

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2225408	(X3) Date Survey Completed 04/24/2023
Name of Provider or Supplier Jp Express Laboratory Inc	Street Address, City, State 935 S Mount Vernon Ave Ste 109, Colton, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient test records, and interview with the laboratory director and testing person on April 24, 2023, at 12:50 pm, the laboratory failed to retain patient test records. The findings include: 1. The laboratory performed SARS-CoV-2 PCR test. The test method includes signal detection with the PCR instrument. The laboratory transcribed the PCR results from the instrument and entered into the laboratory information system for reporting. Therefore, the transcribed data considered as part of patient test records and the laboratory must retain the original and the transcribed copy for 2 years. However, the laboratory did not retain the copy of the transcribed data. Therefore, the accuracy of the transcribed data can not be assured and may have affected patient care. 2. The laboratory testing person on April 24, 2023, at 12:50 pm, affirmed that the laboratory did not save the copy of the transcribed data. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/24/2023 stated that the laboratory performs approximately 3,600 tests, annually.</p>
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p>

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, quality control records, and interview with the laboratory director and testing person on April 24, 2023, at 1:15 pm, the laboratory failed to have corrective action policies and procedures. The findings include: 1. The laboratory did not have corrective action policies and procedures. The laboratory must take corrective action when unacceptable test values occur. Therefore, the quality of the test cannot be assured and might have harmed patients. 2. The laboratory director and testing person on April 24, 2023, at 1:15, affirmed that the laboratory did not have corrective action policies and procedures. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/24/2023 stated that the laboratory performs approximately 3,600 tests, annually.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, quality control records, and interview with the laboratory director and testing person on April 24, 2023, at 1:15 pm, the laboratory failed to document the corrective actions taken when the results of control was unacceptable. The findings include: 1. The laboratory performed SARS-CoV-2 PCR test (run ID 230422-P1/P2/P3 and 230423-P1/P2/P2API) which included quality control materials, patients' samples, and proficiency testing samples. The laboratory repeated the test 6 times because the quality control failed. It then performed some corrective actions according to the testing person, however, did not document the actions taken. The laboratory must document all the corrective actions taken when the control fails. Therefore, the quality of the test cannot be assured and might have harmed patients. 2. The laboratory director and testing person on April 24, 2023, at 1:15, affirmed that the laboratory did not document the corrective actions taken. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/24/2023 stated that the laboratory performs approximately 3,600 tests, annually.

D5800

POSTANALYTIC SYSTEMS
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patient test records, and interview with the laboratory director and testing person on April 24, 2023, at 1:25 pm, and the severity of the deficiency found, it was determined that the laboratory did not meet the requirement under 493.1291 and 493.1299 to fulfil the postanalytic systems condition. The laboratory's failure to meet the condition may have potential to harm and affect patient care. The findings include: 1. The laboratory did not 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 to final report destination, see D5801. 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems, see D5891.

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 patient test records, and interview with the laboratory director and testing person on April 24, 2023, at 12:50 pm, the laboratory failed to have a system in place to ensure transcribed results are reported correctly. The findings include: 1. The laboratory performed PCR test for SARS-CoV-2. It manually transcribed the results and entered the results into the laboratory information system for reporting. It did not save the copy of the transcribed data. The test result showed the sample 22123004 was negative, however the laboratory reported the result as invalid. It can not be determined if the transcribed data was wrong or entered incorrectly into the information system. Therefore, the accuracy of the patients' test results reported by the laboratory cannot be assured and might have harmed patients. 2. The laboratory testing person on April 24, 2023, at 12:50 pm, affirmed that the result was negative and may have transcribed wrong or entered incorrectly. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/24/2023 stated that the laboratory performs approximately 3,600 tests, annually.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

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 director and testing person on April 24, 2023, at 1:25 pm, the laboratory failed to establish and follow written policies and procedures for an

ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings include: 1. The laboratory did not have an established policy and procedure to monitor, assess and correct problems in the postanalytic system. Hence, it did not save the copy and notice the problems in the manually transcribed data, and in failing to generate the test report for sample 221230023 that was positive. Therefore, the quality and accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director and testing person on April 24, 2023, at 1:25 pm, affirmed that the laboratory did not establish a quality assessment policy and procedure for the postanalytic systems. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/24/2023 stated that the laboratory performs approximately 3,600 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, patient test records and interview with the laboratory director and testing person on April 24, 2023, at 1:25 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 be 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. See D6079. 2. The laboratory director failed to ensure all personnel testing personnel have the appropriate education and experience. See D6102. 3. The laboratory director failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D6094. 4. The laboratory director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. See D6096.

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 reapportions 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 director and testing person on April 24, 2023, at 1:25 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D3031, D5779, D5783 and D5800.

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 & procedure and interview with the laboratory director and testing person on April 24, 2023, at 1:25 pm, the laboratory director failed to 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. The findings include: See D5891.

D6096

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control and patient testing records, and interview with the laboratory director and testing person on April 24, 2023, at 1:15 pm, the laboratory director failed to ensure that the remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. The findings include: See D5783.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's testing personnel records and interview with the laboratory director and testing person on April 24, 2023, at 1:25 pm, the laboratory director failed to ensure that all the testing personnel have the appropriate education and experience. The findings include: See D6168.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on Surveyor review of laboratory's testing personnel and patient test records and interview with the laboratory director and testing person on April 24, 2023, at 1:15 pm, it was determined that the laboratory failed to have sufficient number of individuals who meet the qualification requirements of 493.1489, hence the Condition: Laboratories performing high complexity testing; testing personnel was not met. The laboratory's failure to have qualified testing personnel has a consequence of potential erroneous test result reporting and patient harm. The findings include: The laboratory put 2 California licensed testing persons on the personnel report form but none of them performed any test. They just had reviewed the test results. On the other hand, it put 2 lab assistants on the form. However, the testing persons did not perform the test, but lab assistants did. The lab assistants were not qualified as testing person to perform the test. See D6171

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's testing personnel records and interview with the laboratory testing person on April 24, 2023, at 1:25 pm, the laboratory testing personnel failed to meet the required qualification. The findings include: 1. The laboratory performed PCR test for SARS-CoV-2. The PCR test include manual sample processing, running the test and interpreting the test results. The laboratory had 2 lab assistants who performed the test. However, none of them met the required qualifications. The testing person must be qualified to perform the high complexity test as required by the outlined regulations. Therefore, the quality and accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory director and testing person on April 24, 2023, at 1:25 pm, affirmed that the lab assistants performed the test who are not qualified by the regulations. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/24/2023 stated that the laboratory performs approximately 3,600 tests, annually.