

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1106919	(X3) Date Survey Completed 06/15/2018
Name of Provider or Supplier New Vision Medical Diagnostic ,Llc	Street Address, City, State Urb Hermanas Davila J-23 Ave Betances, Bayamon, PR	
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
D5413	<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 review of the refrigerator temperature chart and interview with the laboratory director on 6/15/2018 at 11:45 Am, it was determined that the laboratory did not take nor document any remedial actions when the white General Electric refrigerator temperatures were outside the acceptable range. The findings include: a. On June 15, 2018 the General Electric refrigerator temperature chart showed as an acceptable range 2 -8 C. It was used to store general chemistry reagents. b. The manufacturer instructed the laboratory to store the reagents between 2 - 8C. c. Review of the temperature chart from year 2018 showed out of range temperatures on 49 out of 101 days. d. The laboratory director stated that no remedial action was documented.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for</p>

example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of Vitamin D quality control records and interview with the laboratory director and the testing personnel, it was determined that the laboratory did not take nor document any remedial actions when the quality control Levy Jennings graphs showed shifts to the right since July 2017. The findings include: a. On June 15, 2018 at 10:00 AM the routine chemistry Levy Jennings graphs (year 2017 and 2018) was reviewed. b. The Vitamin D Levy Jennings graphs showed shifts to the right since July 2017. c. There was no documentation of remedial actions. d. The testing personnel stated that they were having some difficulties with the laboratory information system in which the quality control was evaluated. e. The laboratory director stated that she was not aware of the problem because she was recently hired for the position. f. The laboratory processed and reported approximately 500 patients samples for Vitamin D since July 2017.

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 quality control records and interview with the laboratory director on June 15, 2018, it was determined that the laboratory director did not assure that remedial actions were taken when quality control deviations occurred. Refer to D 5413 and D5469.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on review of Levy Jennings graphs and temperatures charts on June 15, 2018, it was determined that the laboratory testing personnel did not take nor document remedial actions when quality control records showed shifts to the right for Vitamin D

nor take remedial actions when the refrigerator showed values outside of the acceptable range. Refer to D 5413 and D5469.