Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2028603	11/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hoover Family Medicine	774 Shades Mountain Plaza, Hoover, 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 review of the test menu on tour with the testing personnel, a review of American Proficiency Institute (API) proficiency testing records, a review of the patient test log, and an interview with the testing personnel and technical consultant, the surveyor determined the laboratory failed to enroll in proficiency testing for serum hcg (human chorionic gonadotropin) testing in 2018 - 2020 (the survey review period). The findings include: 1. During the initial tour of the laboratory on 11/23 /2020 at 10:15 AM, the testing personnel stated serum hcg testing was performed using the Dectector hcg Combi Kit. The surveyor observed the combi kit on the shelf and asked the testing personnel again if serum was used to perform the testing. The testing personnel again stated serum and urine specimens were used to perform the testing with the kit observed. 2. The API proficiency testing records did not include any testing of serum hcg specimens. 3. A review of the type-written patient test log revealed from 2/14/2019 - 9/06/2019, seven (7) patient serum hcg tests were performed; and from 1/08/2020 - 7/08/2020, ten (10) patient serum hcg tests were performed. 4. During an interview on 11/23/2020 at 1:05 PM, the surveyor asked the testing personnel again if patient tests had been performed using serum samples with the hcg combi kit. The testing personnel stated a handful of tests had been done, all in

	2019, and none in 2020. The surveyor asked the testing personnel to review the patient test log. The testing personnel reviewed the log and confirmed serum hcg patient testing was also performed in 2020. 5. During the exit interview on 11/23 /2020, beginning at 1:10 PM, the surveyor asked the testing personnel about the enrollment in proficiency testing for serum hcg testing. The testing personnel stated the laboratory was not enrolled in proficiency testing for hcg tests, only for CBC (Complete Blood Count) testing. At 1:44 PM, the Technical Consultant stated serum hcg testing was send-out testing. The testing personnel stated the laboratory staff had performed the testing in-house on serum samples.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration records for the Beckman Coulter Act Diff 2, a review of the manufacturer's instructions, and an interview with the testing personnel, it was determined the laboratory failed to calibrate the instrument every six months, as stated was the usual policy; and further failed to run the quality control following a calibration to verify the accuracy of the calibration. This affected the survey review period from July 2018 to current survey date (11/23/2020). The findings include: 1. A review of the calibration records for the Act Diff 2 revealed documentation of calibration performed on 3/22/2019, ten months after the calibration performed on 5 /2018 (reviewed on the previous survey 6/12/2018). The next calibrations were performed on 9/11/2019 and 9/17/2019 and then 11/19/2020, exceeding one year. The calibration performed on 3/22/19 after 1:00 PM failed to include quality control testing after the calibration to verify the accuracy. 2. A review of the manufacturer's instruction revealed: "...17. Verify calibration by running 4C Plus cell control..." The laboratory's policy and procedure only outlined the procedure how to perform a calibration, but failed to include the frequency or when to calibrate. 3. During an interview on 11/23/2020 at 1:10 PM, the testing personnel stated the Act Diff is calibrated when "anything" is off, and usually every six months. The surveyor asked the personnel to review the policy and procedure and explain when the calibrations were to be performed. The testing personnel stated the procedure outlines how to do the calibration, but not why or the frequency. The testing personnel confirmed the more than one year lapse between 9/17/2019 and 11/19/2020, stating the laboratory was closed for a time during the pandemic (March 27 - May 11), and the calibration was not done when the laboratory reopened, May 11, 2020. When asked in quality control should be run after a calibration, the testing personnel answered, "Yes." The surveyor asked the personnel to review the calibration record, dated 3/22/19, for quality control testing. The testing personnel confirmed the quality controls were not run after the calibration, but could not explain why.

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 a review of the test menu on tour with the testing personnel, a review of the patient test log, a lack of documentation of quality control testing, and an interview with the testing personnel, the surveyor determined the laboratory failed to perform external quality control testing for serum hcg (human choriuonic gonadotropin) testing in 2018 - 2020 (the survey review period). The findings include: 1. During the initial tour of the laboratory on 11/23/2020 at 10:15 AM, the testing personnel stated serum hcg testing was performed using the Detector hcg Combi Kit. The surveyor observed the combi kit on the shelf and asked the testing personnel again if serum was used to perform the testing. The testing personnel again stated serum and urine specimens were used to perform the testing with the kit observed. The surveyor asked how often controls were run, and the testing personnel stated the controls were run "sporadically." After further discussion, the surveyor concluded the testing personnel was confusing external quality control testing with proficiency testing. 2. During an interview on 11/23/2020 at 1:05 PM, the surveyor asked the testing personnel if any external controls were run with the hcg combi kit. The testing personnel stated other than the internal quality control, no other quality control was run, nor was there an IQCP (Individualized Quality Control Plan). The testing personnel stated the problem will be corrected in the future, by not using a serum sample to perform the tests. 3. A review of the type-written patient test log for preganancy serum tests revealed at the top of the log, "NO CONTROL TO TEST." From 2/14/2019 - 9/06/2019, seven (7) patient serum hcg tests were performed; and from 1/08/2020 - 7/08/2020, ten (10) patient serum hcg tests were performed. At 1:07 PM, the testing personnel reviewed the patient test log and confirmed the patient testing was performed in-house.