Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1093662	02/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Health Concepts, Llc	1615 Bluff City Hwy, Bristol, TN	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: ========== Based on a review of the Laboratory's Calibration Verification records for the Hematology analyzer and upon interview with the Lead Testing Personnel and Laboratory Director determined the laboratory failed to ensure that calibration verification was performed at six month intervals for 2018 and 2019. The findings include: 1. A review of Calibration Verification records for the hematology analyzer revealed no calibration verification

	documented for 2018 and 2019, thus not being performed at 6 months intervals. 2. An interview with the Lead Testing Personnel and Laboratory Director at 2:30 p.m. on February 18, 2020 confirmed no documentation for calibration verifications could be located for the Hematology Analyzer for 2018 and 2019. ==========
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 review of patient CBC (Complete Blood Count) test audit which lacked CBC QC (Quality Control) documentation for 11/5/2018 and 6/26/2018 and patient Progesterone test audit which lacked 2 levels of acceptable QC for 2/6/2020 and interview with the Lead Testing Personnel and Laboratory Director, determined the laboratory failed to perform daily CBC and Progesterone QC prior to patient testing. The findings include: 1. Review of patient CBC test audit revealed no documentation of daily CBC QC being performed 11/5/2018 and 6/26/2018 on the Hematology Horiba-ABX analyzer prior to testing and reporting 2 patient results. 2. Review of patient Progesterone test audit revealed daily QC level 1 to be unacceptable on 2/6/2020 on the Chemistry Access 2 analyzer prior to testing and reporting 25 patient results. 3. Interview at approximately 2:30 p. m. February 18, 2020 with the Lead Testing Personnel and Laboratory Director confirmed the laboratory failed to perform daily CBC QC on 11/5/2018 and 6/26/2018 and 2 levels of acceptable Progesterone QC on 2/6/2020 prior to testing and reporting patient results. ==========
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: ========== Based on review of the Laboratory's Quality Assessment (QA) Plan, lack of Director review of QC and QA for May 2019 through January 2020, and an interview with the Lead Testing Personnel and Laboratory Director, determined the Laboratory Director did not ensure quality of laboratory services was maintained for the 8 month time period per QA plan. The findings include: 1. A review of the QA Plan demonstrated a monthly quality review will be completed by the Laboratory Director to ensure the quality of the laboratory services and identify failures as they occur. 2. There was no documentation of

	Director review for Quality Controls or Qualtiy Assessments for May 2019 through January 2020. 3. An interview with the Lead Testing Personnel and Laboratory Director at approximately 2:30 p.m. February 18, 2020 confirmed there was no documentation of Director review of quality controls or quality assessment records to ensure quality of the laboratory services were maintained for the 8 month time period. ==========