

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0930454	(X3) Date Survey Completed 01/22/2024
Name of Provider or Supplier Michael F Bishara, Md, Lab	Street Address, City, State 6896 Magnolia Ave, Riverside, 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient and quality control testing records, and interview with the laboratory director on January 22, 2024, at 2:20 pm, it was determined that the laboratory did not meet the requirement under 493.1251, 493.1256, 493.1281 and 493.1289 to fulfil the analytic systems condition. The laboratory's failure to meet the condition may have potentially harmed and affected patient care. The findings include: 1. The laboratory did not have policy and procedure for quality control and imminently life-threatening test results, see D5403. 2. The laboratory failed to run quality control material on the day of patient testing, see D5447. 3. The laboratory failed to do test results comparison with the clinical data, see D5777. 4. The laboratory failed to assess analytical systems quality, see D5791.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic</p>

examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, and interview with the laboratory director on January 22, 2024, at 2:30 pm, the laboratory failed to have quality control procedure and imminently life-threatening result policy. The findings include: 1. The laboratory performed glucose test on AU 480 automated chemistry analyzer on January 11, 2023 and obtained a life-threatening value of 28 mg/dL. It did not run quality control materials on that day. The laboratory could not show the policy and procedure for quality control or life-threatening value. The laboratory may have reported wrong results and harmed patients without assessing the quality of the test according to an established policy and procedure which the laboratory lacked off. 2. The laboratory director on January 22, 2024, at 2:30 pm, affirmed that the laboratory did not have the quality control and life-threatening value policy and procedure due to a move. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 21,600 tests in routine chemistry, annually.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

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.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's quality control records, and interview with the laboratory director on January 22, 2024, at 2:20 pm, the laboratory failed to test quality control material on the day of patient testing. The findings include: 1. The laboratory performed glucose test on AU 480 automated chemistry analyzer on January 11, 2023 and obtained a life-threatening value of 28 mg/dL. It did not run quality control materials on that day. Without testing a quality control material on the day of patient testing the instrument's proper performance cannot be assessed. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director on January 22, 2024, at 2:20 pm, affirmed that the laboratory did not run the quality control material on the day of patient testing. 3. The laboratory's testing declaration form, signed by

the laboratory director on 1/22/2024 stated that the laboratory performs approximately 21,600 tests in routine chemistry, annually.

D5777

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(b)(c)

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's patients test records, and interview with the laboratory director on January 22, 2024, at 1:50 pm, the laboratory failed to do the comparison of the test results with the patient's clinical data. The findings include: 1. The laboratory obtained a very low glucose value of 28 mg/dL for the patient sample ID 29617. However, the laboratory failed to identify the inconsistent tests results with the patient clinical data and reported possibly the inaccurate glucose results. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director on January 22, 2024, at 1:50 pm, affirmed that the laboratory failed to identify the inconsistency and accepted the wrong glucose result. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 1,000 glucose tests, annually.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, quality control and patients test records, and interview with the laboratory director on January 22, 2024, at 2:30 pm, the laboratory failed to establish the quality assessment for the analytical system. The findings include: 1. The laboratory performed glucose test on AU 480 automated chemistry analyzer on January 11, 2023 and obtained a life-threatening low value of 28 mg/dL. It did not run quality control materials on that day. The laboratory could not show the policy and procedure for quality control or life-threatening value. The laboratory did not have a system in place to assess the quality of its work. Quality assessment is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. QA of the Analytic System includes assessing: Test procedures; Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; Specimen and reagent storage condition; Equipment/instrument/test/system

maintenance and function checks; Establishment and verification of method performance specifications; Calibration and calibration verification; Control procedures; Comparison of test results; Corrective actions; and Test records. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director on January 22, 2024, at 2:30 pm, affirmed that the laboratory did not establish a quality assessment system and failed to identify the problems. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 21,600 tests in routine chemistry, annually.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's final report and instrument print out, and interview with the laboratory director on January 22, 2024, at 1:50 pm, the laboratory failed to report the correct results for Glucose for 1 sample out of 10 samples reviewed. The findings include: 1. The laboratory performed glucose test on AU 480 automated chemistry analyzer on November 11, 2023. The laboratory tested only one sample on that day. The instrument print out showed glucose result was 28 mg/dL for the sample ID 29617. However, the final report showed the glucose result was 68 mg /dL. The instrument was interfaced with the laboratory's Medcom Lab Information System and the record showed the glucose result was edited on January 6, 2024, and then reported. Therefore, the accuracy of the glucose test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director on January 22, 2024, at 1:50 pm, affirmed that the laboratory did not report the instrument glucose result correctly. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 1,000 glucose tests, annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, proficiency testing, quality control and patient test records and interview with the laboratory director on January 22, 2024, at 2:30 pm, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide

effective direction over the operation of the laboratory, hence the Condition: Laboratories performing moderate complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to provide accurate test results and assure compliance with the applicable regulations. (See D6004) 2. The laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. (See D6019) 3. The laboratory director failed to ensure that the quality control and quality assessment programs are established and identify the problems as they occur. (See D6020, D6021 and D6022)

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 reappoints 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 & procedure, quality control and patient test records and interview with the laboratory director on January 22, 2024, at 2:30 pm, the laboratory director failed to provide accurate test results and assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D5801, and D5400.

D6019

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's proficiency testing records and interview with the laboratory director on January 22, 2024, at 1:00 pm, the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. The findings include: 1. The laboratory failed to report the proficiency testing results for the 3rd event in 2023 for TSH, T4 etc. Later the laboratory ran the proficiency testing sample as of a corrective action plan. However, it ran only 3 samples out of 5 samples for the TSH and T4 tests. Moreover, it did not review the obtained results. Therefore, it failed

to follow an established corrective action plan for the failed proficiency testing. So, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director on January 22, 2024, at 1:00 pm, affirmed that the laboratory did not run 2 proficiency testing samples as part of the corrective action plan. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 21,600 tests in routine chemistry, annually.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control records, and interview with the laboratory director on January 22, 2024, at 2:20 pm, the laboratory director failed to ensure that the quality control material was tested on the day of patient testing. The findings include: See D5447.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, quality control and patients test records, and interview with the laboratory director on January 22, 2024, at 2:30 pm, the laboratory director failed to ensure that the laboratory established and maintained the quality assessment programs to assess the quality of laboratory services provided. The findings include: See D5791.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control and patients test records, and interview with the laboratory director on January 22, 2024, at 2:30 pm, the laboratory director failed to ensure that the laboratory identified the poor quality of testing. The findings include: See D5801, and D5400.