

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2247735	(X3) Date Survey Completed 01/23/2024
Name of Provider or Supplier Riverside Clinical Laboratory Inc	Street Address, City, State 7177 Brockton Ave, Ste 338, 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
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test report and interview with the laboratory technical supervisor on January 23, 2024, at 2:04 pm, the laboratory failed to retain its discontinued test procedure. The findings include: 1. The laboratory performed COVID PCR test using Biospeedy reagents on the Atila instrument. A total of 15 samples reviewed. The laboratory reported negative test result for the sample ID 221200093. The internal control for the sample had a Ct value of 44.96. However, the laboratory could not provide the test procedure used therefore, the sample's results cannot be assessed. The laboratory had an ownership change and did not have the test procedure used for the testing. Therefore, the accuracy of the COVID test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory technical supervisor on January 23, 2024, at 2:04 pm, affirmed that the laboratory did not know what test procedure was used and the laboratory did not have a copy of the test procedure used. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 9,600 tests in virology, annually.</p>
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</p>

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.

This CONDITION is not met as evidenced by:
Based on Surveyor review of laboratory's test validation and quality assessment records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 pm, it was determined that the laboratory did not meet the requirement under 493.1253, 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 failed to establish and verify (validation) its test performance specifications, see D5423. 2. The laboratory failed to document all validation activities, see D5427. 3. The laboratory failed to assess analytical systems quality, see D5791.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's test validation records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 pm, the laboratory failed to establish and verify (validation) its UTI and RPP tests panels. The findings include: 1. The laboratory developed and performed molecular PCR test for its UTI and RPP panels using Biospeedy reagents on Atila instrument. However, the laboratory did not have any records showing that it had validated the UTI panel test and performed precision for the RPP panel test. Therefore, the accuracy of the UTI and RPP panels tests results rendered by the laboratory cannot be assured and might have had harmed patients. 2. The laboratory technical supervisor on January 23, 2024, at 2:40 pm, affirmed that the laboratory did not have the tests validation records. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22 /2024 stated that the laboratory performs approximately 12,000 tests, annually.

D5427

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(c)

(c) Documentation. The laboratory must document all activities specified in this section.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's test validation records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 pm, the laboratory failed to document all test validation activities. The findings include: see D5423

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, patients test and quality assessment records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 pm, the laboratory failed to establish the quality assessment for the analytical system. The findings include: 1. The laboratory developed and performed tests in bacteriology and virology by molecular PCR technique. It ran UTI and RPP panels which include COVID test. The laboratory lacked its test validation records. 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 had harmed patients. 2. The laboratory technical supervisor on January 23, 2024, at 2:40 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 12,000 tests, annually.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, test validation, quality control and patient test records and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 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 high 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 ensure compliance with the applicable regulations, see D6079. 2. The laboratory director failed to ensure that the test verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method, see D6086. 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 D6094. 4. The laboratory director failed to specify, in writing, the responsibilities and duties of each individual involved in the laboratory operation including consultants and supervisors, see D6107.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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, patient test records and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D3029 and D5400.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's test validation records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 pm, the laboratory director failed to ensure that the test verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. The findings include: The laboratory failed to establish and verify (validation) its UTI and RPP tests panels So, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have had harmed patients, see D5423.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, test validation, patients test and quality assessment records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:40 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.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, patients test records, and interview with the laboratory technical supervisor on January 23, 2024, at 2:20 pm, the laboratory director failed to specify, in writing, the responsibilities and duties of each individual involved in the laboratory operation including consultants and supervisors. The findings include: 1. The laboratory's personnel report form signed by the laboratory director on January 22, 2024, showed that it had 1 CC, TC, TS, GS and 4 TP. Two of the testing persons (TP) did not have California State issued license. On the other hand, the clinical consultant (CC), technical consultant (TC), technical supervisor (TS) and general supervisor (GS) was licensed in chemistry from the State of California, but the laboratory was testing in bacteriology and virology. Therefore, the accuracy of the patients' test results furnished by the laboratory cannot be assured and might have had harmed patients. 2. The laboratory technical supervisor on January 23, 2024, at 2:20 pm, affirmed that the laboratory director did not specify, in writing, the responsibilities and duties of each individual involved in the laboratory operation including consultants and supervisors. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/22/2024 stated that the laboratory performs approximately 12,000 tests, annually.