Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0721023	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Infusion Clinic Laboratory	228 N Bliss Ave, Tahlequah, OK	

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	The recertification survey was performed on 04/20/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 and technical consultant #3 at the conclusion of the survey.
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 records, written policy, and interview with technical consultant #2, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 04/20/2022, a review of the competency assessment policy revealed there was no guidance, including the frequency, for assessing the competency of the technical consultants; (2) A review of personnel records for competency assessments performed from 2020 through the current date in 2022 revealed competencies had not been performed in 2021 for two of three technical consultants (technical consultant #1 and technical consultant #2), based on job responsiblitilies; (3) The findings were reviewed with technical consultant #2 who stated on 04/20/2022 at 11:49 am, a policy had not been written and competencies had not been performed for the two technical consultants in 2021 as shown above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to ensure the reportable ranges had been utilized for two of six analytes reviewed. Findings include: (1) On 04/20/2022 at 10:00 am, technical consultant #2 stated the following: (a) The laboratory began performing AST (Aspartate Aminotransferase), Calcium, Glucose, LD (Lactate Dehydrogenase), CA (Cancer Antigen) 15-3, and Ferritin testing using the Cobas 6000 analyzer on 06/01/2021; (2) A review of the performance specification records, reportable ranges programmed in the analyzer, and the manufacturer's package inserts for the analytes revealed the laboratory was not using the reportable ranges that had been demonstrated for two of six analytes reviewed as follows: (a) CA 15-3 - The laboratory had demonstrated a reportable range of 3.047-247.567 U/ml and was using the manufacturer's reportable range of 1.0-300 U/ml; (b) Ferritin - The laboratory had demonstrated a reportable range of 0.9960-1762.0 ng/ml and was using the manufacturer's reportable range of 0.5-2000 ng/ml. (3) On 04/20/2022 at 01:10 pm, the findings were reviewed with technical consultant #2, who stated the laboratory was not able to enter the demonstrated reportable ranges for CA 15-3 and Ferritin into the analyzers and did not have access to update the reportable ranges in the LIS (Laboratory Information System), therefore the system defaulted to using the manufacturer's reportable ranges.