| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D0464385 | 11/30/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Allen L Spires, Md, Amc | 301 Davenport Avenue, Mer Rouge, LA | |

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** | A Certification survey was performed on November 30, 2023 at Allen Spires MD, APMC, CLIA ID # 19D0464385. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **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 review of the laboratory policy, personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for Technical Consultant was complete. Findings: 1. Review of laboratory policy revealed the "Laboratory Director is responsible for ensuring that competency is assessed at least annually for laboratory staff". 2. Review of personnel records for 2022 and 2023 revealed the competency assessment for Personnel 2 who serves as Technical Consultant was not performed. 3. In interview on November 30, 2023 at 2:09 pm, Personnel 2 confirmed the Laboratory Director did not perform competency assessments in 2022 and 2023 for personnel serving as Technical Consultant. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within |

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| | the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of manufacturer's user manual, laboratory's start up logs, patient records and interview with personnel, the laboratory failed to ensure the daily background checks for the Horiba Medical ABX Micros 60 analzyer were within the manufacturer's parameter limits prior to patient testing for one (1) of six (6) months reviewed in 2023. Findings: 1. Observation by surveyor during the laboratory tour on November 30, 2023 at 1:30 pm revealed the laboratory utilizes the Horiba Medical ABX Micros 60 analyzer for Complete Blood Count (CBC) testing in the specialty of Hematology. 2. Review of the manufacturer's user manual for the Horiba Medical ABX Micros 60 under "Startup" revealed the following "If Backgrounds are unacceptable, the ABX Micros 60 automatically performs a Second and Third count. If the counts are still unacceptable, perform a Concentrated Cleaning. Run another Startup. If the second Startup fails, call ABX Technical Support". 3. Review of the laboratory's startup logs from March 20, 2023 revealed the laboratory performed six (6) Startup checks from 3:57 pm through 4:06 pm with documentation of the status as "Failed". 4. Further review of the startup logs from March 20, 2023 revealed the background counts exceeded the acceptable parameter limits for the six (6) startup checks identified above. 5. Review of the laboratory's patient test records revealed the following three (3) patients were performed with no documentation of troubleshooting or maintenance performed prior to patient testing: a) Patient 25957: Complete Blood Count (CBC) performed at 4:23 pm b) Patient 6668: Complete Blood Count (CBC) performed at 4:25 pm c) Patient 7923: Complete Blood Count (CBC) performed at 5:06 pm 6. In interview on November 30, 2023 at 3: 45 pm, Personnel 2 confirmed the identified patients above were resulted after background checks failed multiple times with no documentation of troubleshooting by the laboratory. |
| **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 observation by surveyor, review of the manufacturer instructions and laboratory calibration records, and interview with personnel, the laboratory failed to perform calibrations as required by the manufacturer in 2022 and 2023 for the Horiba Medical ABX Micros 60 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on November 30, 2023 at 1:30 pm revealed the laboratory utilizes the Horiba Medical ABX Micros 60 Hematology analzyer for the testing of Complete Blood Counts (CBC). 2. Review of the Horiba Medical ABX Micros 60 user manual |

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| | revealed that calibration procedures are to be performed every six (6) months per manufacturer instructions. 3. Review of the laboratory's calibration records from 2022 and 2023 revealed the laboratory did not perform a calibration in April 2022 and September 2023. 4. In interview on November 30, 2023 at 2:52 pm, Personnel 2 confirmed the Horiba ABX Micros 60 six (6) month calibrations were not performed as required. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy and temperature records and interview with personnel, the laboratory failed to have documentatioof n of corrective action performed when the room temperature was not maintained between 18 - 25 degrees celsius per laboratory policy for sixteen (16) of five hundred seventy nine (579) days reviewed. Findings: 1. Review of the laboratory general maintenance policy under "Room temperature/Humidity" revealed "Document corrective action: If temperature deviates slightly, adjust thermostat accordingly. If temperature indicates the integrity of stored items may be in jeopardy, move contents to another monitored storage facility and have unit repaired". 2. Review of the laboratory's room temperature logs from May 2022 through November 2023 revealed the following sixteen (16) of five hundred seventy nine (579) dates reviewed had room temperature readings outside the laboratory's acceptable range of 18 - 25 degrees celsius: a) June 23, 2022: documented room temperature of 26 degrees celsius b) July 21, 2022: documented room temperature of 26 degrees celsius c) July 22, 2022: documented room temperature of 26 degrees celsius d) July 25, 2022: documented room temperature of 26 degrees celsius e) July 26, 2022: documented room temperature of 26 degrees celsius f) July 27, 2022: documented room temperature of 26 degrees celsius g) July 28, 2022: documented room temperature of 26 degrees celsius h) July 29, 2022: documented room temperature of 26 degrees celsius i) August 8, 2022: documented room temperature of 26 degrees celsius j) August 29, 2022: documented room temperature of 26 degrees celsius k) January 16, 2023: documented room temperature of 26 degrees celsius l) January 20, 2023: documented room temperature of 26 degrees celsius m) April 28, 2023: documented room temperature of 26 degrees celsius n) July 7, 2023: documented room temperature of 27 degrees celsius o) September 5, 2023: documented room temperature of 26 degrees celsius p) September 6, 2023: documented room temperature of 29 degrees celsius 3. In interview on November 30, 2023 at 4:09 pm, Personnel 2 confirmed the laboratory did not have documentation of corrective actions for unacceptable room temperatures for the dates identified above. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2) |

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, review of laboratory policy and quality control records and interview with personnel, the laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Hematology testing as required by laboratory policy. Findings: 1. Observation by surveyor during the laboratory tour on November 30, 2023 at 1:30 pm revealed the laboratory utilizes the Horiba Medical ABX Micros 60 analyzer along with Horiba Medical Minotrol 16 quality control (QC) for Complete Blood Count (CBC) testing. 2. Review of the laboratory Quality Control and Assessment policy under "Three Control Protocol" revealed the following: a) Reject the run if: * All levels are outside of 2 SD of the established mean * Two of three levels are outside of 2 SD (2 of 3-2S) * The same level is out of 2 SD and within 3 SD on two consecutive runs (2-2S) b) If the run is rejected: * Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient results. c) If the run is rejected: * Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient results. * If after rerun, the controls are out of acceptable limits, check the following variables: expiration date of reagents, change in lot numbers of controls or reagents, date of last calibration, and maintenance procedures. * If control values are still unacceptable, troubleshoot according to the manufacturer's guidelines. * If the situation persists, do not run patient samples. Send specimens to the appropriate reference laboratory. * When the situation is corrected and controls are again acceptable, patient testing may resume and results may be reported Always document any corrective actions taken on the Corrective Action Log for followup review. 3. Review of the quality control (QC) records for the Horiba ABX Micros 60 Hematology analyzer revealed the laboratory did not take corrective action when QC results were unacceptable for the following two (2) of six (6) months reviewed in 2023: a) October 17, 2023 at 08:32 am: High level quality control for platelets reported as 562 H (no documentation of rerun of high control) b) October 19, 2023 at 08:33 am: High level quality control for platelets reported as 564 H (no documentation of rerun of high control) c) October 24, 2023 at 08:39 am: High level quality control for platelets reported as 597 H (no documentation of rerun of high control) d) October 25, 2023 at 08:45 am: High level quality control for platelets reported as 585 H (no documentation of rerun of high control) e) October 26, 2023 at 08:44 am: High level quality control for platelets reported as 596 H (no documentation of rerun of high control) f) October 27, 2023 at 08:26 am: High level quality control for platelets reported as 593 H (no documentation of rerun of high control) g) October 30, 2023 at 08:30 am: High level quality control for platelets reported as 610 H (no documentation of rerun of high control) h) October 31, 2023 at 08:39 am: High level quality control for platelets reported as 608 H (no documentation of rerun of high control) i) November 1, 2023 at 08:57 am: High level quality control for platelets reported as 629 H (no documentation of rerun of high control) j) November 2, 2023 at 08:35 am: High level quality control for platelets

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| | reported as 598 H (no documentation of rerun of high control) k) November 3, 2023 at 08:55 am: High level quality control for platelets reported as 636H (no documentation of rerun of high control) l) November 21, 2023 at 08:46 am:High level quality control for platelets reported as 586H (no documentation of rerun of high control) m) November 22, 2023 at 08:29am:High level quality control for platelets reported as 587H (no documentation of rerun of highcontrol) n) November 27, 2023 at 09:07am: High level quality control for platelets reported as 601H (no documentation of rerun of highcontrol) o) November 28, 2023 at 09:11 am:High level quality control for platelets reported as 602H (no documentation of rerun ofhighcontrol) 4. In interview on November 30, 2023 at 3:48 pm, Personnel 2 confirmed the high level quality control for platelets was not rerun as required by laboratory policy for the identified dates above. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of laboratory policy, maintenance, quality control, temperature, and patient test records as well as interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to ensure the daily background checks for the Horiba Medical ABX Micros 60 analzyer were within the manufacturer's parameter limits prior to patient testing for one (1) of six (6) months reviewed in 2023. Refer to D5431. 2. The laboratory failed to perform calibrations as required by the manufacturer in 2022 and 2023 for the Horiba Medical ABX Micros 60 analyzer. Refer to D5437. 3. The laboratory failed to have documentatioof n of corrective action performed when the room temperature was not maintained between 18 - 25 degrees celsius per laboratory policy for sixteen (16) of five hundred seventy nine (579) days reviewed. Refer to D5781. 4. The laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Hematology testing as required by laboratory policy. Refer to D5783. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy and records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel |

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| | performed test methods as required. Findings: 1. The laboratory failed to ensure the daily background checks for the Horiba Medical ABX Micros 60 analzyer were within the manufacturer's parameter limits prior to patient testing for one (1) of six (6) months reviewed in 2023. Refer to D5431. 2. The laboratory failed to perform calibrations as required by the manufacturer in 2022 and 2023 for the Horiba Medical ABX Micros 60 analyzer. Refer to D5437. |
| **D6021** | 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5793. |
| **D6024** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(7)<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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to have documentatioof n of corrective action performed when the room temperature was not maintained between 18 - 25 degrees celsius per laboratory policy for sixteen (16) of five hundred seventy nine (579) days reviewed. Refer to D5781. 2. The laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Hematology testing as required by laboratory policy. Refer to D5783. |
| **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 |

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| | 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 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 review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure the daily background checks for the Horiba Medical ABX Micros 60 analzyer were within the manufacturer's parameter limits prior to patient testing for one (1) of six (6) months reviewed in 2023. Refer to D5431. 2. The laboratory failed to perform calibrations as required by the manufacturer in 2022 and 2023 for the Horiba Medical ABX Micros 60 analyzer. Refer to D5437. |
| **D6043** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(5)<br><br>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy and records and interview with personnel, the Technical Consultant failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to have documentatioof n of corrective action performed when the room temperature was not maintained between 18 - 25 degrees celsius per laboratory policy for sixteen (16) of five hundred seventy nine (579) days reviewed. Refer to D5781. 2. The laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Hematology testing as required by laboratory policy. Refer to D5783. |