

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2115911	(X3) Date Survey Completed 02/03/2022
Name of Provider or Supplier Henry Mayo Newhall Urgent Care	Street Address, City, State 23929 Mcbean Pkwy Ste 102, Valencia, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, American Proficiency Institute (API) testing worksheets, quality control records, and interview with the laboratory Technical Consultant on October 19, 2021 at approx. 12:00 pm, the laboratory failed to perform the repeat testing following the manufacturer's instructions for reporting results on their proficiency testing material. The findings include: 1) The Laboratory uses the Horiba ABX for testing Moderate complexity CBC. Manufacturer requires repeat of samples when an error flag is generated while running a sample. 2) Technical Consultant provided policy of laboratory manual which states, "TAB 6: POSTANALYTIC POLICIES AND PROCEDURE" reject flags such as \$ must be repeated. 3) The laboratory Technical Consultant could not provide proof that one of five API sample was retested when the error flag occurred, as required in their policy. 4) Technical Consultant affirmed that the laboratory reported the results for API 2nd event 2020 without rerunning the sample as their protocol states. One of five (20%) API samples observed at the time of survey showed rejection criteria which was not retested. Based on the laboratory's annual test volume declaration, the laboratory analyzed and reportedes approximately 251 CBC samples annually. Potentially, one in five (20%) patients tested or 50 patients, may have been effected in this time.</p>
D5463	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g)</p>

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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patient test records, quality control testing records, and interviews with the laboratory Testing Personnel and Technical Consultant the laboratory failed to rotate control material testing, over time, among all operators who perform the test. The findings include: 1). The laboratory has a total of 6 testing persons who perform the testing of patient samples. However, a random review of Quality Control charts and maintenance logs showed that only 2 testing persons had performed all the QC the testing. 2). Interviews with both the Technical Consultant and the laboratory testing person, on 10/19/2021 at 12:00pm, affirmed that the laboratory did not rotate the quality control material among the testing persons for testing. Two of six competent personel performed QC with an annual volume of 21,568 tests potentially effected 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 review of the laboratory's records and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the quality control program was established, documented and maintained to assure the quality of laboratory services provided. the findings included: See D-5463 and D-5411

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on observations, review of the QC records, interview with the testing personel and Technical Consultant, it was determined that the laboratory consultant failed to be responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed. The findings included: 1) Two of six testing personal were documented as responsible for all QC on the Istadt. The

remaining four testing personal have not been provided regular in service education, training, and evaluation. 2) Continuous in service training and education was not provided prior to API 2nd event 2020, which led to reporting of rejected results. See D5411 and D5463