

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0474846	(X3) Date Survey Completed 09/03/2020
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 following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database on 09/03/2020. The laboratory was found out of compliance with the following CLIA regulations: 493.803: D2016: Condition: Successful Participation 493.807: D2017: Condition: Reinstatement of Laboratories Performing Non-waived Testing 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity Testing
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing scores, the laboratory failed to successfully participate in a proficiency testing program for the Specialty of</p>

	<p>Hematology. Findings include: (1) The laboratory failed to achieve satisfactory performance for 3 of 4 testing events for Cell ID/WBC Diff (Cell Identification/White Blood Cell Differential) testing. Refer to D2131.</p>
<p>D2017</p>	<p>REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)</p> <p>(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing scores, the laboratory failed to successfully participate in a proficiency testing program for Cell ID/WBC diff testing. Findings include: (1) The laboratory failed to successfully participate in Hematology proficiency testing for Cell ID/WBC Diff (Cell Identification/White Blood Cell Differential) testing. Refer to D2131.</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing scores, the laboratory failed to achieve satisfactory performance for Cell ID/WBC Diff testing in three of four testing events. Findings include: (1) The laboratory received the following scores: (a) A score of 60% was received on the First 2019 Hematology event; (b) A score of 60% was received on the Third 2019 Hematology event; (c) A score of 60% was received on the First 2020 Hematology event.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p>

This CONDITION is not met as evidenced by:
Based on a desk review of proficiency testing scores, the laboratory demonstrated initial and non-initial unsuccessful participation for Cell ID/WBC Diff. The laboratory failed to achieve a passing score of 80% for the First 2019 Hematology event, Third 2019 Hematology event, and First 2020 Hematology event. It is the responsibility of the laboratory director to ensure 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. Refer to D6018.

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 proficiency testing scores, the laboratory demonstrated initial and non-initial unsuccessful participation for Cell ID/WBC Diff. The laboratory failed to achieve a passing score (80%) for the First 2019 Hematology event, Third 2019 Hematology event, and First 2020 Hematology event. It is the responsibility of the laboratory director to 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. Refer to D2016, D2017, and D2131.