Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0904183	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier Gigi Wood Davis, Do Family Practice	**Street Address, City, State** 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Sysmex XP300 manufacturer instructions for use, document request, and interview with the lab director, the laboratory did not monitor the room temperature or humidity for operation of the Sysmex XP300 complete blood count (CBC) instrument in 2020, 2021, or 2022. The findings include: 1. Observation of the laboratory on 08/24/2022 at 8:20 am revealed the Sysmex XP300 (serial # B6106) in use for patient testing for complete blood count (CBC). 2. Review of the Sysmex XP300 manufacturer instructions for use revealed the instrument has an operating temperature of 15-30 degrees Celsius and a humidity range of 30-85%. 3. Request on 08/24/2022 at 9:30 am to the lab director for temperature and humidity monitoring records revealed no records were available. 4. Interview on 08/24/2022 at 3:30 pm with the lab director confirmed the lab did not monitor the room temperature or humidity in the area where the Sysmex XP300 CBC instrument was being used in 2020, 2021 and 2022.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system

	must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of verification of performance specifications (VoPS) studies for the Sysmex XP300, review of patient test records, interview with the lab director, and review of an email communication, the laboratory failed to verify the manufacturer normal ranges for the Sysmex XP 300 complete blood count (CBC) instrument in 2020, 2021 and 2022, with approximately 5,147 patient CBCs performed since testing began. The findings include: 1. Review of the VoPS studies performed for the Sysmex XP300 CBC instrument revealed a normal range (reference range) study was not performed. 2. Review of patient test records revealed the first patient was reported on 06/23/2020 (specimen id 2736). 3. During an interview with the lab director on 08/24/2022 at 3:30 pm the lab director stated the laboratory uses the manufacturer's normal range and confirmed that a normal range study was not performed to verify the manufacturer ranges were appropriate for the laboratory's patient population. The laboratory began testing patients on 06/23/2020 until date of survey on 08/24/2022. 4. Review of an email communication received on 08/31/2022 at 10:01 am revealed the laboratory performed approximately 5,147 patient CBCs since testing began on 06/23/2020.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of refrigerator temperature records, the laboratory procedure manual, quality assessment records and interview with the laboratory director, the laboratory failed to follow the written quality assurance procedure in May 2021, resulting in storage of complete blood count (CBC) controls that were outside the acceptable range for eight of nineteen days in May 2021. The findings include: 1. Observation of the laboratory on 08/24/2022 at 8:20 am revealed a refrigerator used for storing CBC controls. 2. Review of the refrigerator temperature log/record for May 2021 revealed an acceptable storage range of 2-8 degrees Celsius. Eight of nineteen days had temperatures recorded that were outside the acceptable temperature range. No corrective action for the out of range temperatures was performed. 3. Review of the laboratory's procedure titled "Quality Assurance Plan" revealed that the laboratory would identify problems and apply corrective actions. 4. Review of the May 2021 quality assurance checklist revealed that "All necessary remedial action was performed and documented." 5. Interview with the laboratory director on 08/24/2022 at 3:30 pm confirmed the laboratory failed to perform

	corrective action for refrigerator temperatures that were outside the acceptable range, resulting in the storage of CBC quality control material outside acceptable ranges for eight of nineteen days in May 2021.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, verification of performance specification (VoPS) records for the Sysmex XP300 and interview with the laboratory director, the laboratory director failed to ensure VoPS studies for the Sysmex XP300 were adequate for patient complete blood count (CBC) testing beginning 06/23/2020 until the date of the survey on 08/24/2022. The findings include: 1. Observation of the laboratory on 08/24/2022 at 8:20 am revealed the Sysmex XP300 CBC instrument (serial #B6106) on the counter in use for patient testing. 2. Review of patient test records revealed the first patient CBC was reported on 06/23/2020 (specimen id 2736). 3. Review of VoPS records performed for the Sysmex XP300 revealed no evidence of review or approval by the laboratory director. 4. Interview with the lab director on 08/24/2022 at 3:30 pm confirmed the lab director failed to review and approve the VoPS studies for the Sysmex XP300 used for performing patient CBC testing. Patient testing began on 06/23/2020 until the date of the survey on 08/24/2022 without approved verification studies.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, record request, and interview with the laboratory director, the laboratory director failed to ensure an approved procedure manual was available to testing personnel for use of the Sysmex XP300 complete blood count (CBC) instrument from 06/23/2020 to the date of the survey on 08/24/2022. The findings include: 1. Observation of the laboratory on 08/24 /2022 at 8:20 am revealed the Sysmex XP300 CBC instrument (serial #B6106) on the counter in use for patient testing. 2. Review of patient test records revealed the first patient CBC was reported on 06/23/2020 (specimen id 2736). 3. Request to the lead testing person on 08/24/2022 at 11:45 am for an approved procedure for the use of the

	Sysmex XP300 CBC instrument revealed no approved procedure was available. 4. Interview with the lab director on 08/24/2022 at 3:30 pm confirmed the lab director failed to ensure an approved procedure manual was available to testing personnel for the use of the Sysmex XP 300 CBC instrument. Patient testing began on 06/23/2020 until the date of the survey on 08/24/2022.