

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0656628	(X3) Date Survey Completed 06/08/2018
Name of Provider or Supplier Seiling Municipal Hospital	Street Address, City, State 809 Ne Hwy 60, Seiling, 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. The laboratory was found out of compliance with the following CLIA regulations: 1. 493.803; D2016: Successful Participation 2. 493.807; D2017: Reinstatement of Nonwaived Laboratories 3. 493.1441; D6076: Laboratory Director, High Complexity
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 subspecialty of Compatibility Testing. Findings include: (1) The laboratory failed to achieve</p>

	<p>satisfactory performance for three consecutive testing events for Compatibility Testing. Refer to D2181.</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 Compatibility Testing. Findings include: (1) The laboratory failed to successfully participate in proficiency testing for Compatibility Testing. Refer to D2181.</p>
<p>D2181</p>	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory 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 Compatibility Testing in three consecutive testing events. Findings include: (1) The laboratory received a score of 80% on the second event in 2017, a score of 80% on the third event in 2017 and a score of 80% on the first event in 2018.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <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 Compatibility Testing. The</p>

laboratory failed to achieve a passing score (100%) for the second 2017 event, the third 2017 event, the first 2018 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 D6091.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must 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.

This STANDARD 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 Compatibility Testing. The laboratory failed to achieve a passing score (100%) for the second 2017 event, the third 2017 event, the first 2018 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 D2181.