

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2078131	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Action Urgent Care Inc	Street Address, City, State 1680 E Capitol Expy Ste 10, San Jose, 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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's client complaint log, and interview with the laboratory technical supervisor on January 12, 2023, at 3:40 pm, the laboratory failed to have a system in place to ensure patient-specific data are reliably sent from the point of data entry to final report destination, in a timely manner. The findings include: 1. The laboratory used LabDaq, laboratory information system to accession and report patient data. The LabDaq system is interfaed with the patient test ordering software. On 01/05/2023, client entered test order into the system for the patient R.V. Five patients' samples reviewed. The laboratory received the patient sample on 01/06 /2023. However, due to the incorrect information LabDaq did not generate the requisition. The laboratory staff put the sample in the 'no requisition' rack without filling out the specimen rejection log form. The laboratory did not process the sample until the client inquired on 01/10/2023. The laboratory's average turnaround time is 2 days, however, due to the problem in the laboratory's information system the patient report was delayed and thus have harmed the patient. 2. The laboratory technical supervisor on January 12, 2023, at 3:40 pm, affirmed that the laboratory has problem</p>

with its laboratory information system. 3. The laboratory's testing declaration form, signed by the laboratory director's designee on 1/12/2023, stated that the laboratory performs approximately 300,000 tests in virology, annually.

D5815

TEST REPORT
CFR(s): 493.1291(h)

When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's client complaint log, patient test results, and interview with the technical supervisor on January 12, 2023, at 3:50 pm, the laboratory failed to notify the appropriate individual of delayed patients testing for 6 patients out of 20 patients, reviewed. The findings include: 1. The laboratory performed Influenza A/B, SARS-COV-2 and RSV PCR testing. The laboratory's client #1 complained on 01/10/2023 about not receiving the test report after 5 days for the following patients: A.L., R.C., A.C., S.V., R.V., M.A. The laboratory's average turnaround time was 2 days. However, the laboratory did not notify the client regarding the delay in testing. Therefore, the relevant patients did not receive the test results on time and might have been harmed. 2. The laboratory technical supervisor on January 12, 2023, at 3:50 pm, affirmed that the laboratory did not notify the client when the testing was delayed. 3. The laboratory's testing declaration form, signed by the laboratory director's designee on 1/12/2023, stated that the laboratory performs approximately 300,000 tests in virology, annually.

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 client complaint log, patient test results, and interview with the technical supervisor on January 12, 2023, at 3:50 pm, it was determined that the laboratory director failed to direct the overall operation and administration of the laboratory. The findings include: See D5801 and D5815.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each

of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's client complaint log, patient test results, and interview with the technical supervisor on January 12, 2023, at 3:50 pm, it was determined that the laboratory director failed to ensure the quality of the laboratory services provided. The findings include: See D5801 and D5815.