

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2141117	(X3) Date Survey Completed 05/13/2022
Name of Provider or Supplier Healthcare Express-Moore	Street Address, City, State 551 Se 4th St, Moore, 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 05/13/2022. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant and laboratory operations director at the conclusion of the survey.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and laboratory operations director, the laboratory failed to perform quality control as stated in the IQCP for CKMB and Troponin I testing for two of 16 months. Findings include: (1) On 05/13/2022 at 09:30 am, the laboratory operations director stated the following: (a) CKMB and Troponin I testing were performed using the Quidel Triage Meter; (b) Two levels of QC (quality control) materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan). (2) A review of QC records for testing performed from January 2021 through April 2022 revealed there was no documentation to prove QC had been performed for two of 16 months as follows: (a) Between 04/04/2021 and 06/01/2021 (b) Between 07/01/2021 and 09/01</p>

/2021 (3) The records were reviewed with the technical consultant and laboratory operations director. Both stated on 05/13/2022 at 10:17 am, although the QC had been performed the records had not been maintained.