

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0697025	(X3) Date Survey Completed 12/13/2019
Name of Provider or Supplier Hebrew Rehabilitation Center	Street Address, City, State 1200 Center Street, Roslindale, MA	
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	A CLIA paper desk review of proficiency testing was conducted for the the Hebrew Rehabilitation Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the blood gas pCO2 analyte, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
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 proficiency testing review for calendar year 2019 (three testing events), of the College of American Pathologists (CAP) proficiency testing results, the laboratory</p>

	<p>failed to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the blood gas pCO₂ analyte as evidenced by the following: The laboratory achieved a score for Cell Identification of zero (0) percent for the second and third testing events of 2017 resulting in unsuccessful performance for the analyte. Refer to D2087 and D2096. .</p>
<p>D2087</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review of calendar year 2019 proficiency testing results (three testing events), the laboratory failed to attain an overall testing event score of at least 80 percent leading to unsatisfactory performance. Findings showed that for the blood gas pCO₂ analyte the laboratory received a testing event score of sixty (60) percent for the first testing event of 2019 and the third testing event of 2019 leading to unsatisfactory performance for each of the two testing events. .</p>
<p>D2094</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review, the laboratory failed to ensure that appropriate remedial action was taken in response to unacceptable analyte scores as evidenced by the following: A review of proficiency testing results for calendar year 2019 (three testing events) revealed that the laboratory obtained unacceptable analyte scores (scores of less than 80% for each parameter) for the blood gas pCO₂ analyte for the first and third testing events of 2019 resulting in unsuccessful performance for the analyte (refer to D2016). Based on the second unacceptable proficiency testing result for the blood gas pCO₂ analyte, there was no assurance that the laboratory had undertaken the appropriate training and employed the technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the blood gas pCO₂ analyte. .</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>

This STANDARD is not met as evidenced by:
Based on proficiency testing review for calendar year 2019 (three testing events), the laboratory failed to achieve satisfactory performance for the blood gas pCO₂ analyte. The laboratory achieved a score of sixty (60) percent for blood gas pCO₂ for the first and third testing events of 2019 resulting in unsuccessful performance. Refer to D2016.