

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1011845	(X3) Date Survey Completed 08/20/2019
Name of Provider or Supplier Northwest Family Medicine	Street Address, City, State 7301 N Comanche Ave, Oklahoma City, OK	
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
D0000	The recertification survey was performed on 08/20/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with testing person #1 at the conclusion of the survey.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) During the survey, the surveyor reviewed 2017, 2018, and 2019 Hematology proficiency testing records. The following failures were identified, for which corrective action documentation could not be located: (a) Second 2018 Event (i) Hematocrit - The laboratory failed the result for 1 of 5 samples (HD-6), and attained a score of 80%; (ii) Lymphocyte % - The laboratory failed the result for 1 of 5 samples (HD-7) and attained a score of 80%. (2) The surveyor asked testing person #1 if corrective action had been taken for the failures. After reviewing the records, testing person #1 stated corrective action had not been taken for the failures.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell Dyn Emerald analyzer; (2) The surveyor reviewed the manufacturer's maintenance instructions (in Section 9 of the operators manual) for the analyzer which stated under the heading "Semi-Annual Maintenance": (a) "Lubricating the Pistons - For optimal operation, the Syringe Pistons should be lubricated every six months". (3) Maintenance records were reviewed by the surveyor for 24 months (September 2017 through August 2019). The semi-annual maintenance had not been documented as performed prior to 07/08/19; (4) The surveyor reviewed the records with testing person #1 who stated there was no evidence the above maintenance had been performed as required.

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 a review of patient test reports and interview with testing person #1, the laboratory failed to ensure test reports included either the patient's name and identification number, or a unique patient identifier and identification number. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell Dyn Emerald analyzer; (2) The surveyor reviewed 6 patient CBC test reports. Each report included a first and last name as an identifier, but a second unique identification number was not included (e.g. accession number, chart number, etc.); (3) The surveyor reviewed the reports with testing person #1 who stated the reports did not include a second unique identifier in addition to the patient's first and last name.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with testing person #1, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed

using the Cell Dyn Emerald analyzer; (2) The surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 05/03/19 at 01:04 pm; the second report was for an adult female patient with the testing performed on 06/03/19 at 08:45 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 4.2 - 6.3 (x 10⁶/uL) (b) Hemoglobin - 12.0 - 18.0 g/dL (c) Hematocrit - 37.0 - 51.0 % (3) The surveyor reviewed the findings with testing person #1, who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.