

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089973	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Saint Francis Lab-Tulsa Hills	Street Address, City, State 7858 S Olympia Ave, Tulsa, 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 findings were reviewed with technical consultant #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 the laboratory director and technical consultant #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: BIAS (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) 2016 Hematology 2nd Event - 5 of 5 results exhibited a negative bias for WBC (White Blood Cell): (i) Hem 01- SDI -1.9 (ii) Hem 02- SDI -3.3 (iii) Hem 03- SDI -3.4 (iv) Hem 04- SDI -4.5 (v) Hem 05 - SDI -4.5 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) Surveyor #2 reviewed the above findings with technical consultant #1 who stated the biases had not been identified and addressed.</p> <p>FAILURES (1) During the review of the proficiency testing records. The following failures were identified: (a) 2016 Hematology 2nd Event (i) Erythrocyte- The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (ii) Hematocrit - The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (iii) Hemoglobin -The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure;</p>

(iv) Leukocyte Count -The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (v) MCV (Mean Corpuscular Volume) -The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (vi) Platelet Count - The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (vii) RDW (Red Cell Distribution Width) - The laboratory received a score of 20% (failed 4 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (2) The surveyors reviewed the above findings with laboratory director and technical consultant #1 who stated the laboratory had not taken corrective action for the failures.

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 a review of records and interview with technical consultant #1, the technical consultant failed to annually evaluate persons for all moderate complexity testing performed. Findings include: (1) At the beginning of the survey, the technical consultant #1 stated to surveyor #2 that Wet Prep testing was performed in the laboratory; (2) The surveyors then reviewed personnel records. The following was identified: (a) Testing Person #2 - Although evaluations had been performed on 11/22/16 and 11/16/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (b) Testing Person #3 - Although evaluations had been performed on 11/16/16 and 01/05/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (c) Testing Person #4 - Although evaluations had been performed on 02/01/17 and 11/08/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (d) Testing Person #5 - Although evaluations had been performed on 04/06/17 and 11/02/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (e) Testing Person #6 - Although evaluations had been performed on 11/23/16 and 11/11/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (f) Testing Person #7 - Although evaluations had been performed on 11/09/16 and 11/01/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (g) Testing Person #8 - Although evaluations had been performed on 10/29/16 and 10/27/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (h) Testing Person #9 - Although evaluations had been performed on 11/18/16 and 11/22/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (i) Testing Person #10 - Although evaluations had been performed on 11/16/16 and 11/22/17, there was no evidence the person had been evaluated for performing Wet Prep testing; (j) Testing Person #11 - Although evaluations had been performed on 10/23/16 and 10/27/17, there was no evidence the person had been evaluated for performing Wet Prep testing. (3) The surveyors reviewed the findings with technical consultant #1, who stated that evaluations did not include Wet Prep testing.