

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0470030	(X3) Date Survey Completed 10/26/2022
Name of Provider or Supplier Purcell Municipal Hospital	Street Address, City, State 2301 N 9th Ave, Purcell, 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 and from the proficiency testing providers. The laboratory was found out of compliance with the following CLIA Conditions of Participation: 493.803; D2016: Successful Participation 493.1407; D6000: Laboratory Director, Moderate 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 obtained from the American Association of Bioanalysts and the laboratory for the third 2021 event; and the proficiency testing Comparative Evaluation obtained from American Proficiency</p>

	<p>Institute for the first 2022 event; the laboratory failed to successfully participate in a proficiency testing program for the subspecialty of Routine Chemistry for the analyte CK (Creatine Kinase). Findings include: (1) The laboratory failed to achieve satisfactory performance for two consecutive testing events for the analyte CK. Refer to D2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 obtained from the American Association of Bioanalysts and the laboratory for the third 2021 event; and the proficiency testing Comparative Evaluation obtained from American Proficiency Institute for the first 2022 event; the laboratory failed to achieve satisfactory performance for the analyte CK (Creatine Kinase) in two consecutive events. Findings include: (1) The laboratory received a score of 0% on the third 2021 event and a score of 0% on the first 2022 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> <p>This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing scores obtained from the American Association of Bioanalysts and the laboratory for the third 2021 event; and the proficiency testing Comparative Evaluation obtained from American Proficiency Institute for the first 2022 event; the laboratory failed to achieve satisfactory performance for the analyte CK (Creatine Kinase) in two consecutive events. The laboratory failed to achieve a passing score of 80% for the third 2021 event and first 2022. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing scores obtained from the American</p>

Association of Bioanalysts and the laboratory for the third 2021 event; and the proficiency testing Comparative Evaluation obtained from American Proficiency Institute for the first 2022 event; the laboratory failed to achieve satisfactory performance for the analyte CK (Creatine Kinase) in two consecutive events. The laboratory failed to achieve a passing score of 80% for the third 2021 event and first 2022. Refer to D2096.