Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1088893	04/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advent Health Lenexa	23401 Prairie Star Parkway, Lenexa, KS	

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
D0000	A validation survey was completed 4/15/25 on Advent Health Lenexa laboratory was found not in compliance with the following CONDITIONAL LEVEL DEFICIENCIES: D5800 - 42 C.F.R. 493.1290 Condition: Postanalytic Systems D6076 -42 C.F.R 493.1441 Condition: Laboratories Performing High Complexity Testing; Laboratory Director
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from College of American Pathologists (CAP) for 2023 and to date of survey 2025, and interview with general supervisor (GS), the laboratory failed to evaluate its unacceptable proficiency testing results for one analyte in 2024. Findings: The following sample was scored unacceptable by CAP. No documentation of the laboratory's evaluation was provided at the time of survey. Listed by event, sample ID, and analyte. 1. C-A 2024 General Chemistry/Therapeutic Drugs, sample CHM-02 for acetaminophen. 2. Interview with the GS on 04/15/25 at 11:30 a.m. confirmed the laboratory failed to evaluate its unacceptable proficiency testing results for one analyte in 2024.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records from College of American Pathologists (CAP) and interview with technical consultant #1(TC#1), the laboratory failed to evaluate its proficiency testing results that were not scored by the PT program for twelve events in 2024. Findings: Review of PT results from CAP for 2024 revealed the following ungraded results with no evaluation provided at the time of survey. 1. BCP-B 2024 Blood Cell Identification Ungraded five samples missing self-assessments for BCP-16, BCP-17, BCP-18, BCP-19, and BCP-20. 2. BCP-C 2024 Blood Cell Identification Ungraded five samples missing self-assessments for BCP-26, BCP-27, BCP-28, BCP-29, and BCP-30. 3. C-A 2024 General Chemistry /Therapeutic Drugs missing self-assessments for one sample CHM-02 Bilirubin, Direct 4. FH9-A 2024 Hematology Auto-Differentials are missing self-assessments for ten samples: a. IG % Sysmex XN-L Series: FH9-01, FH9-02, FH9-03, FH9-04, and FH9-05. b. IG Absolute Sysmex XN-L Series: FH9-01, FH9-02, FH9-03, FH9-04, and FH9-05. 5. FH9-B 2024 Hematology Auto-Differentials are missing self-assessments for ten samples: a. IG % Sysmex XN-L Series: FH9-06, FH9-07, FH9-08, FH9-09, and FH9-10. b. IG Absolute Sysmex XN-L Series: FH9-06, FH9-07, FH9-08, FH9-09, and FH9-10. 6. FH9-C 2024 Hematology Auto-Differentials are missing self-assessments for ten samples: a. IG % Sysmex XN-L Series: FH9-11, FH9-12, FH9-13, FH9-14, and FH9-15. b. IG Absolute Sysmex XN-L Series: FH9-11, FH9-12, FH9-13, FH9-14, and FH9-15. 7. J-B 2024 Transfusion Medicine (Comp) missing self-assessments for 18 samples: a. ABO Conf for J in EXM: J-08R, J-09R, and J-11R. b. ABO Subgroup Conf in EXM: J-08R, J-09R, and J-11R. c. Rh Conf for J in EXM: J-08R, J-09R, and J-11R. d. Unit ABO Conf: EXM-04R, EXM-05R, and EXM-06R. e. Unit Rh Conf: EXM-04R, EXM-05R, and EXM-06R. f. Electronic Crossmatch: EXM-04, EXM-05, and EXM-06. 8. J-C 2024 Transfusion Medicine (Comp) missing self-assessments for 18 samples: a. ABO Conf for J in EXM: J-15R, J-16R, and J-17R. b. ABO Subgroup Conf for EXM - J-15R, J-16R, and J-17R. c. Rh Conf for J in EXM: J-15R, J-16R, and J-17R. d. Unit ABO Conf: EXM-07R, EXM-08R, and EXM-09R. e. Unit Rh Conf: EXM-07R, EXM-08R, EXM-09R. f. Electronic Crossmatch: EXM-07, EXM-08, and EXM-09. 9. K-A 2024 Ligand General hCG, serum quant had five samples missing self-assessments: K-01, K-02, K-04, and K-05. 10. K-B 2024 Ligand General hCG, serum quant had five samples missing self-assessments: K-06, K-07, K-08, K-09, and K-10. 11. K-C 2024 Ligand General hCG, serum quant had five samples missing self-assessments: K-11, K-12, K-13, K-14, and K-15. 12. CAR-C 2024 Cardiac Markers, Troponin T, quant had one sample missing self-assessments: HCR-14. 13. Interview with TC#3 on 4/15/25 at 11:30 a.m. confirmed the laboratory failed to evaluate its proficiency testing results that were not scored by the CAP PT program for twelve events in 2024.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the review of the Individualized Quality Control Plan (IQCP) for eleven drugs of abuse utilizing the MedTox Diagnostics, Profile - V MedTox Scan Drugs of

	Abuse Test System (MedTox), MedTox quality control (QC) records, MedTox patient logs, and interview with technical consultant #1 (TC#1), the laboratory failed to perform QC as required for 11 of 11 drugs of abuse as required by the IQCP from 11/5 /24 thru 11/9/24. Findings: 1. Review of the IQCP for drugs of abuse panel using the MedTox required positive control and negative control QC to be performed weekly. This IQCP was approved by the Laboratory Director and the last annual review was on 3/24/25. 2. The drugs of abuse panel included the following analytes: amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine, methadone, methamphetamine, opiates, oxycodone, phencyclidine (PCP), and tricyclic antidepressants (TCA). 3. Review of QC records for 11/5/24, revealed: a. QC for amphetamines, negative control performed, no positive control performed. b. QC for barbiturates, negative control performed, no positive control performed. c. QC for benzodiazepines, negative control performed, no positive control performed. d. QC for THC, negative control performed, no positive control performed. e. QC for cocaine, negative control performed, no positive control performed. f. QC for methadone, negative control performed, no positive control performed. g. QC for methamphetamine, negative control performed, no positive control performed. h. QC for opiates, negative control performed, no positive control performed. i. QC for oxycodone, negative control performed, no positive control performed. j. QC for PCP, negative control performed, no positive control performed. k. QC for TCA, negative control performed, no positive control performed. l. No corrective action documentation for the failure to perform the positive control on 11/5/24 was provided at the time of survey. 3. Review of the Medtox IQCP Biennial Assessment of IQCP signed 3/24/25 revealed no documentation of the failure to perform the positive QC on 11/5/24. 4. Review of the MedTox patient log revealed one patient was tested during week of 11/5/24 thru 11/9/24 with no corrective actions provided at the time of survey. 5. Interview with TC#1 on 4/15/2024 at 12:20 p.m. confirmed, the laboratory failed to perform QC as required for 11 of 11 drugs of abuse on the MedTox as required by the IQCP from 11/5/24 thru 11/9/24.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a lack of suspected transfusion reaction determination documentation, lack of transfusion review documentation, and interview with the GS, the laboratory failed to document that all necessary remedial actions were taken to ensure the safety of 15 patients who were transfused 45 units of red blood cell (RBC) from 4/4/23 to 3/31/25. (See cross reference D6076)
D5800	POSTANALYTIC SYSTEMS

	CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a lack of post analytical policies and procedures, lack of post analytical review documentation, and interview with GS, the laboratory failed to have policies and procedures (See D5891), and failed to have post analytical review documentation (See D5893).
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based upon the lack of procedures, and interview with the GS, the laboratory failed to have written policies and procedures for an ongoing process to monitor, assess, and correct problems in the postanalytic system. Findings: 1. The surveyor requested the post analytic quality assessment procedure. No postanalytic system procedure was made available for review at the time of survey. 2. Interview with the GS on 4/15 /245at 2:55 p.m. confirmed, the laboratory failed to have written policies and procedures for an ongoing process to monitor, assess, and correct problems in the postanalytic system.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the lack of postanalytic review documentation, and interview with GS, the laboratory failed to document postanalytic quality assessment. Findings: 1. The surveyor requested documentation of post transfusion review for blood products. No documentation was made available at the time of survey. 2. The surveyor request documentation of any post analytical review. No documentation was made available at the time of survey. 3. Interview with GS on 4/15/25 at 2:45 p.m. confirmed, the laboratory failed to document postanalytic quality assessment. (Cross reference D6076).

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445. Refer to D6079 and D6103.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of the CMS 209, lack of post transfusion review by the technical supervisor (TS) of immunohematology, and interview with the GS., the LD failed to ensure that post transfusion review was performed for 45 units given to 15 patients from 4/4/23 to 3/31/25. Findings: 1. Review of the CMS 209 personnel form revealed that the LD has also served as the TS of immunohematology. 2. No documentation of post transfusion review was provided at the time of survey. 3. No suspected transfusion reaction determination was provided at the time of survey. If transfusion review had been performed, the TS could have determined in timely manner that suspected transfusion reaction determination was not being performed. (Cross reference D5559) 3. Interview with GS on 4/15/25 at 2:45 p.m. confirmed, the LD failed to ensure that post transfusion review was performed for 45 units given to 15 patients from 4/4/23 to 3/31/25.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:

	Based on a lack of policies and procedures, lack of review documentation, and interview with the GS, the laboratory director failed to ensure the laboratory performed postanalytical quality assessment. (Cross reference D5800, D5891, and D5893)