| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D0904183 | 03/25/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gigi Wood Davis, Do Family Practice | 1010 Wayne Rd, Suite 100, Savannah, TN | |

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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| **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 observation of the laboratory, review of the manufacturer's instructions for use, the laboratory's environmental records, recorded humidity readings, and staff interview, the laboratory failed to ensure it monitored humidity according to the manufacturer's requirements for 12 of 18 months reviewed for 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 03/25/24 at 8:20 am revealed the Sysmex XP 300 instrument used for performing patient testing for Complete Blood Count with White Blood Cell Differential (CBC w/Diff). 2. The manufacturer's stated operating humidity range was 30 to 85%. 3. Review of the laboratory's environmental records revealed a humidity range of 10-80% for the months of 11/2022, 12/2022, 01/2023, 03/2023, 04/2023, 09/2023, 10/2023, 11/2023, 11/2023, 12/2023, 01/2024, 02/2024 and 03/2024. 4. The laboratory director stated during interview on 03/25/24 at 2 pm that the laboratory had somehow used the wrong form for monitoring humidity for several months since November 2022. This confirmed the survey findings. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d) |

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| | Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and staff interview, the laboratory failed to ensure capillary tubes used for collecting patient fingerstick samples for CBC w/Diff had not expired on the date of the survey (03/25/24.) 1. Observation of the laboratory on 03/25/24 at 8:20 am revealed capillary tubes used for collection of CBC samples that were expired. The observed expiration dates ranged from 9/30/2020 to 12/31 /2023. 2. The lead testing person confirmed during interview on 03/25/24 at 8:50 am that the capillary tubes used for collecting fingerstick samples for CBC were expired. |
| **D5461** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, staff interview during observation, and subsequent interview with the laboratory director, the laboratory failed to perform QC on the Sysmex XP 300 CBC instrument after changing reagents. 1. Observation of the laboratory on 03/25/24 at 8:20 am revealed the Sysmex XP 300 instrument used for performing patient testing for CBC w/Diff. The lead testing person was asked to describe when quality control was performed. She stated each morning before patient testing. When asked if QC was performed after changing reagents she stated they did not perform QC after reagent changes. 2. The laboratory director confirmed the survey findings during interview on 03/25/24 at 2 pm. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of the manufacturer's QC package insert, the laboratory's QC ranges in the Medicus Laboratory Information System (LIS), Sysmex Insight QC records, and staff interview, the laboratory failed to ensure it verified the manufacturer's stated QC ranges for the hematocrit analyte before use on 03/04/24 for lot number 40510710 (one of fifteen lots reviewed). The findings include: 1. Observation of the laboratory on 03/25/24 at 8:20 am revealed the Sysmex XP 300 instrument used for performing patient testing for Complete Blood Count with White Blood Cell Differential (CBC w/Diff). The current QC lot observed was 4051 (levels low-40510710, normal-40510711, and high-40510712). 2. The manufacturer QC range for hematocrit for lot 40510710 was 16.3 +/- 1.5. 3. The QC range entered in the Medicus LIS system for hematocrit for lot 40510710 was 16.6 +/- 1.5. 4. Sysmex Insight QC records revealed the laboratory put lot 40510710 in use on 03/04 /24. 4. The laboratory director confirmed the survey findings during an interview on 03 /25/24 at 2 pm. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's QC data, lack of documentation, and staff interview, the laboratory failed to follow the laboratory policy for review of quality control data for the period from 01/03/23 to 01/06/23 for QC lot 2277 (low, normal and high levels). The findings include: 1. Review of the laboratory's Sysmex Insight QC report for lot 2277 (levels low, normal and high) revealed the lots were used in January 2023 from 01/03/23 to 01/06/23. 2. There was no documented review of the QC data for lot 2277 for the period in January 2023 when the lot number was in use. 3. The laboratory director confirmed during interview on 08/25/24 at 2 pm that the laboratory failed to print and review the QC data for lot 2277 in January 2023 after changing lot numbers on 01/09/23. |