of 2020. |
| **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 review of quality control (QC) records, observation, and interview, the laboratory failed to ensure the Sysmex Eightcheck-3WP X-TRA control values were accurately input into the pocH-100i Hematology analyzer. Findings follow. Review of the QC files (#4-6) stored on the pocH-100i showed target values for Red Blood Cell (RBC), Mean Corpuscular Hemoglobin Concentration (MCHC), and Mean Corpuscular Hemoglobin (MCH) were missing or incorrect. The assay sheet for the |

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| | current lot of Sysmex Eightcheck-3WP X-TRA control in use, Lot 03370710, was compared against the values in the QC files used to evaluate QC on the analyzer. 1. The RBC for the Normal Control input into the analyzer had a target of 4.43: the control package insert target mean value was 4.55. 2. The RBC for the High control input into the analyzer had no target or limit (range): the control package insert target mean value for RBC was 5.55 with a limit of 0.26. 3. The MCHC for the Normal control input into the analyzer was 33.6: the control package insert target value for MCHC was 33.7. 4. The MCH for the Low control input into the analyzer was 24.9: the control package insert target mean value for MCH was 23.7. Review of the QC files (#1-3) stored on the pocH-100i showed target values for RBC and MCHC were incorrect. The assay sheet for the last lot of Sysmex Eightcheck-3WP X-TRA control in use, Lot 02520710, was compared against the values in the QC files used to evaluate QC on the analyzer. 1. The RBC for the Low Control input into the analyzer had a target of 2.31: the control package insert target mean value was 2.23. 2. The RBC for the High control input into the analyzer had a target of 5.47: the control package insert target mean value for RBC was 5.36. 3. The MCHC for the High control input into the analyzer was 34.4: the control package insert target value for MCHC was 34.7. Surveyor observed on February 9, 2021 at 1105 hours in the laboratory each indicy had a barcode on the package insert that the laboratory scanned to enter the values into the analyzer. Interview with testing personnel #3, on the CMS form 209, on February 9, 2021 at 1100 hours in the laboratory confirmed the values did not match the package insert and they may not have scanned the barcode. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of quality control (QC) records and interview, the laboratory failed to ensure 2 levels of QC were within range before performing and reporting patient test results on the pocH-100i Hematology analyzer. Findings follow. Review of the daily quality control print-outs from 10/12/2020 to 02/09/2021 showed 2 out of 3 levels of QC were out of range on 10/22/2020 for RBC (Red Blood Cell) levels Low and Normal controls as displayed with a "-" out of range symbol. One patient test was performed at 10:03 am and reported at 11:08 am. Interview with testing personnel #3, on the CMS form 209, on February 9, 2021 at 1150 hours in the office acknowledged she has "told them not to do that." |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Review laboratory records, personnel records and interview facility personnel found the laboratory director failed to provide overall management and direction of the |

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| | laboratory. 1. The laboratory director failed to ensure that Hematology proficiency testing specimens were integrated into the routine workload.(See D6016) 2. The laboratory director failed to ensure that proficiency testing results were reviewed and evaluated for corrective actions by qualified personnel ( see D 6018) 3. The laboratory director failed to ensure that the quality control program for Hematology had been established and maintained. (See D 6020) 4. The laboratory director failed to ensure that all testing personnel performing moderate complexity testing met the minimum education requirements. (See D6028) 5. The laboratory director failed to ensure that all testing personnel had received the appropriate training prior to testing patient specimens for CBC. ( See D 6029) |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Review of proficiency testing results and interview of facility personnel found that the laboratory director failed to ensure that attestation statements were signed by testing personnel and the laboratory director. (See D2009) |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<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)(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;<br><br>This STANDARD is not met as evidenced by:<br>Review of proficiency testing records, policies and procedures and interview facility personnel found that the laboratory director failed to ensure that proficiency testing reports were reviewed to evaluate the laboratory's overall performance. (see D 5221) |
| **D6020** | 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 program is established and maintained to assure the quality of laboratory services provided. |

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| | This STANDARD is not met as evidenced by:<br>Review quality control records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that the Hematology quality control program had been established and maintained. (See D5441, D5469, D5481) |
| **D6028** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(10)<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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;<br><br>This STANDARD is not met as evidenced by:<br>Review of personnel files, laboratory test records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that one of five testing personnel performingCBC testing had the appropriate education and training for performing non waived procedures. (see D 6065 and D6066) |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on observations, review of temperature records, proficiency testing records, laboratory policies and procedures, patient testing records, manufacturer's instructions for use and assay sheet, quality control (QC) records, review of the laboratory's personnel records, and confirmed in interview with laboratory staff, the technical consultants failed to provide technical and scientific oversight. 1. The technical consultant failed to ensure that a quality control program had been established and maintained to ensure the accuracy and reliability of results for CBC testing. (See D6042) 2. The technical consultant failed to perform competency assessments on four of five testing personnel performing CBC testing in 2019 and 2020 .(refer to D6054) |
| **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; |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedures, quality control (QC) records, observation, and interview failed to ensure quality control was acceptable prior to reporting patient test results and the appropriate QC target values were entered into the pocH-100i Hematology analyzer used to access the acceptability of quality control. Findings follow. 1. The laboratory failed to ensure 2 of 3 levels of QC were within range before performing and reporting patient test results on the pocH-100i Hematology analyzer (refer to D5469). 2. The laboratory failed to ensure the Sysmex Eightcheck-3WP X-TRA control values were accurately input into the pocH-100i Hematology analyzer (refer to D5481). |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of personnel records and interview of facility personnel, the laboratory failed to have documentation of competency assessment for four of five testing personnel performing Hematology testing . The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 5 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of annual competency assessments for 2019 and 2020 for four of five testing personnel performing Complete Blood Counts (CBC). 3. Interview of testing person one conducted on February 9, 2021 at 10:25 confirmed that no competency assessments were available for review. She went on to say that she "might have other records for review but they are not organized". |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to ensure all testing personnel met the minimum education and training requirements to perform moderate complexity testing in Hematology. (refer to D6065 and D6066). |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor |

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| | 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<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of personnel records and interview of facility personnel, the laboratory failed to have documentation of education for one of five testing personnel performing Hematology testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 5 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for testing person five. 3. The laboratory offered a vocational nursing certificate as evidence of education. 4. Interview of testing person one conducted on February 9, 2021 at 10:32 AM confirmed that no documentation of education available for review. |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of personnel records and interview of facility personnel, the laboratory failed to have documentation of education for one of five testing personnel performing Hematology testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 5 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed a hire date for testing person 5 as October 2020. The laboratory failed to have documentation of training for testing person five. 3.Interview of testing person one conducted on February 9, 2021 at 10:32 AM confirmed that no documentation of education available for review. |