

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D2090360	<b>(X3) Date Survey Completed</b>  04/17/2018
<b>Name of Provider or Supplier</b>  Healthcare Express-Midwest City	<b>Street Address, City, State</b>  1701 S Douglas Blvd, Midwest City, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The findings were reviewed with the technical consultant, director of laboratory operations, and assistant to the director of laboratory operations at the conclusion of the survey.
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and director of laboratory operations, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) The laboratory performed CKMB and Troponin I testing using the Quidel Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 06/06/16). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results. There was no evidence of QA reviews since the IQCP effective date; (3) The surveyor reviewed the records with the technical consultant and director of laboratory operations, and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if QA reviews had been performed since the IQCP had been implemented. Both stated a policy had not been written and QA reviews had not been performed.</p>