Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521272	04/19/2021
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
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 record review of competency assessment documentation, the CMS-209 personnel form, and an interview with the interim laboratory manger on 04/19/2021, the laboratory failed to document competency assessments for testing personnel listed on the CMS-209. The findings include: 1. A record review of competency assessment documentation revealed that the laboratory failed to document competency assessments for 6 of 7 testing personnel listed on the CMS-209 personnel form in accordance with 42 C.F.R. 493.1451(b)(8). 2. A record review of 6-month competency assessment documentation revealed that the laboratory failed to document 6-month competency assessments for 6 of 6 new testing personnel since the last survey on 11/05/2018. 3. An interview with the interim laboratory manager on 04 /19/2021 at 10:00 AM confirmed that competency assessments had not been performed on the testing personnel listed on the CMS-209 personnel form. 4. The laboratory reports performing 148,818 patient tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

	acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review of calibration documentation and an interview with the interim laboratory manager on 04/19/2021, the laboratory failed to provide documentation, at the time of survey, for calibration verification being performed at least every 6 months on the Sysmex XN 550 analyzer. The findings include: 1. A record review of calibration and calibration verification documentation for the Sysmex XN 550 revealed that the laboratory failed to provide documentation, at the time of survey, of calibration verification at least every 6 months for the Sysmex XN 550 analyzer since 03/25/2020. 2. An interview with the interim laboratory manager on 04/19/2021 at 1:30 PM confirmed that the laboratory was unable to provide calibration verification documentation for the Sysmex XN 550 analyzer at the time of survey. 3. The laboratory reports performing 38,962 patient tests annually on the Sysmex XN 550 analyzer.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on record review of testing personnel training documentation, the CMS-209 form, and an interview with the interim laboratory manager on 04/19/2021, the laboratory failed to provide documentation of initial training for new testing personnel, since the previous survey on 11/05/2018, prior to analyzing patient specimens. The findings include: 1. A record review of testing personnel documentation and the CMS-209 personnel form revealed that the laboratory failed to document initial training for 6 of 6 new testing personnel since the previous survey on 11/05/2018. 2. An interview with the interim laboratory manager on 04/19/2021 at 10: 00 AM confirmed that the laboratory failed to document initial training for 6 of 6 initial training. 3. The laboratory reports performing 148,818 patient tests annually.