

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0686626	<b>(X3) Date Survey Completed</b>  05/23/2019
<b>Name of Provider or Supplier</b>  El Monte Comprehensive Health Center	<b>Street Address, City, State</b>  10953 Ramona Blvd, El Monte, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observations, review of the temperature charts, and interview with the laboratory supervisor and the laboratory personnel, it was determined that the laboratory failed to monitor temperature continuously and document properly for the temperature records. The findings included: a. See D-5791, and b. Review of the temperature record charts for Follet H.S.M.S. #31869 in the month of April, 2019, the laboratory failed to monitor and record the laboratory temperature-controlled space, equipment, refrigerators, and freezers on all Sundays. c. The laboratory's written policies and procedures requires "Temperature dependent equipment containing reagents and patient specimens are to be monitored daily." d. The laboratory stored the patient specimens and the supplies, including reagents, calibrators and quality control materials in temperature-controlled refrigerators and freezers. e. The laboratory failed to assure the temperature conditions of the refrigerators and freezers were within the acceptable ranges on all Sundays or dates when the laboratory closed. f. The laboratory failed to follow its established written policies and procedures that require "Temperature dependent equipment containing reagents and patient samples are to be monitored daily." f. The laboratory personnel affirmed (5/23/19 @ 11:45 AM) that the laboratory failed to follow and assure the temperature controlled equipments were within acceptable ranges while the laboratory closed.</p>

**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 observations, review of the laboratory records and interview with the laboratory supervisor and the laboratory personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess the temperature conditions and document properly for the temperature monitor records when the laboratory closed. The findings included: See D-5413 and a. The laboratory has refrigerators and freezers with build-in temperature control sensors for laboratory storage purpose. b. The laboratory also used digital thermometers by Fisher Scientific, which offer features including functions for "Min" and "Max", and "Alarm" systems in addition to current temperature display. c. The laboratory failed to understand and find ways with the digital thermometer features to assure the temperature were within acceptable ranges when the laboratory closed. d. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's final patient testing result reports, and interview with the laboratory personnel, it was determined that the laboratory's final patient testing result reports failed to indicate the test report date clearly. The findings included: a. The laboratory has implemented an electronic medical record (EMR) computer system, Orchid, since 2015. b. Review of 6 final patient testing result reports (ID # 123968637; #123968530; #123968402; #123959013; #123961163; #123961105) from April 1, 2019 thru April 22, 2019 which were printed out from the Orchid EMR system. c. There are no "Test report date" clearly indicated on the print-out final reports. d. CLIA regulations 42 CFR part 493.121 (c)(1) thru (7) state that the final patient testing result reports must include and indicate "The test report date". e. The laboratory personnel affirmed (5/23/2019 @ 12:05 PM) that no "The test report date" indicated on the final patient testing result reports.