

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2167888	(X3) Date Survey Completed 04/05/2022
Name of Provider or Supplier Respirecare Open Access	Street Address, City, State 2832 E 101st St, Tulsa, 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 provider.
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 Casper 0155D report and the proficiency testing graded evaluation obtained from the proficiency testing provider, the laboratory failed to successfully participate in a proficiency testing program for the specialty of Hematology and the subspecialty of Routine Chemistry. Findings include: (1) The laboratory failed to achieve satisfactory performance for two consecutive testing events for the analytes pH Blood Gas, pO2</p>

Blood Gas, pCO₂ Blood Gas, Glucose, Potassium, and Sodium. Refer to D2094 and D2096; (2) The laboratory failed to achieve satisfactory performance for two consecutive testing events for the analytes Hemoglobin and Hematocrit. Refer to D2128 and D2130.

D2094

ROUTINE CHEMISTRY

CFR(s): 493.841(e)

(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.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the proficiency testing information obtained from the proficiency testing provider, the laboratory failed to achieve a successful performance for the analytes Blood Gas pH, Blood Gas pCO₂, Blood Gas pO₂, Potassium, Sodium, and Glucose. Findings include: (1) The laboratory failed to achieve satisfactory performance on the third 2021 and first 2022 events. NOTE: The only acceptable plan of correction for this deficiency is to undertake training of personnel and obtain the necessary technical assistance.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

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.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the proficiency testing information obtained from the proficiency testing provider, the laboratory failed to achieve satisfactory performance for the analytes Blood Gas pH, Blood Gas pCO₂, Blood Gas pO₂, Potassium, Sodium, and Glucose in two consecutive events. Findings include: (1) Blood Gas pH - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022; (2) Blood Gas pCO₂ - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022; (3) Blood Gas pO₂ - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022; (4) Potassium - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022; (5) Sodium - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022; (6) Glucose - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022. NOTE: The only acceptable plan of correction for this deficiency is to undertake training of personnel and obtain the necessary technical assistance.

D2128

HEMATOLOGY

CFR(s): 493.851(e)

(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.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the proficiency testing information obtained from the proficiency testing provider, the laboratory failed to achieve a successful performance for the analytes Hemoglobin and Hematocrit. Findings include: (1) The laboratory failed to achieve satisfactory performance on the third 2021 and first 2022 events. NOTE: The only acceptable plan of correction for this deficiency is to undertake training of personnel and obtain the necessary technical assistance.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the proficiency testing information obtained from the proficiency testing provider, the laboratory failed to achieve satisfactory performance for the analytes Hemoglobin and Hematocrit in two consecutive events. Findings include: (1) Hemoglobin - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022; (2) Hematocrit - The laboratory received a score of 0% on the third event in 2021 and a score of 0% on the first event in 2022. NOTE: The only acceptable plan of correction for this deficiency is to undertake training of personnel and obtain the necessary technical assistance.