

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0585142	(X3) Date Survey Completed 08/13/2019
Name of Provider or Supplier Family Healthcare Network - Delano	Street Address, City, State 1230 Jefferson St, Delano, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on reviews of laboratory proficiency testing records, API (American Proficiency Institute) proficiency testing reports for 2018: 2nd event (November), and patients test records; the lack of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to verify the accuracy of Ferritin. Findings included: a. The laboratory chose to enroll in API's proficiency testing program to satisfy the requirement to at least twice annually verify the accuracy of testing for Ferritin. b. Review of laboratory proficiency testing records and API's proficiency testing report for 2nd event, 2018, revealed that 2 out of 3 laboratory results failed to meet the acceptable range: PT Lab Acceptable sample result range ----- IA-05 87 97 - 128 IA-06 52 56 - 76 c. The laboratory was unable to provide other documents verifying the accuracy of testing during this timeframe. d. Laboratory personnel affirmed (8/12/19 at 3pm) the aforementioned findings and lack of alternate method for verifying testing accuracy; and thus, the accuracy of testing for Ferritin failed to be verified. e. Although accuracy failed to verify, the laboratory continued testing for Ferritin. Thus, the reliability and quality of results reported for Ferritin could not be assured during the timeframe November 2018 - May 2019. A few examples are as follows: Date Accession # ----- 11/09/18 935674 12/08/18 941779 1/30/19 945398 2/28/19 107941 4/25/19 190308069 4/25/19 190315098 5/09/19 190402006 .</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on observation of the Siemens Dimension Xpand chemistry analyzer, review of laboratory records verifying instrument calibrations, the lack of records verifying calibrations, and interview with laboratory personnel, the laboratory failed to perform calibration verification procedures at least once every 6 months in 2019. Findings included: a. Laboratory records verifying calibrations were performed as follows: September 2017 March 2018 September 2018 * May 2019 b. The laboratory was unable to provide for review documents verifying calibrations at least once within 6 months after September 2018 (*). c. Laboratory personnel, including the Technical Consultant, affirmed (8/13/19 at 5pm) the aforementioned lack of laboratory records; and thus, the laboratory's failure to verify calibrations for Chloride, Sodium, and Potassium at least once every 6 months after September 2018. d. Testing for the electrolytes continued even though the laboratory failed to verify that calibrations were acceptable. Thus, the reliability and quality of results reported during the timeframe March - April 2019 could not be assured. A few examples are as follows:
Date Accession ----- 3/12/19 190307024 3/26/19
190314015 4/02/19 190320007 4/03/19 190401037 4/03/19 190402017 4/03/19
190402029 4/23/19 190419028 .

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) 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 observation of the Cobas e411 chemistry analyzer in use December 2018, review of laboratory records, the lack of laboratory documents, and interview with laboratory personnel, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure that personnel demonstrated reliable performance in obtaining accurate results prior to testing patients specimen. Findings included: a. Review of the Laboratory Personnel Report (8/13/19) revealed there were two testing persons. b. Laboratory records documented the Cobas e411 (serial number 1422-28) was put into use December 2018. c. The Technical Consultant affirmed (8/13/19 at 2:30pm) that Testing Person-1 had the responsibility for operating the e411 analyzer. d. The laboratory failed to provide instrument records of results and documents for Testing Person-1 demonstrating reliable operation of the e411 prior to testing patients specimen. e. The Technical Consultant affirmed (8/13/19 at 2:30pm) the aforementioned lack of laboratory records and documents. f. Although the Laboratory Director failed to ensure that reliable operation of the e411 had been demonstrated, Testing Person-1 began testing patients specimen using the e411. And thus, the reliability and quality of results reported could not be assured. A few examples are as follows: Date Accession # -----. 4/23/19
190419028 5/07/19 190502046 5/07/19 190404022 5/09/19 190502051 7/02/19
190701015 7/02/19 190701025