

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0694296	(X3) Date Survey Completed 03/23/2018
Name of Provider or Supplier Evernorth Care Group	Street Address, City, State 5891 W Eugie Ave, Glendale, AZ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on lack of proficiency testing (PT) records presented for review for 2016 and interview with the facility personnel, the laboratory failed to provide a copy of the PT program report form, instrument printouts and PT attestation statements. Findings include: 1. The laboratory participates in PT for the analytes: Amylase and Lipase, performed under the specialty of Chemistry; Complete Blood Count (CBC) testing performed under the specialty of Hematology; and for KOH testing performed under the specialty of Microbiology, with an approximate annual total test volume of 9,364. 2. The PT records presented for review from the 2nd and 3rd events of 2016 for CBC and KOH testing were missing the testing printouts from the analyzer (if applicable), the proficiency testing program report form used by the laboratory to record PT results and the PT attestation statements. 3. The PT records presented for review from the 1st, 2nd and 3rd events of 2016 for testing performed under the specialty of Chemistry were missing the testing printouts from the analyzer, the proficiency testing program</p>

report form used by the laboratory to record PT results and the PT attestation statements. 4. The facility personnel acknowledged that the PT test records indicated above were not available for review at the time of the survey.

D3037

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:
Based on lack of documentation presented for review and interview with the laboratory personnel during the survey, the laboratory failed to retain proficiency testing (PT) records for the first event of 2016 for testing performed under the specialty of Hematology. Findings include: 1. No documentation for the first PT event of 2016 was presented including PT worksheets, hematology instrument print outs, and signed attestation statements. 2. The facility personnel acknowledged that the documentation indicated above could not be located.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on lack of a microscope maintenance policy for review and interview with the facility personnel, the laboratory failed to have a microscope maintenance policy that indicates specific routine maintenance procedures as well as scheduled preventative maintenance procedures. Findings include: 1. The policy and procedure manual presented for review during the survey conducted on March 23, 2018 did not contain any policies with regards to microscope maintenance. 2. The facility personnel acknowledged that there was no microscope maintenance policy contained in the manual. 3. The laboratory has one microscope used to perform KOH testing on patient specimens. The laboratory's approximate annual test volume for KOH testing is 12.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on lack of competency evaluation documentation for review and interview with the facility personnel, the technical consultant failed to evaluate and document the

performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. No 2016 annual competency evaluation documentation was presented for review for five out of five testing personnel. 2. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2016 for the five testing personnel indicated above.