Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521272	07/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Valor Health	1202 E Locust St, Emmett, ID	

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 a review of proficiency testing (PT) documentation from the American Association of Bioanalysts (AAB), the College of American Pathologists (CAP), the American Proficiency Institute (API), and an interview with the technical supervisor (TS) on 7/9/2024, the laboratory failed to have testing personnel and the laboratory director attest to the integration of PT samples with routine testing of patient samples in 2023 and 2024. The findings include: 1. A review of PT records from AAB for 2023 identified that the laboratory failed to have the laboratory director attest that the PT samples were integrated with patient samples for chemistry event one, urine drug screen event one and non-chemistry event one. 2. A review of PT records from API for 2024 identified that the laboratory failed to have the testing personnel and laboratory director attest that the PT samples were integrated with patient samples for chemistry events one and two and immunology/immunohematology event one. 3. A review of PT records from CAP for 2024 identified that the laboratory failed to have the testing personnel and laboratory director attest that the PT samples were integrated with patient samples for automated body fluid event one and laboratory director attest for alcohols event one. 4. An interview with the TS on 7/9/2024 at 11:37 am confirmed the above findings. 5. The laboratory reports performing 87,275 tests annually.
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: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory policies, competency assessment records and an interview with the technical supervisor (TS) on 7/9/2024, the laboratory failed to follow written policies and procedures to assess testing personnel in 2023 and 2024. The findings include: 1. A review of the CMS 209 form identified nine testing personnel. 2. The laboratory policy "Laboratory Competency Assessment" states that there will be an initial training, six month competency then annual competency each year after. 3. A review of competency assessment records identified the laboratory failed to have six month competency assessments for one of three testing personnel in 2023 and three of four testing personnel in 2024. 4. A review of competency assessment records identified the laboratory failed to have annual competency for three of four testing personnel in 2023. 5. An interview with the TS on 7/9/2024 at 11:37 am confirmed the above findings. 6. The laboratory reports performing 87,275 tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Cepheid GeneXpert maintenance logs and an interview with the technical supervisor (TS) on 7/9/2024, the laboratory failed to perform maintenance as required by the manufacturer in 2023 and 2024. The findings include: 1. A review of Cepheid GeneXpert maintenance logs identified that the laboratory failed to perform quarterly maintenance of disinfection of the cartridge bay interior and the plunger rod for four of four quarters since 7/2/2023 as required by the manufacturer. 2. A review of Cepheid GeneXpert maintenance logs identified that the laboratory failed to perform monthly maintenance of archiving tests, purging tests and cleaning the fan filter in November 2023, December 2023, January 2024 and February 2024 as required by the manufacturer. 3. An interview with the TS on 7/9/2024 at 12: 05 pm confirmed that the above findings. 4. The laboratory reports performing 505 tests annually on the Cepheid.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

	(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 record review of immunohematology quality control (QC), patient test reports and an interview with the technical supervisor (TS) on 7/10/2024, the laboratory failed to document control material results for immunohematology testing in 2023. The findings include: 1. A review of immunohematology QC for 2022, 2023 and 2024 identified that the laboratory failed to document QC on 9/10/2023 and 10/24 /2023 for ABO grouping, Rh typing, and unexpected antibody detection. 2. A review of patient test reports identified ABO grouping, Rh typing, and unexpected antibody detection was performed on one patient on 9/10/2023 and one patient on 10/24/2023. 3. An interview with the TS on 7/10/2024 at 10:59 am confirmed the above findings. 4. The laboratory reports performing 316 immunohematology tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of laboratory policies, temperature logs and an interview with the technical supervisor (TS) on 7/10/2024, the laboratory failed to perform alarm checks of the immunohematology refrigerator with the frequency prescribed in their policy in 2023 and 2024. The findings include: 1. A review of the policy " Blood Banking Temperature and Alarm Monitoring System" identified that the laboratory would perform quarterly alarm checks on the blood bank refrigerator and freezer. 2. A review of laboratory temperature logs identified that the laboratory failed to perform quarterly alarm checks on the blood bank refrigerator in October 2023 and January 2024. 3. An interview with the TS on 7/10/2024 at 10:14 am confirmed the above finding. 4. The laboratory reports performing 316 immunohematology tests annually.