

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0214558	(X3) Date Survey Completed 01/14/2019
Name of Provider or Supplier Crossroads Medical Laboratory Llc	Street Address, City, State 4801 Dorsey Hall Drive Suite 200, Ellicott City, MD	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory manager, the laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Findings: 1. The laboratory currently has 3 testing personnel listed on the "Laboratory Personnel Report (CMS-209)" who perform hematology testing. 2. A review of hematology PT attestation worksheets from 2017 and 2018 showed that PT was performed by the same testing person in 3 of 6 events; and 3. During an interview on 1/14/19 at 4:00 PM, the laboratory manager confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.</p>
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and interview with laboratory manager, the laboratory failed to ensure that corrective action was taken and documented for failed PT. Findings: 1. The laboratory failed Hematology Cell ID PT (60%) for 2nd event, 2017 and received an unsatisfactory score (80%) for 1st event, 2017 and 1st event, 2018. 2. No corrective action was documented for the failed PT. 3. During an interview on 1/14/19 at 4:00 PM, the laboratory manager confirmed that there was no corrective action taken or documented for the failed PT.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and interview with the laboratory manager, the laboratory director did not ensure that corrective action was taken and documented for failed hematology PT for 2nd event, 2017 and unsatisfactory PT for 1st event, 2017 and 1st event, 2018. Refer to D2128.