Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0474846	(X3) Date Survey Completed 05/21/2018
Name of Provider or Supplier Saint Francis Lab-Warren Clinic Vinita	Street Address, City, State 715 N Foreman St, Vinita, 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 the technical consultant and testing person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 1. 493.801: D2000: Condition: Enrollment and Testing of Samples 2. 493.1403: D6000: Conditon: Laboratory Director, Moderate Complexity 3. 493.1409: D6033: Condition: Technical Consultant
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to enroll in an approved proficiency testing program for the testing performed by the laboratory. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed Hemogram (e.g. WBC-White Blood Count, RBC (Red Blood Count), Hemoglogin, Hematocrit, MCV (Mean Corpuscular Volume), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Cell Distribution Width), Platelet count, and MPV (Mean Platelet Volume) testing on all patients using the Cell Dyn Emerald analyzer. In addition, the technical consultant stated to the surveyor the laboratory did not report the automated WBC differential obtained from the analyzer; (2) The surveyor asked the technical consultant if the laboratory performed manual WBC

	differentials. The technical consultant stated to the surveyor the laboratory would perform a manual WBC differential if ordered by the provider. The surveyor asked the technical consultant if a manual WBC differential had been performed since the previous recertification survey (on 06/29/16). The technical consultant stated one manual WBC differential had been reported during the last two years; (3) The surveyor then reviewed hematology proficiency testing records from the First, Second, and Third events of 2017, and the First event of 2018. The surveyor could not find documentation which proved the laboratory enrolled in WBC differential (i.e. WBC Cell identification) proficiency testing for 4 of the 4 events; (4) The surveyor located the laboratory's 2017 and 2018 "Order Confirmation" documents for proficiency testing. The order confirmations indicated the laboratory enrolled in a "Hematology-3" module, which did include the option to report the automated differential. The technical consultant stated to the surveyor, the laboratory did not report the automated WBC differentials for patients and did not report the automated WBC differentials for the proficiency testing samples; (5) The surveyor asked the technical consultant if the laboratory had enrolled in a manual WBC differential proficiency testing module since it did not report the automated differential and would report manual WBC differentials if ordered by the physician. The technical consultant stated to the surveyor the laboratory believed it had enrolled in a manual WBC differential proficiency testing module for 2017 and 2018; (6) The surveyor reviewed the records and the order confirmation documents with the technical consultant who stated to the surveyor, the laboratory failed to enroll in an approved proficiency testing program for manual WBC differentials during 2017, and to date in 2018; (7) There is no example of patient testing performed when the laboratory failed to enroll in proficiency testing for WBC differentials, because the technical consultant and testing person #1 could not recall the date and patient on which a manual WBC differential had been performed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant, the laboratory failed to establish a written policy/procedure for assessing the competency of the technical consultant. Findings include: (1) At the beginning of the survey, the surveyor reviewed the Laboratory Personnel Report (Form 209) completed by the laboratory prior to the survey. The form listed one individual as the technical consultant for the moderate complexity testing performed by the laboratory. The individual had not been listed on the Form 209 from the previous recertification survey (on 06/29/16). The surveyor asked when the technical consultant was hired at the laboratory. The technical consultant stated to the surveyor the hire date was in July 2017; (2) The surveyor then reviewed personnel records but could not find documentation a competency assessment had been completed for the duties of the technical consultant from July 2017 through the date of the survey. The surveyor asked the technical consultant if a competency assessment had been conducted for the duties of the technical consultant. The technical consultant stated a competency assessment had not been performed; (3) The surveyor asked the technical consultant if the laboratory had a written competency policy for performing

	an assessment of the duties performed by the technical consultant. The technical consultant stated to the surveyor a policy/procedure for competency assessment of the technical consultant had not been written. NOTE: The interpretive guidelines at 493.1235, states "Competency Assessment Guidelines: Technical consultant, clinical consultant, technical supervisor, general supervisor - Documented competency assessment is required for the following named positions on the Form 209: technical consultant clinical consultant, technical supervisor, general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must performed at a frequency determined by the laboratory. If these people perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities (see 493.1413(b)(8)/493.1451(b)(8)).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory used the Abbott Cell Dyn Emerald analyzer to perform patient Hemogram testing, which included a Platelet Count; (2) Hematology proficiency testing records for 2017 and 2018 to date were reviewed. The surveyor could not locate documentation which proved corrective action had been taken for an unacceptable proficiency testing result in the Second 2017 event for Platelet Count: (a) The laboratory failed the result for 1 of the 5 samples and attained a score of 80%; (b) For sample Hem-06, the laboratory reported "91." The proficiency testing program's acceptable response was, "51-87." (3) The surveyor reviewed the findings with the technical consultant and asked if corrective action had been taken for the failure. The technical consultant reviewed the records and stated to the surveyor corrective action had not been taken for the failure.
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 a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant, the laboratory failed to have an effective ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. Findings include: (1) The laboratory failed to have a written policy

	/procedure for performing competency assessments of the technical consultant. Refer to D5209; (2) The laboratory failed to review and evaluate proficiency testing results. Refer to D5211.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to follow its written policy and procedure for the testing performed. Findings include: i-STAT TESTING QUALITY CONTROL (1) At the beginning the survey, the technical consultant stated to the surveyor the laboratory performed PT/INR (Prothrombin Time/ International Normalized Ratio) testing using the i-STAT analyzer and PT testing cuvettes. In addition, the technical consultant stated to the surveyor, the laboratory had developed an IQCP (Individualized Quality Control Plan) to reduce the frequency of testing external liquid QC (Quality Control) materials from 2 levels (Level 1 and Level 2) each day of patient testing, to monthly, and/or with a new lot number of cartridge, and on new shipments; (2) The surveyor reviewed the laboratory's IQCP for the testing, which verified 2 levels of external liquid QC materials were to be analyzed on a monthly basis, and/or with lot a new number of cartridges, and on new shipments; (3) The surveyor then reviewed records from 07/01/16 through 04/30/18 and identified the laboratory failed to test 2 levels of external liquid QC materials each month as required by its IQCP, during 1 of the 20 months reviewed (December 2016); (4) The surveyor reviewed the findings with the technical consultant and testing person #1, who stated the laboratory failed to follow its IQCP for testing external liquid QC materials; (5) Examples of patient testing when the laboratory failed to follow its policy and procedure, include the following: (a) Patient #1 - PT/INR testing performed on 12/02/16 at 8:15 AM (b) Patient #2 - PT/INR testing performed on 12/06 /16 at 10:39 AM (c) Patient #3 - PT/INR testing performed on 12/06/16 at 11:49 AM (d) Patient #4 - PT/INR testing performed on 12/07/16 at 01:41 PM (e) Patient #5 - PT /INR testing performed on 12/08/16 at 11:29 AM ABBOTT CELL DYN EMERALD QUALITY CONTROL (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory used the Abbott Cell Dyn Emerald analyzer to perform patient Hemogram testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglogin, Hematocrit, and MCHC -Mean Corpuscular Hemoglobin Concentration); (2) In addition, the technical consultant stated to the surveyor the laboratory analyzed 3 levels (Low, Normal, and High) of Cell Dyn 18 Plus QC materials each day of patient testing. The technical consultant also stated patient test results could be reported if results of 2 of the 3 levels of QC were within the laboratory's established acceptable limits; (3) The surveyor reviewed the laboratory's QC policy and procedure for hematology testing. Under, "Evaluation of Quality Control Results," the following instructions were listed: (a) "Reject run if: More than one control is outside of the established acceptable limits; (b) If run is rejected: (i) "No patient testing will be performed." (ii) "Rerun control: If results are within acceptable limits, patient results may be reported." (iii) "If results are unacceptable: Use a fresh bottle of control:" (aa) "If results are within acceptable limits, patient

	results may be reported." (bb) If results are again unacceptable: "Replace reagents and rerun control" (i) "If the QC results continue to be out of range, notify supervisor." (ii) "If backup analyzer is not available, patient samples will be sent to SFH Tulsa by courier for testing." (4) The surveyor then reviewed records for 12 QC lot numbers tested between 07/06/16 and 04/30/18. From the records the surveyor identified on 03 /14/17 the results of 2 of the 3 QC lot numbers (Normal-Lot #N6354 and High-Lot #H6354, in use January 2017-April 2017) were unacceptable at initial testing, remained unacceptable after repeat testing, and patient testing was reported. The findings follow: (a) The RBC, Hemoglobin, Hematocrit, and MCHC results were unacceptable.The corrective action log included a note, "Re-ran 6x-still out." Although corrective action had been documented, the following could not be found: (i) There was no documentation a new QC vial was tested; (ii) There was no documentation reagents were replaced; (iii) There was no documentation the supervisor was notified. (b) Three patient Hemograms were tested and results reported (Patient #6, patient #7, and patient #8) (5) The surveyor reviewed the findings with the technical consultant who stated the laboratory did not follow its QC policy and procedure as listed above, and the laboratory reported patient results when QC was unacceptable.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure, and interview with the technical consultant, the laboratory failed to ensure quality control results were acceptable before patient testing was reported. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed patient Hemogram testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglogin, Hematocrit, and MCHC-Mean Corpuscular Hemoglobin Concentration) using the Abbott Cell Dyn Emerald analyzer. In addition, the technical consultant stated to the surveyor the laboratory analyzed 3 levels (Low, Normal, and High) of QC (Quality Control) (Cell Dyn 18 Plus) materials each day of patient testing and patient results were reported if results of 2 of the 3 levels were acceptable; (2) The surveyor reviewed the laboratory's QC policy and procedure for the Abbott Cell Dyn Emerald. Under, "Evaluation of Quality Control Results," it stated the following: (a) "Reject run if: More than one control is outside of the established acceptable limits." (b) "If run is rejected:" (i) "No patient testing will be performed." (ii) "Rerun control: If results are within acceptable limits, patient results may be reported." (3) The surveyor then reviewed records between 07/01/16 through 04/30/18. From the records the surveyor identified on 03/14/17, results of 2 of the 3 QC lot numbers (Normal-Lot #N6354 and High-Lot #H6354, in use January 2017-April 2017) were unacceptable at initial testing, remained unacceptable after repeat testing, and patient test results were reported. The findings follow: (a) The RBC, Hemoglobin, Hematocrit, and MCHC results were unacceptable. The corrective action taken was "Re-ran 6x-still out;" (b) Three patient Hemograms were tested and results reported (Patient #6, patient #7, and patient #8). (4) The surveyor reviewed the findings with the technical consultant who stated the laboratory reported patient Hemogram results when 2 of 3 levels of QC were unacceptable.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to have an effective ongoing mechanism for performing analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow its policy and procedure for quality control testing. Refer to D5401; (b) The laboratory failed to ensure quality control results were acceptable before patient test results were reported. Refer to D5481. NOTE: D5791 was cited at the previous recertifiction survey performed on 06/26/16.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems requiring corrective action. Refer to D6018; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure an effective quality assessment program had been established and maintained. Refer to D6021; (4) The laboratory director failed to ensure the laboratory had a written policy/procedure for performing competency assessment of the technical consultant. Refer to D6030. NOTE: D6000 was cited at the previous recertifiction survey performed on 06/26/16.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems that require corrective action. Findings include: (1) The laboratory director failed to ensure proficiency testing results were reviewed and evaluated. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory director failed to ensure an effective quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory followed its written policy and procedure for the testing performed. Refer to D5401; (2) The laboratory director failed to ensure quality control results were acceptable before patient test results were reported. Refer to D5481. NOTE: D6020 was cited at the previous recertifiction survey performed on 06/26/16.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory director failed to ensure effective quality assessment programs were maintained to assure the quality of laboratory services provided. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. Refer to D5291 and D5791. NOTE: D6021 was cited at the previous recertifiction survey performed on 06/26/16.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant, the laboratory director failed to ensure a policy and procedure was established to assure technical consultant competency. Findings include: (1) The laboratory director failed to ensure the laboratory had a written policy/procedure for the competency assessment of the technical consultant. Refer to D5209.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant and testing person #1, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to enroll and participate in an approved proficiency testing program for the testing performed in the laboratory. Refer to D6041; (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (3) The technical consultant failed to ensure patient test results were not reported until all corrective actions have been taken and the test system is functioning properly. Refer to D6044.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the technical consultant failed to ensure enrollment in a proficiency testing program commensurate with the testing performed in the laboratory. Findings include: (1) The technical consultant failed to ensure enrollment in a proficiency testing program for White Blood Cell differential testing. Refer to D2000.

D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with the technical consultant and testing person #1, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure a policy and procedure had been written. Refer to D5209; (2) The technical consultant failed to ensure a written policy and procedure was followed. Refer to D5401.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant, the technical consultant failed to ensure quality control results were acceptable before patient test results were reported. Findings include: (1) The technical consultant failed to ensure quality control results met the laboratory's criteria for acceptability; and failed to ensure patient results obtained in an unacceptable test run were evaluated to see if they had been adversely affected. Refer to D5481.