

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2072541	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Valley Medical And Wellness	Street Address, City, State 2438 East 117th Street, Burnsville, MN	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure Chemistry (Toxicology) proficiency testing was performed consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Toxicology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/16/18 at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) for analytes not available through an approved PT provider using 5C Laboratories. 3. Toxicology PT from the 5C Laboratories SK2 December 2017 event was completed by a former testing personnel and Testing Personnel 2 as indicated on laboratory testing forms. 4. In an interview on 10/16/18 at 12:30 p.m., the GS confirmed the PT had been performed by multiple testing personnel and patient specimens would not routinely be handled in this manner.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed</p>

to ensure Chemistry (Toxicology) testing materials were not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory performed Chemistry testing under the subspecialty of Toxicology as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/16/18 at 10:05 p.m. 2. Review of laboratory reagent records located in the Maintenance, SOP's Training, Supplies manual indicated the Needle Rinse had been used after the solution had expired. See below. Prep date Expiration date Subsequent prep date 01/17/18 02/17/18 04/10/18 3. Laboratory records indicated 16 days of patient specimen testing occurred between 02/18/18 and 04/09/18. 4. In an interview on 10/16/18 at 1:40 p.m., the GS confirmed the above finding.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
. Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a function check procedure and perform functions checks on all ancillary laboratory equipment. Findings are as follows: 1. Pipettors, thermometers, a centrifuge and a digital timer were observed as present and available for use during a tour the laboratory on 10/16/18 at 10:05 a.m. 2. A function check procedure for the pipettors, thermometers, centrifuge and timer was not found in the laboratory's established procedure manuals. Documentation of function checks for this equipment was not found in laboratory records. The laboratory was unable to provide a function check procedure or documentation of function checks performed since May 2017 for the above equipment upon request. 3. A hand written tag on the back of a digital timer with serial number 140653914 indicated the most recent function check had been performed 12/23/14. The original calibration date and expiration date had been removed from the manufacturer's tag. 4. In an interview on 10/16/18, at 1:55 p. m., the General Supervisor confirmed the above finding.