Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2164936	(X3) Date Survey Completed 05/18/2022
Name of Provider or Supplier Univ South Alabama Mitchell Cancer Springhill	**Street Address, City, State** 101 Memorial Hospital Drive Suite 302, Mobile, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the poorly organized CAP (College of American Pathologists) proficiency testing (PT) records and an interview with the General Supervisor, the laboratory failed to ensure the Laboratory Director or Designee signed the attestation statements for four of four 2022 PT surveys. The findings include: 1. A review of the poorly organized CAP PT records revealed no signature by the Laboratory Director or Designee on the attestation statements for the following 2022 surveys: A) FH9-A [Hematology] B) RT4-A [Reticulocyte Count] C) VPBS-A [Virtual Peripheral Blood Smear] D) AQI-A for the Basic Chemistry profile (Chem 8) performed on the Abbott I-Stat 2. A review of the instructions on the CAP attestation statement revealed, "The Laboratory Director or Designee and the testing personnel must sign this form." [The surveyor noted the word "sign" was in bold print and underlined.] 3. During an interview on 5/18/2022 at 11:40 AM, the surveyor reviewed the PT records with the General Supervisor, and confirmed the above noted findings. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on a review of the poorly organized CAP (College of American Pathologists) Proficiency Testing (PT) records and an interview with the General Supervisor, the laboratory failed to perform and document reviews on one of one 2022 Chemistry surveys. The findings include: 1. A review of the poorly organized CAP PT records revealed no results (scores) for the 2022 AQI-A survey. A review of the I-Stat instrument printouts for the Chem 8 (Basic Chemistry Profile) revealed the PT testing was performed on 3/10/2022, however there was no evidence the laboratory had printed or reviewed the survey scores, as of the day of the survey on 5/18/2022. 2. During an interview on 5/18/2022 at 11:40 AM, the surveyor reviewed the PT records with the General Supervisor, and confirmed the above noted findings. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the poorly organized CAP (College of American Pathologists) proficiency testing (PT) records and an interview with the General Supervisor, the laboratory failed to perform and document evaluations and reviews for non-regulated analytes on Hematology surveys. This was noted on two of four 2021-2022 Hematology surveys, one of one 2022 Reticulocyte surveys, and three of four 2021-2022 Virtual Peripheral Blood Smear (VPBS) surveys. The findings include: 1. A review of the poorly organized CAP PT records revealed the laboratory had failed to obtain the results (scores) for completed surveys, or failed to evaluate ungraded analytes on the following survey events: A) 2021 FH9-A and 2022 FH9-A [Hematology]-The laboratory had printed the results, however there was no evaluation of the ungraded analytes. B) 2022 RT4-A [Reticulocyte Count]: The survey was performed 1/24/2022, however there was no documentation of the survey results or review. C) 2021 VPBS-A and -B [Virtual Peripheral Blood Smear]: There was no documentation of the survey results or review. D) 2022 VPBS-A: The results were printed, however there was no evaluation of the ungraded analytes. [Note: All results on VPBS surveys are ungraded Educational Challenges (Code 26) and require internal evaluations.] 2. During an interview on 5/18/2022 at 11:40 AM, the surveyor reviewed the PT records with the General Supervisor, and confirmed the above noted findings. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on a review of the Abbott I-Stat CHEM 8 (Basic Chemistry Profile) quality control (QC) records, "Patient Report Preview" notes (provided in a 5/19/2022 e-mail) and an interview with the General Supervisor, the laboratory failed to perform monthly QC as required by the IQCP (Individualized Quality Control Plan). This was noted to occur three out of twelve months in 2021. The findings include: 1. A review of the IQCP for the Abbott I-Stat CHEM 8 cartridges revealed two levels of external QC should be performed with each new lot number or shipment, each month, and as needed for troubleshooting. 2. A review of the 2021 monthly records for the Abbott I-Stat CHEM 8 revealed the laboratory failed to perform and document QC in July, August, and December 2021. 3. During an interview on 5/18/2022 at 3:00 PM, the General Supervisor stated she was on leave the above months in 2021, and the testing personnel did not do the I-Stat CHEM 8 QC. The surveyor then asked how many patient tests were performed during those months; the Supervisor stated she would forward this information to the CLIA office. 4. A review of an e-mail from the General Supervisor dated 5/19/2021 at 11:33 AM revealed "Patient Report Preview" notes with CHEM 8 results on patients as follows: A) July 2021: 29 patients performed 7/1-7/28/2021; B) August 2021: 33 patients performed 8/2-8/31/2021; and C) December 2021: 10 patients performed 12/2-12/29/2021. .
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 a review of quality assurance (QA) documentation and an interview with the General Supervisor, the surveyor determined the laboratory failed to perform effective quality assessment reviews to identify and correct problems cited during the survey process in the analytical systems. The findings include: 1. A review of the QA records revealed the laboratory documented monthly QA reviews on a checklist, however the laboratory failed to identify and correct problems cited during the survey, as follows: A) Proficiency Testing a) Failure to ensure the Laboratory Director or Designee signed the proficiency testing attestation statements. (Refer to D2009.) b) Failure to perform and document reviews on one of one 2022 Chemistry surveys (Refer to D5211.) c) Failure to perform and document evaluations and reviews for non-regulated analytes on Hematology surveys. (Refer to D5217.) B) Quality Control (QC) -Failure to perform monthly QC as required by the IQCP (Individualized Quality Control Plan) three out of twelve months in 2021. (Refer to D5445.) C) Personnel a) Failure to evaluate and document the performance of one of four testing personnel at least semiannually during the first year of patient testing. (Refer to D6053.) b) Failure to evaluate and document the performance of one of four testing personnel annually after the first year of patient testing. (Refer to D6054.) 3. During the exit summation on 5/18/2022 at 3:05 PM, the surveyor reviewed and confirmed the above noted findings with the General Supervisor and her Corporate Supervisor. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the

	performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #4, the Technical Consultant (also the Laboratory Director) failed to evaluate the performance of testing personnel at least semiannually during the first year of moderate-complexity patient testing. This was noted on one out of four testing personnel listed on the Form CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of the testing personnel records revealed the initial training for Testing Personnel #4 was on 2/8/2021, however there was no documentation of the semiannual competency evaluation due in August 2021. 2. During an interview on 05/18/2022 at 12:05 PM, Testing Personnel #4 confirmed she worked only when needed (PRN), had no set schedule, and had been unable to coordinate time with the Supervisor and Technical Consultant (also the Laboratory Director) for the competency evaluations to be performed. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #4, the Technical Consultant (also the Laboratory Director) failed to evaluate the performance of testing personnel annually after the first year of moderate-complexity patient testing. This was noted on one out of four testing personnel listed on the Form CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of the testing personnel records revealed the initial training for Testing Personnel #4 was on 2/8/2021, however there was no documentation of the annual competency evaluation due in February 2022. 2. During an interview on 05/18/2022 at 12:05 PM, Testing Personnel #4 confirmed she worked only when needed (PRN), had no set schedule, and had been unable to coordinate time with the Supervisor and Technical Consultant (also the Laboratory Director) for the competency evaluations to be performed. SURVEYOR ID#32558 Licensure and Certification Surveyor