

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0642731	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier Med Science Center Inc	Street Address, City, State 435 Arden Ave, Ste 140, Glendale, CA	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory director on January 13, 2021 at 2:05 pm, the laboratory failed to test the proficiency testing samples the same number of times that it routinely tests patient samples at 1 testing event out of 1 event, reviewed. The findings include: 1. The laboratory tested 5 CAP Q1-2020 BMP/CMP samples first at 18:48 on 2/14/2020 and then again at 19:29 on the same day using the automated device number 4053200. However, it routinely tests the patient sample only one time unless the results fall within the repeat criteria. 2. The laboratory director on January 13, 2021 at 2:05 pm, affirmed that the laboratory tested the PT samples 2 times. 3. The laboratory's testing declaration form, signed by the laboratory Director on 1/7 /2021, stated that the laboratory performs 276,000 tests in routine chemistry, annually.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's random patient samples test order records for the years of 2019 and 2020, and interview with the laboratory director on January 13, 2021 at 2:35 pm, the laboratory failed to document the date and time it received</p>

specimens for 1 patient out of 1 sample, reviewed. The findings include: 1. The laboratory received a patient sample that was collected on 12/30/2020, accession number 00931856 with a test order form. However, the laboratory did not document the date and time it received the specimen. 2. The laboratory director on January 13, 2021 at 2:35 pm, affirmed that the laboratory did not document the date and time it received the specimen. 3. The laboratory's testing declaration form, signed by the laboratory Director on 1/7/2021, stated that the laboratory performs approximately 426,000 tests, annually.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, PT records for the years of 2019 and 2020, and interview with the laboratory director on January 13, 2021 at 2:05 pm, the laboratory director failed to ensure that the proficiency testing samples are tested as required under subpart H of this part for 1 PT event out of 1 event, reviewed. The findings include: See D2010.