

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0928366	(X3) Date Survey Completed 10/08/2019
Name of Provider or Supplier Norton Children's Medical Group - Jeffersonville	Street Address, City, State 3118 E 10th Suite B, Jeffersonville, IN	
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
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> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to take and document appropriate training and remedial action for three of three unacceptable analyte scores [red blood cell count (RBC), hematocrit (Hct), and platelet] for one of three challenges (2018-C) in Hematology for 2018. Findings include: 1. The laboratory was enrolled in the American Academy of Family Physicians (AAFP) for proficiency testing (PT). The results of challenge C from 2018 (print date 11/16/2018) were: --RBC: 60% --Hct: 60% --Platelet: 60% 2. The policy, 'Proficiency Testing', reviewed 7/22/11, read: 'Compares results with previous testing. Implement and documents corrective action for problem as necessary'. 3. Upon request for remedial action for event 2018, on 10/09/19 at 12:00 p.m. staff person (SP) #3, laboratory manager, acknowledged that no remedial actions had been taken for the PT 2018-C challenge (analytes RBC, HCT, or platelet: each 60%). SP #3 further confirmed no documentation of remedial action or training for those personnel involved with the 60% scoring was available for review. 3. Upon request for remedial action for event 2018, on 10/09/19 at 12:00 p.m. staff person (SP) #3, laboratory 4. Annual test volume: --RBC = 3,888 --Hct = 3,888 --Platelet = 3,888</p>
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow policies for reviewing and resolving three of three unacceptable analyte scores (RBC, Hct, and platelet) for one of three challenges (2018-C) in Hematology for 2018, as part of the laboratory's quality assessment (QA) program. Findings include: 1. The laboratory was enrolled in the American Academy of Family Physicians (AAFP) for PT. The results of challenge C from 2018 (print date 11/16/2018) were: --RBC: 60% --Hct: 60% --Platelet: 60% 2. The laboratory's QA criteria policy entitled 'Statement of Fact', no approval date listed, read: 'Section 6: 100% of the time all proficiency testing (PT) failures are resolved'. 3. The QA minutes for the fourth quarter of 2018, dated 12/31/18, read: 'The following QA section(s) were met: 6'. There was no mention of the unsatisfactory scores of 60% for RBC, Hct, or platelet, and no documentation of remedial action taken or reviewed as part of the quality assessment. 4. On 10/09/19 at 12:00 p.m. SP #3, acknowledged that no remedial actions had been taken for the PT 2018-C challenge (analytes RBC, HCT, or platelet: each 60%). SP #3 further confirmed section 6 of the laboratory's QA meeting minutes was incorrectly listed as Met instead of Not Met, and there was no documentation or review of these unsatisfactory scores included as part of the laboratory QA.