Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521272	08/11/2022
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from the College of American Pathologists (CAP) and an interview with the laboratory manager on 8/10/2022, the laboratory failed to prove the testing accuracy of Gamma Glutamyl Trans (GGT) for 2022 . The findings include: 1. A review of PT results from CAP for the analyte GGT identified that the laboratory failed two consecutive PT events for GGT with scores of 0% for 2022 event A and a 20% for 2022 event B. 2. An interview with the laboratory manager on 8/10/2022 at 9:50 am confirmed that the laboratory failed to prove testing accuracy for GGT in 2022. 3. The laboratory reports performing 15 GGT tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a record review of proficiency testing (PT) documents from the College of American Pathologists (CAP) and an interview with the laboratory manager on 8/10 /2022, the laboratory failed to review unsatisfactory PT results and take corrective actions for 2022 event A General Chemistry/ Therapeutic Drug. The findings include: 1. A review of PT records from CAP for 2022 event A identified that the laboratory failed to evaluate results and take corrective actions for the following analytes:

	Lithium 80%, Salicylates 20%, Acetaminophen 80%, Phosphorus 0%, Gamma Glutamyl Trans 0%, hCG 80%, and Bilirubin, direct 40%. 2. An interview with the laboratory manager on 8/10/2022 at 9:39 am confirmed that the laboratory failed to evaluate and take corrective actions for the PT General Chemistry/ Therapeutic Drug results for 2022 event A. 3. The laboratory reports performing 60,455 chemistry tests annually.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of immunohematology quality control (QC) records, patient immunohematology records and an interview with testing personnel 1 (TP1) on 8/11/2022, the laboratory failed to document immunohematology control results for each day of patient testing in April of 2022. The findings include: 1. A random record review of immunohematology QC for 2021 and 2022 identified that the laboratory failed to document positive QC (1-4+) and negative QC on 4/27/2022, and 4/29/2022 as required by regulation for blood and Rh type, antibody screen and crossmatch testing before reporting patient results. 2. A review of immunohematology patient test results identified two blood and Rh types were performed on 4/27/2022, one blood and Rh type, antibody screen and crossmatch of two units was performed on 4/29/2022. 3. An interview with TP1 on 8/11/2022 at 9:50 am confirmed the above patient immunohematology testing was performed without the documentation of QC. 4. The laboratory reports performing 1,051 immunohematology tests annually.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) 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 the laboratory's Microscan individualized quality control plan (IQCP), the manufacturer's instructions for use (IFU), the laboratory's Microscan quality control (QC) documents, and an interview with the laboratory manager on 8/10 /2022, the laboratory failed to have acceptable QC including all organisms specified by the manufacturer for Microscan negative urine combo panel type 85 (NUC85). The findings include: 1. The laboratory Microscan IQCP states they will follow

	manufacturers IFU. The manufacturer's IFU for QC is as follows: NUC85 weekly QC organisms are E. coli 25922, P. aeruginosa 27853, E. coli 35218 and K. pneumoniae 700603. 2. A review of the laboratory Microscan QC records identified that the laboratory failed to have acceptable weekly QC for NUC85 panels for the weeks of 7/8 /2022, 7/15/2022 and 7/21/22. On 7/8/2022 they failed to have acceptable QC for P. aeruginosa 27853 and on 7/15/2022 and 7/21/22 they failed to have acceptable QC for E. coli 35218 on the NUC85 panels lot 2022-07-06. 3. An interview with the laboratory manager on 8/10/2022 at 2:45 pm confirmed that the laboratory failed to have acceptable results for all required QC organisms weekly on NUC85 panels. 4. The laboratory reports performing 1809 cultures and susceptibilities.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 prothrombin time quality control (QC) records, patient reports and an interview with the laboratory manager on 8/10/2022, the laboratory failed to perform two levels of QC every eight hours of patient testing. The findings include: 1. A random review of prothrombin time QC identified that the laboratory failed to perform two levels of QC every eight hours on 12/27/2021. 2. A review of patient prothrombin time test reports from 12/27/2021 identified that the laboratory failed to have QC for one patient prothrombin time resulted at 13:51 on 12/27/2021. 3. An interview with the laboratory manager on 8/10/2022 at 11:50 am confirmed that the above patient result was reported without QC. 4. The laboratory reports performing 572 prothrombin time tests annually.