| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D1038982 | 12/15/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Medical Specialists Of Texarkana | 1002 Texas Blvd Suite 201, Texarkana, 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** | An onsite survey conducted 12/15/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. |
| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory failed to test proficiency testing samples the same number of times that it routinely tests patient samples for five out of five samples reviewed for hematology PT event three in 2022. The findings include: 1. Review of the laboratory policy titled "Proficiency Testing" stated the following: "Laboratory personnel are to perform proficiency testing in the same manner as patient specimens." 2. Review of proficiency testing analytical records for the hematology/coagulation 2022 event 3 had the following PT specimens that were ran multiple times: HEM-11 - ran 3 times HEM-12 - ran 5 times HEM-13 - ran 4 times HEM-14 - ran 3 times HEM-15 - ran 3 times Surveyor queried testing person (TP) 2, on 12/15/2022 at 11:30 hours in the laboratory, as to why they were run multiple times, and do they test patients in the same manner. TP2 stated they ran it multiple times to obtain an average value for test submission, and that patients were only run once before they were resulted. 3. In an interview on 12/15/2022 at 11:32 hours, in the laboratory, the laboratory director confirmed that the laboratory had not tested the PT samples the same number of times that it routinely tested patients. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a) |

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| | A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory policy, quality control (QC) records, laboratory documents, and confirmed in an interview, the laboratory failed to follow its own policy for QC troubleshooting on the Cell-Dyn Emerald hematology analyzer for 3 of 28 corrective action events reviewed in October and November 2022. The findings include: 1. Review of the laboratory policy titled "Quality Control Policy" section "Acceptable Limits" stated the following: "D. If the control results indicate a problem, appropriate actions must be taken and documented in the remedial action log. 1. Re-run the same control sample a. If the result is acceptable, patient samples can be tested and results reported if patient data analysis proves acceptable; if patent data is unacceptable, consult the lab director or clinical consultant for advice. 2. If control sample is not acceptable, open a fresh vial of control material and re-test a. If the result is acceptable, patient samples can be tested and results reported. b. If the control result is not acceptable: 1. Check all reagents for signs of deterioration and/or contamination 2. Check instrument maintenance logs to be sure that instrument service is up to date. 3. Re-calibrate and re-run controls a. if result is acceptable, patient samples can be tested and results reported if patient data analysis proves acceptable; if patient data analysis is unacceptable, consult with the lab director or clinical consultant for recommendations. b. If control result is unacceptable, contact manufacturer of control material to see if there has been any widespread reports of problems with the given lot # and contact manufacturer of instrument for technical assistance. .." 2. Review of the laboratory document titled "CBC Cell-Dyn Daily QC Results" had the following corrective action documentation for October and November 2022: Date - Corrective action documentation 10/20 - "could not get high control to work" High control level ran 5 times; Hgb never came within acceptable limits 10/25 - "ran all 3 controls again 'till they were ok" Normal control level ran 3 times High control level ran 3 times 11/29/22 - "ran until it worked only 2 ok" Low control level ran 3 times; MCV and PLT out of acceptable limits High control level ran 5 times 3. In an interview on 12/15/2022 at 12:50, in the laboratory, the laboratory director confirmed that the laboratory was not following its policy on QC troubleshooting. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review laboratory quality control (QC) records, laboratory policy, patient test records, and confirmed in interview, the laboratory failed to remediate 11 of 11 |

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| | patients to the last acceptable quality control for QC failures, on the Cell Dyn hematology analyzer that could not be resolved with repeat testing documented in October 2022. The findings include: 1. Review of the laboratory document titled "CBC Cell-Dyn Daily QC Results" had the following QC events that could not be resolved with repeat testing in October 2022: 10/19/2022: "Checked values and did a bleach clean. Worked after." Surveyor queried the laboratory director for a policy with instructions for patient remediation after QC events that could not be resolved with repeat testing and none was provided. 2. Review of patient records had the following 11 patients with CBC testing performed since the last acceptable QC on 10 /18/2022: Patient ID: 1000758 1002019 1003478 1000119 2006417 2010250 2015312 2013906 1000034 1002522 2005446 3. In an interview on 12/15/2022 at 12: 50 pm, in the laboratory, the laboratory director confirmed that patient remediation had not occurred for the above patients for QC failures that could not be solved with repeat testing. |