

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0975423	(X3) Date Survey Completed 12/13/2022
Name of Provider or Supplier Medical City Mckinney Senior Health Clinic	Street Address, City, State 4201 Medical Center Drive Ste 300, Mckinney, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's records, patient results, and confirmed in an interview found the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing for moderate complexity tests, PT /INR, for one of one Abott i-STAT. The findings were: 1. Reviewed of the laboratory's records revealed the i-STAT (SN: 399160) currently in-use was installed on 9/15/22. 2. Reviewed the the laboratory's patient results revealed 10 patients had PT /INR testing performed on i-STAT, SN:399160 after 9/15/22. 9/19/22 Sample ID: Q00053267342 9/23/22 Sample ID: Q00053277877 9/27/22 Sample ID: Q00053287404 9/29/22 Sample ID: Q00053019024 9/29/22 Sample ID: Q00053115805 9/29/22 Sample ID: Q00053292592 10/13/22 Sample ID: Q00053334093 10/21/22 Sample ID:Q00053357932 10/25/22 Sample ID: Q00053367821 10/27/22 Sample ID:Q00053373772 3. Review of the laboratory's QC records for the above dates revealed no documentation of two quantitative QC materials with different concentrations. 4. An interviiw with the Point-of-care coordinator (POCC) on 12/13/2022 at 11:40 am in a small conference room confirmed</p>

the above findings. Key: QC=Quality Control PT=Prothrobim time INR=International normalized ratio