

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2216067	(X3) Date Survey Completed 03/06/2023
Name of Provider or Supplier Tower Medical Laboratory	Street Address, City, State 8631 W 3rd St Ste 815e, Los Angeles, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records and results from API and interview with the laboratory technical consultant on March 6, 2023, at 1:25 pm, the laboratory failed to verify the accuracy of PTH and glycated hemoglobin tests. The findings include: 1. The laboratory participated in the API proficiency testing program for the PTH and glycated hemoglobin tests accuracy in 2022. However, the laboratory received "0" score from API. Therefore, the PTH and glycated hemoglobin tests accuracy and validity of the patients' test results rendered by the laboratory in 2022 cannot be assured. Reporting inaccurate results might have harmed patients. 2. The laboratory technical consultant on March 6, 2023, at 1:25 pm, affirmed that the laboratory received "0" score from API. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023, stated that the laboratory performs approximately 893 PTH and 1,891 glycated hemoglobin tests, annually.</p>
D5813	<p>TEST REPORT CFR(s): 493.1291(g)</p> <p>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Surveyor review of laboratory's policy and procedure, patient test results and critical value report, and interview with the laboratory technical consultant on March 6, 2023, at 1:20 pm, the laboratory failed to alert the ordering physician about the panic or critical value obtained for 2 patients out of 9 patients, reviewed. The findings include: 1. The laboratory obtained WBC critical value for the patient # 230214008 on 2/13/2023 and RBC and HCT critical values for the patient# 230202017 on 2/2/2023. However, the laboratory did not have any documentation showing that it had reported the results to the test ordering physician. The laboratory records should document the date, time, test results, and person to whom the test results were reported. The laboratory's critical results reporting policy stated that it will immediately call the ordering physician's office or report directly to the physician after hours. Therefore, it can be assured that the critical value was immediately reported and thus might have harmed the patient. 2. The laboratory technical consultant on March 6, 2023, at 1:20 pm, affirmed that the laboratory did not have any documentation of the critical value reporting. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023, stated that the laboratory performs approximately 19,020 hematology tests, annually.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on March 6, 2023, at 1:20 pm, it was determined that the laboratory director failed to oversee overall operation and administration of the laboratory. The findings include: See D5217 and D5813.

D6012

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care;

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, patient test results

and interview with the laboratory technical supervisor on March 6, 2023, at 1:20 pm, it was determined that the laboratory director failed to assure the quality of laboratory services provided. The findings include: See D5217.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical supervisor on March 6, 2023, at 1:20 pm, it was determined that the laboratory director failed to assure the laboratory personnel are following the policy and procedure for the accurate reporting. The findings include: See D5813.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on March 6, 2023, at 1:20 pm, it was determined that the laboratory testing person #1 failed to follow the laboratory's procedures for reporting of patient critical test results. The findings include: See D5217.