Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0692409	01/20/2026
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of the Piccolo Xpress Quick Reference Guide, and interviews with the Technical Consultant (TC), the Clinical Director (CD) and Testing Personnel 1 (TP1), the laboratory failed to follow the manufacturer's instructions to use Lithium Heparin for the Piccolo testing. The surveyor noted the Sodium Heparin tubes in the blood collection area which may have been used for the Piccolo patient testing. Findings Included: 1. During a tour of the facility on 01-20-2026 at 11:27 AM, surveyor observation revealed Sodium Heparin tubes were available for use in the Piccolo testing. 2. Review of the Piccolo Xpress Quick Reference Guide on page 9 revealed manufacturer's requirement as follows, " ... Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." 3. Interviews with TC, CD and TP1 revealed the Sodium Heparin tubes may have been utilized for patient testing when the Piccolo testing went live. The CD stated that during the analyzer training in another location, the Piccolo trainer did not emphasize the necessity of using the Lithium Heparin for testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the

	overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the reviews of the CLIA Standard Operating Manual, Policy and Procedure Manual, Personnel and Evaluation records, Proficicency Testing records, Piccolo Quick Reference Guide, the laboratory failed to monitor and assess the overall quality of its pre-analytical and analytical systems and be able to provide appropriate corrective actions when problems are identified. Refer to D1001, D5423, D6007, D6088, D6120, D6142, D6171.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the Piccolo Xpress Quick Reference Guide and interviews with the Technical Consultant (TC) and the Clinical Director (CD), the laboratory failed to provide documentation of accuracy, precision, reportable range, reference intervals, specificity and sensitivity for a modified test system, Piccolo Xpress. Surveyor noted the missing documentation occurred from the date of the last survey (08-16-2023) to the date of the current survey (01-20-2026). Findings included: 1. Review of the Piccolo Xpress Quick Reference Guide on page 9 revealed the following manufacturer's instruction, " ... Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." 2. Interview with the TC and CD revealed all TP listed on the CMS 209 (Laboratory Personnel Report) were not aware of the requirement and had been using any green top tubes with the Sodium or Lithium Heparin anticoagulant. "Modified by the laboratory" means any change to the assay that could affect its performance specifications. A modified test (including modifications in its intended use) is considered uncategorized for CLIA and therefore becomes a high complexity test. 3. TC and CD confirmed the above findings during the exit conference on 01-20-2026 at 3 PM.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Based on reviews of the Laboratory Director's (LD) duties and responsibilities, the Policy and Procedure (P&P) manual, and interviews with the Technical Consultant (TC) and the Clinical Director (CD), the LD failed to ensure the testing system developed and utilized in the laboratory provided quality test performance from preanalytical, analytical to post analytical testing. The surveyor noted there was no written procedure reviewed and signed by the LD when the Piccolo test system was modified to high complexity testing. The findings include: 1. A review of the LD duties and responsibilities from the CLIA Standard Operating Manual revealed the LD is responsible for ensuring the quality of patient testing in all phases of testing. 2. A review of the P&P manual revealed a lack of written procedure for the modified Piccolo testing reviewed and signed by the LD. 3. The TC and CD confirmed the above findings during the exit conference on 01-20-2026 at 3 PM.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on reviews of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, the Laboratory Director failed to ensure the laboratory was enrolled in a PT program for testing performed on the modified Piccolo test system. The surveyor noted the failure to participate in a PT program occurred from the date of the last survey (08-16-2023) to the date of the current survey (01-20-2026). The findings include: 1. A review of the AAB-MLE PT records revealed a lack of PT documentation for testing performed on the modified Piccolo test system. 2. The TC and CD confirmed the above findings during the exit conference on 01-20-2026 at 3 PM.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the Personnel records listed on Form CMS-209 (Laboratory Personnel Report) and interview with the Technical Consultant (TC) and the Clinical Director (CD), the laboratory did not have a qualified Technical Supervisor (TS) who provided technical supervision in the Chemistry specialty for the modified Piccolo system. This was noted for the patient testing performed on the modified Piccolo system from 2023-2025. Findings included: 1. Based on review of the Personnel records, the laboratory could not provide documentation of credentials for a qualified TS in the Chemistry specialty where the modified Piccolo testing was performed from

	September 2023 through January 2026. 2. Interview with the TC and CD on 01-20-2026 at 3 PM confirmed the document and credentials needed to qualify a TS were not available for review.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of personnel competency records and an interview with the Technical Consultant (TC) and the Clinical Director (CD), the Technical Supervisor failed to assess and document the annual competency of individuals responsible for the high complexity testing on the modified Piccolo system. This was noted on three of the three Testing Personnel (TP) listed on the CMS 209 Form (Laboratory Personnel Report) from September 2023 through January 2026. The findings include: 1. A review of personnel records listed on the CMS 209 (Laboratory Personnel Report) revealed the TS failed to perform and document the annual competency assessments for TP 1-3 from 2023-2025. 2. During the exit conference on 01-20-2026 at 3 PM, the TC and the CD confirmed the above findings.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the Personnel records listed on Form CMS-209 (Laboratory Personnel Report) and interview with the Technical Consultant (TC) and the Clinical Director (CD), the laboratory did not have a qualified General Supervisor (GS) who will be responsible for the supervision of Testing Personnel performing testing on the modified Piccolo system from 2023-2025. Findings included: 1. Based on review of the Personnel records, the laboratory could not provide documentation of credentials for qualified GS employed in the laboratory from September 2023 through January 2026. 2. Interview with the TC and CD on 01-20-2026 at 3 PM confirmed the document and credentials needed to qualify a GS were not available for review.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a

	doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the Testing Personnel (TP) listed on Form CMS-209 (Laboratory Personnel Report) and interview with the Technical Consultant (TC) and the Clinical Director (CD), the laboratory failed to provide academic credentials to qualify three of the three TP performing high complexity testing on the modified Piccolo system from 2023-2025. Findings included: 1. Based on review of the TP records, the laboratory could not provide documentation (academic credentials) to show TP 1-3 were qualified to perform high complexity testing. 2. Interview with the TC and CD on 01-20-2026 at 3 PM confirmed the documents needed to qualify all TP were not available for review.