Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1093662	08/20/2024
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control (QC) records, lack of records, and staff interviews, the laboratory failed to retain two of two QC package inserts for the Beckman Coulter Access-2 (Access-2) immunoassay chemistry analyzer and one of one QC package insert for the Ortho Clinical Diagnostics Vitros-350 (Vitros-350) chemistry analyzer used for patient testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 08.20.2024 at 9:30 a.m. revealed an Access-2 (serial number 511210) immunoassay chemistry analyzer and a Vitros-350 (serial number 27005665) chemistry analyzer used for patient testing. 2. A review of the laboratory's daily chemistry QC records revealed the following: -Access-2: Lot Numbers 85301-L1 and 85303 L-3 used on 02.15.2023 -Access-2: Lot Numbers 85351 and 85353 used on 03.26.2024 -Vitros-350: Lot Numbers 45911 and 45913 used on 03.16.2023 and 08.09.2023 3. The laboratory was unable to provide the QC package inserts for Access-2 lots 85301-L1, 85303 L-3, 85351, 85353, and Vitros-350 lots 45911 and 45913. 4. An interview with testing person one (TP #1) and the office manager on 08.20.2024 at 1:30 p.m. confirmed the survey findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's policy, patient test reports, quality control (QC) records, and staff interviews, the laboratory failed to follow its quality control and assessment procedure in 2023 and 2024. The findings include: 1. Observation of the laboratory on 08.20.2024 at 9:30 a.m. revealed a Beckman Coulter Access-2(Access-2) (serial number 511210) immunoassay chemistry analyzer and an Ortho Clinical Diagnostics Vitros-350(Vitros-350) (serial number 27005665) chemistry analyzer used for patient testing. 2. A review of the laboratory's Quality Control and Assessment policy under the section titled "Two Control Protocol" stated: "Reject the run if: a. Both controls are greater than 2SD from the mean (2-2SRule) b. One control is greater than 2SD and less than 3 SD on two consecutive runs (2-2S Rule) c. One control is greater than 3 SD from the mean (1-3S Rule)" 3. A random review of patient test reports revealed that a patient with accession number 9845 was tested for alanine aminotransferase (ALT) on 03.16.2023, a patient with accession number 10898 was tested for calcium on 08.09.2023, and a patient with accession number 12661 was tested for folate on 03.26.2024 when quality control fell outside of the laboratory's established acceptable limits. 4. A review of quality control records revealed the following, which fell outside of the laboratory's established acceptable limits; -Vitros-350 ALT QC on 03.16.2023: level 3 QC unacceptable at greater than 2 SD for 2 consecutive runs -Vitros-350 Calcium QC on 08.09.2023: level 3 QC unacceptable at 3 SD -Access-2 Folate QC on 03.26.2024: both level 1 and level 3 QC were unacceptable at greater than 2 SD 5. An interview with TP #1 and the office manager on 08.20.2024 at 1:30 p.m. confirmed the survey findings. Word Key: SD = Standard Deviation
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on laboratory observation, manufacturer instructions, environment records, and staff interviews, the laboratory failed to monitor and document temperature ranges that were consistent with the manufacturer's requirement for the storage of the Ortho Clinical Diagnostics Vitros-350 (Vitros-350) chemistry reagent slides used on the Vitros-350 analyzer in 2023 and 2024. Findings include: 1. Observation of the laboratory on 08.20.2024 at 9:30 a.m. revealed the Ortho Clinical Diagnostics Vitro-350 (Vitros-350) analyzer (serial number 27005665) used for patient testing. Additional observation of the laboratory revealed an M3 Turbo air refrigerator (serial number M3R1LAY015) used to store the following Vitros-350 reagent slides: -Three boxes of TP -Five boxes of ALKP -Three boxes of ECO2 -Three boxes of TBIL -Three boxes of ALB -Three boxes of CL- -Four boxes of Ca -Two boxes of Bun/Urea

	-Two boxes of K+ 2. A review of manufacturer instructions revealed the storage requirements of 8 degrees Celsius or less. 3. A review of environment records revealed no documentation of temperature monitoring for the ME Turbo air refrigerator. 4. An interview with TP #1 on 08.20.2024 at 9:35 a.m. confirmed the above findings. Word Key: TP = Total Protein ALKP = Alkaline Phosphatase ECO2 = Carbon Dioxide TBIL = Total Bilirubin ALB = Albumin CL- = Chloride Ca = Calcium Bun/Urea = Blood Urea Nitrogen K+ = Potassium
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of laboratory demographic information in Aspen Web 116, final patient test reports, and staff interviews, the laboratory failed to ensure the correct physical address was on the final patient test report for three of three final patient test reports reviewed from 2023 and 2024. The findings include: 1. A review of the laboratory demographic information in Aspen Web 116 revealed a physical address of 1615 Bluff City Hwy, Bristol, TN 37620. 2. A review of final patient test reports revealed the laboratory address listed as 28 Midway Street, Bristol, TN 37620, as follows: -Patient with accession 10898 (Complete Blood Count, Comprehensive Metabolic Panel, Vitamin B12 with Folate reported on 08.09.2023) -Patient with accession number 9845 (Complete Blood count, Comprehensive Metabolic Panel, Hormone Panel, Lipid Panel, Magnesium, Thyroid Panel, Vitamin B12 with Folate, and Vitamin D reported on 03.16.2023) -Patient with accession number 12661 (Complete Blood Count, Comprehensive Metabolic Panel, Hormone Panel, Lipid Panel, Magnesium, Thyroid Panel, Vitamin B12 with Folate, and Vitamin D reported on 03.26.2024) 3. An interview with TP #1 and the office manager on 08.20.2024 at 1: 30 p.m. confirmed the survey findings.