Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0692409	11/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Alabama Health Services	7777 Highway 43 North, Mcintosh, AL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a tour of the Laboratory, a U.S. Food and Drug Administration (FDA) Recall Notice, and an interview with the Technical Consultant, the laboratory failed to enroll in an approved proficiency testing (PT) program for tests performed on the Abbott i-STAT Chemistry 8 (CHEM8) cartridge (this cartridge contains regulated moderate-complexity tests). This was noted from February 18, 2020 (FDA Class 2 Device Recall for i-STAT CHEM8) to the date of the current survey (November 2021). The findings include: 1. A tour of the Laboratory revealed the use of i-STAT CHEM8 cartridges. This cartridge includes the following analytes: a) Sodium b) Potassium c) Chloride d) Carbon dioxide e) Calcium f) Glucose g) Blood Urea Nitrogen h) Creatinine 2. A review of the FDA recall notice revealed the test was classified as waived until the date of the recall on February 18, 2020. After the recall, the FDA categorized CHEM8 tests as moderate complexity, and capillary whole blood was no longer an acceptable sample type. 2. During an interview on 11/04/2021 at 2:20 PM, the Technical Consultant (TC) confirmed the above findings. Also, the TC confirmed the laboratory continued to use the i-STAT CHEM8 for daily patient testing after the recall, and did enroll in an approved PT program.

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 a tour of the Laboratory, a U.S. Food and Drug Administration (FDA) Recall Notice, a lack of verification of performance documents, and an interview with the Technical Consultant, the laboratory failed to demonstrate that it can obtain results comparable to specifications established by the manufacturer for accuracy, precision, reportable range, and reference intervals. This was noted from February 18, 2020 (FDA Class 2 Device Recall for i-STAT CHEM8) to the date of the current survey (November 2021). The findings include: 1. A tour of the Laboratory revealed the use of i-STAT CHEM8 cartridges. This cartridge includes the following analytes: a) Sodium b) Potassium c) Chloride d) Carbon dioxide e) Calcium f) Glucose g) Blood Urea Nitrogen h) Creatinine 2. A review of the FDA recall notice revealed the test was classified as waived until the date of the recall in February 18, 2020. After the recall, the FDA categorized CHEM8 tests as moderate complexity, and capillary whole blood was no longer an acceptable sample type. 3. The laboratory had no documentation of verification of performance. 4. During an interview on 11/04/2021 at 02:20 PM, the Technical Consultant confirmed the laboratory had not performed verification of performance since the FDA recall that changed the complexity from waived to moderate.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Quality Control (QC) records for the i-STAT, a U.S. Food and Drug Administration (FDA) Recall Notice, the Procedure Manual, and an interview with the Technical Consultant, the laboratory failed to run controls at least once each day patient testing was performed, or implement an Individualized Quality Control Plan (IQCP) for the i-STAT Chemistry 8 (CHEM8) cartridge. This was noted from February 18, 2020 (FDA Class 2 Device Recall for i-STAT CHEM8) to the date of the current survey (November 2021). The findings include: 1. A review of the Quality Control records for the i-STAT revealed after the FDA recall in February 2020, the laboratory continued to run QC as if the test was classified as waived. One Level (Level 1) was run monthly. Patient testing continued to be performed daily from February 2020 to November 2021 (day of survey). 2. A review of the FDA recall

	notice revealed the test was classified as waived until the date of the recall on February 18, 2020. After the recall FDA categorized CHEM8 tests as moderate-complexity, and capillary whole blood was no longer an acceptable sample type. 3. A review of the procedure manual revealed, "i-STAT Meter Quality Control (Frequency) 1. One level of control will be tested upon receipt of cartridges and at least once a month for each additional month the lot number is in use...". 4. During an interview on 11/04/2021 at 12:30 PM, the Technical Consultant confirmed the laboratory performed the Level 1 control once a month for the i-STAT CHEM8, and patient testing was performed daily.