

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0973582	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier Methodist Minor Medical Center-Hacks	Street Address, City, State 8071 Winchester Road Ste 3, Memphis, TN	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, patient test records, quality assessment (QA) plan, and quality assessment (QA) records, and interview with the technical consultant, the laboratory's quality assessment process was ineffective at correcting problems with expired controls in August 2021 (two of fifteen lots reviewed). The findings include: 1. Review of the laboratory's quality control records revealed QC lot numbers 2210331 and 2210332 were in use on August 10, 2021. The QC package insert indicated both lots expired on August 9, 2021. 2. Review of patient test records revealed two patients were reported on August 10, 2021 when the expired QC lots were in use (patient numbers 1057244 and 952631). 3. Review of the laboratory's quality assurance plan revealed the following as a goal: "Identify problems in our laboratory and apply corrective action." 4. Document review during the survey revealed review of the August 2021 quality control with no corrective performed for the use of expired controls. 5. Interview with the technical consultant on September 2, 2021 at approximately 1:15 pm confirmed the laboratory's quality assessment process was ineffective when it did not detect and correct the use of expired QC in August 2021 with patient testing performed.</p>