Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0978097	05/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Innovis Health, Llc Dba Essentia Health	Lower Level, Fargo, ND	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review, plan review, policy/procedure review, and staff interview, the laboratory failed to follow their Individualized Quality Control Plan (IQCP) for quality control performance for 1 of 1 month reviewed (January 2025) for oxyhemoglobin testing on the Avoximeter. Findings include: 1. Reviewed on 05/13 /25, the January 2025 QC records for oxyhemoglobin performed on the Avoximeter indicated the performance of QC on the following days: 01/02/25 - level 3 01/08/25 - level 1 01/15/25 - level 2 01/22/25 - level 3 01/29/25 - level 1 The QC records failed to include evidence of performance of three levels of controls each week as stated in the laboratory's IQCP. 2. Reviewed on 05/13/25, the laboratory's "Individual Quality Control Plan Summary Report," dated 12/17/15, stated, "Supplemental components: Based upon your final review of your risk assessment, the following are supplemental risk mitigation components for your laboratory's IQCP. . . . Liquid QC is run with each new lot of cuvettes, or three levels of control per week at the minimum. . . ." 3. Reviewed on 05/13/25, the policy/procedure "Avoximeter 1000E," revised 02/29/24, stated, ". . . Quality Control Frequency . . . Liquid QC material . . . a minimum of one level of liquid QC material will be analyzed weekly. . . ." The policy/procedure failed

	to follow the QC requirements of performance of three levels of control per week as stated in the laboratory's IQCP. 4. During interview at 2:40 p.m. on 05/13/25, a supervisory staff member (#2) confirmed the laboratory's IQCP for oxyhemoglobin on the Avoximeter required performance of three levels of QC each week and the laboratory performed one level of QC each week in January 2025. 5. Upon request on 05/15/25, the laboratory failed to provide the dates and volume of oxyhemoglobin patient testing using the Avoximeter in January 2025.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure review, the laboratory failed to perform a positive and negative control each day of patient testing for Clostridium difficile (C. diff.) toxin A & B tests for 1 of 1 patient testing day (01/27 /25) in January 2025. The laboratory performed one C. diff. toxin A & B patient test in January 2025 with no quality control (QC) performance. Findings include: 1. Reviewed on 05/15/25, the January 2025 patient testing records for C. diff. toxin A & B indicated performance of one patient test on 01/27/25 using the test kit TOX A/B Chek. 2. Reviewed on 05/15/25, the January 2025 QC records for C. diff. toxin A & B failed to include evidence of the performance of positive and negative controls on 01 /27/25. 3. During interview at 9:00 a.m. on 05/15/25, a supervisory staff member (#1) confirmed the laboratory failed to perform QC each day of patient testing for C. diff. toxin A & B in January 2025. 4. Reviewed on 05/15/25, the policy/procedure "TOX A /B Quik Chek," dated 07/24/23, stated, "CLIA Complexity Moderately Complex . . . Quality Control Frequency: QC will be performed once per lot/shipment and once monthly. . . ." The policy/procedure failed to require the performance of a positive and negative external control each day of patient testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to twice annually compare and evaluate test results using different methodologies for identification (ID) of microorganisms for 1 of 1 year reviewed (2024). Findings include: 1. Observation of the microbiology department, beginning at 3:00 p.m. on 05 /14/25, indicated the laboratory performed ID of microorganisms on the MALDI Biotyper CA System (MALDI), Accelerate Pheno System (Pheno), and BD Phoenix M50 (M50). 2. Upon request, the laboratory failed to provide evidence of 2024 comparisons for ID of microorganisms of the MALDI with the Pheno and M50. 3. During interview at 7:30 a.m. on 05/15/25, a supervisory staff member (#3) confirmed the laboratory performed ID of microorganisms patient testing and did not perform comparisons of the MALDI with the Pheno and M50.