Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0694089	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier Moffitt Health Center	**Street Address, City, State** 118 College Drive, Box 5066, Hattiesburg, MS	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for ASI Rapid Plasma Reagin (RPR) test for syphilis, RPR quality control logs from 4/1/2022 through 9/18/2023, and interview with the laboratory director on 9/20/2023 at 3:45 p.m., the laboratory failed to follow manufacturer's instructions for RPR testing for 155 of 155 testing days when needle cleaning, needle accuracy check, and rotator revolutions per minute (rpm) were not documented. Findings include: 1. Manufacturer's instructions for ASI Rapid Plasma Reagin (RPR) test for syphilis state in Handling and Procedural Notes, "In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples. The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. The needle should deliver 60 +/- 2 drops of antigen suspension per milliliter (ml) when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 +/- 1 drops are obtained in 0.5 ml." 2. Manufacturer's instructions for ASI RPR test for syphilis state in the Assay Protocol, "Place the card [with carbon antigen suspension added to patient sample] on an automatic rotator and cover to maintain humidity. Rotate at 100 +/- 5 rpm for 8 minutes." 3. On the day of the survey, 9/20/2023, there was no documentation available for review of needle cleaning, needle accuracy check, or rotator rpm on 155 of 155 RPR testing days from 4/1/2022 through 9/18/2023. 4. In

	an interview on 9/20/2023 at 3:45 p.m., the laboratory director confirmed RPR testing began on 4/1/2022, and that there was no documentation of needle cleaning, needle accuracy check, or rotator rpm each day of testing from 4/1/2022 through 9/18/2023. 5. Review of RPR quality control logs from 4/1/2022 through 9/18/2023 revealed there were 155 testing days for RPR testing during this time frame. The laboratory's annual test volume for RPR testing was 520.
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: A. Based on review of quality control logs for ASI Rapid Plasma Reagin (RPR) test for syphilis from 4/1/2022 through 9/18/2023, interview with the laboratory director on 9/20/2023 at 3:30 p.m., and lack of documentation of verification of performance specifications, the laboratory failed to verify the manufacturer's performance specifications for qualitative testing, to include accuracy and precision, for ASI RPR testing for syphilis before patient testing began on 4/1/2022. Findings include: 1. Review of quality control records and confirmation by the laboratory director revealed patient RPR testing began on 4/1/2022. 2. On 9/20/2023 there was no documentation of verification of performance specifications, to include accuracy and precision, for ASI Rapid Plasma Reagin testing for syphilis available for review. 3. In an interview on 9/20/2023 at 3:30 p.m., the laboratory director confirmed verification of performance specifications for the ASI Rapid Plasma Reagin test was not performed before patient RPR testing began on 4/1/2022. 4. Review of RPR quality control logs from 4/1/2022 through 9/18/2023 revealed RPR testing was performed for 155 days during this time frame. The laboratory's annual test volume for RPR testing was 520. B. Based on review of quality control logs for Streck Sickledex qualitative solubility test kit for sickling hemoglobins from 4/29/2022 through 9/15/2023, interview with the laboratory director on 9/20/2023 at 3:30 p.m., and lack of documentation of verification of performance specifications, the laboratory failed to verify the manufacturer's performance specifications for qualitative testing, to include accuracy and precision, for Streck Sickledex test kit before patient testing began on 4/29/2022. Findings include: 1. Review of quality control logs from 4/29/2022 through 9/15/2023 and confirmation by the laboratory director revealed patient testing with the Streck Sickledex test kit began on 4/29/2022. 2. On 9/20/2023, there was no documentation of verification of performance specifications, to include accuracy and precision, for the Streck Sickledex test available for review. 3. In an interview on 9/20/2023 at 3:30 p.m., the laboratory director confirmed verification of performance specifications for the Streck Sickledex test was not performed before patient testing began on 4/29/2022. 4. Review of Streck Sickledex quality control logs from 4/29/2022 through 9/15/2023 revealed Streck Sickledex testing was performed for 88 days during this time frame. The laboratory's annual test volume for Streck Sickledex testing was 81.