

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0982507	(X3) Date Survey Completed 07/13/2018
Name of Provider or Supplier Family Care Walk-In Clinic Inc	Street Address, City, State 176c W University Pkwy, Jackson, TN	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Citation number one Based on review of the laboratory's quality assessment policy, the laboratory's 2016, 2017, and 2018 proficiency testing attestation statements, and interview with testing personnel number five, the laboratory failed to follow the policy for proficiency testing when it did not rotate proficiency among testing personnel in 2016, 2017, and 2018. The findings include: 1. Review of the laboratory's quality assessment policy under the section titled "PROFICIENCY TESTING" revealed the following statement: "The surveys should be rotated alternately between all testing personnel with each person performing an entire survey." 2. Review of the laboratory's 2016, 2017, and 2018 proficiency testing attestation statements revealed that testing personnel number five had performed five of the last six surveys (2016 event three, 2017 events one, two, and three, and 2018 event one). 3. Interview with testing personnel number five on July 13, 2018 at 12:45 pm confirmed the laboratory failed to follow policy for rotation of proficiency testing when testing personnel number performed five of the last six surveys in 2016, 2017, and 2018.</p> <hr/> <p>Citation number two Based on review of the laboratory's proficiency testing performance evaluation report for 2017 event three for hematology, the laboratory's policy for proficiency testing, the proficiency testing records for 2017 event three for hematology and interview with the laboratory liaison, the laboratory failed to follow policy for investigation of proficiency testing failure for 2017 event three. The</p>

findings include: 1. Review of the laboratory's proficiency testing performance evaluation report for 2017 event three for hematology revealed a score of 60% for the platelet analyte. 2. Review of the laboratory's policy for proficiency testing revealed the following statement: "For any proficiency testing module with a score of less than 80% a corrective action will be filled out and the 'root cause' will be determined and documented." 3. Review of the proficiency testing records for 2017 event three for hematology revealed no investigation into the cause of the proficiency testing failure for the platelet analyte. 4. Interview with the laboratory liaison on July 13, 2018 at 12:30 pm confirmed the laboratory failed to follow the proficiency testing policy for investigation of failed proficiency testing for the platelet analyte for 2017 event three.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment policy, the personnel records for testing personnel number four and interview with the laboratory liaison, the technical consultant failed to perform initial and six month training/competency assessment for testing personnel number four in 2017. The findings include: 1. Review of the laboratory's quality assessment policy revealed the following statement under the section titled "COMPETENCY OF TESTING PERSONNEL: Training /competency will be performed and documented by the technical consultant initially, at 6 months, and annually thereafter." 2. Review of the 2018 training/competency assessment records for testing personnel number four revealed a hire date of January 2017. No records were available documenting initial and 6 month training /competency assessment in 2017. 3. Interview with the laboratory liaison on July 13, 2018 at 12:30 pm confirmed the technical consultant failed to perform initial and six month training/competency assessment in 2017 for testing personnel number four.