Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1093662	01/09/2023
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
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 review and request of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the testing person, it was determined the testing personnel and/or the laboratory director failed to sign the attestation sheets for 12 of 12 PT events for 2021 and 2022. The findings include: 1. Request of the laboratory's PT records revealed the following: -No attestation pages available for the following: Chemistry 2022 event one -Attestation pages not signed by the testing personnel for the following: Hematology/Coagulation 2022 event one and three Chemistry 2021 event one -Attestation pages not signed by the laboratory director for the following: Hematology/Coagulation 2022 event two -Attestation pages not signed by the testing personnel and the laboratory director for the following: Hematology/Coagulation 2021 event one and three, 2022 event two Chemistry 2021 event two and three, 2022 event two and three 2. Interview with the testing person on January 9,2023 at approximately 10:45 am confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Citation #1 Based on review of the laboratory's competency policy, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS-209), review of testing personnel records, and interview with the laboratory testing person, the laboratory failed to follow the policy for competency assessment in 2021 and 2022. Findings include: 1) Review of the laboratory's staff orientation, training and competency policy revealed that "After initial competency assessment at the completion of orientation and training, competency assessment will occur at 6 months, 12 months and annually thereafter." 2) Review of the CMS-209 revealed one of one testing personnel performing moderately complex testing. 3) Review of testing personnel records revealed no documentation of annual competency assessments for one of one testing personnel for 2021 and 2022. 4) Interview with the laboratory testing person at approximately 10:45am on January 9, 2023 confirmed the laboratory failed to follow the policy for competency assessment in 2021 and 2022. Citation #2 Based on review of the laboratory's manual review policy, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS-209), review of procedure manuals, and interview with the laboratory testing person, the laboratory failed to follow the policy for annually reviewing procedures in 2021 and 2022. Findings include: 1) Review of the laboratory's manual review policy revealed that "All policies must be reviewed annually and documentation of review documented on each SOP policy signature page in this manual by Laboratory Director. Laboratory Personnel must document review of this manual by signing below:" 2)Review of the CMS-209 revealed one of one testing personnel performing moderately complex testing. 3)Review of procedure manuals revealed no Laboratory Director or testing personnel signatures in 2021 or 2022. 4)Interview with the laboratory testing person at approximately 10:45am on January 9, 2023 confirmed the laboratory failed to follow the policy for manual review in 2021 and 2022.
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 review of the laboratory's calibration/calibration verification procedure, review of the Horiba Micros 60 calibration records, observation of the laboratory and interview with the testing person, the laboratory failed to follow the laboratory's requirements for CBC instrument calibration frequency in 2021 and 2022. The findings include: 1. Review of the laboratory's Calibration/Calibration Verification procedure revealed, "Calibration verification must be performed minimally every 6 months to substantiate the continued accuracy of the monitors throughout the reportable range, after initial validation studies are performed with the setup of the analyzer. Calibration verification is performed every six months, as stated in current

	CLIA and State regulations." 2. Review of the Horiba Micros 60 calibration records revealed calibration was not performed from November 2021 until November 2022, resulting in the laboratory not following their calibration/calibration verification procedure. 3. Observation of the laboratory revealed a Horibas 60 CBC analyzer in use for CBC testing. 4.Interview with testing person on January 9, 2023 at approximately 10:45 am confirmed the above findings.