

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0721023	(X3) Date Survey Completed 04/15/2024
Name of Provider or Supplier Infusion Clinic Laboratory	Street Address, City, State 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 04/15/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 at the conclusion of the survey.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with technical consultant #2, the laboratory failed to ensure BD Macro-vue RPR card antigen suspension had not exceeded their refrigerated temperature expiration date for one of one dispensing bottles observed. Findings include: (1) On 04/15/2024 at 1:30 pm, technical consultant #2 stated syphilis testing (Rapid Plasma Reagin or RPR) was performed using the BD Macro-vue RPR Card test kit; (2) Observation of the laboratory on 04/15/2024 at 1:30 pm identified one antigen dispensing bottle stored refrigerated, without documentation of when the antigen was transferred to the dispensing bottle; (3) Review of the manufacturer's storage requirements showed the following: (a) The antigen suspension is stable until the expiration date when unopened; (b) Once the antigen is put in the plastic dispensing bottle, it is stable for three months refrigerated. (4) Interview with technical consultant #2 on 04/15/2024 at 1:42 pm confirmed the antigen had been transferred into the plastic dispensing bottle without a method to monitor if they exceeded the manufacturer's modified expiration date.</p>