

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0898826	(X3) Date Survey Completed 04/11/2023
Name of Provider or Supplier Pricare Pa	Street Address, City, State 44 Aliant Parkway, Alexander City, AL	
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
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 review of CMS (Centers for Medicare and Medicaid Services) CASPER report, API (American Proficiency Institute) proficiency testing (PT) evaluations, and an interview, the laboratory failed to successfully participate in PT for Calcium (Ca) and Thyroid Stimulating Hormone [TSH (Endocrinology)]. The laboratory failed these tests for two consecutive testing events, Event #3, 2022 and Event #1, 2023. The findings include: Refer to D2096. Refer to D2104. Refer to D2108.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</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.

This STANDARD is not met as evidenced by:

Based on a review of CMS (Centers for Medicare and Medicaid Services) CASPER report, API (American Proficiency Institute) proficiency testing (PT) evaluations, and an interview with testing personnel, the laboratory failed to perform satisfactorily in Calcium (Ca) testing for two of three consecutive testing events, Event #3, 2022 and Event #1, 2023. The findings include: 1. A review of the CASPER report revealed the laboratory scored the following: a) Event #3, 2022 Calcium = 0 % (zero percent) b) Event #1, 2023 Calcium = 40 % 2. A review of the API PT evaluations confirmed the above noted scores.

D2104

ENDOCRINOLOGY

CFR(s): 493.843(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on a review of CMS (Centers for Medicare and Medicaid Services) CASPER report, API (American Proficiency Institute) proficiency testing (PT) evaluations, and an interview with testing personnel, the laboratory failed to return the proficiency testing results to the PT program within the specified timeframe for grading. This untimely submission resulted in unsatisfactory performance in Calcium and TSH testing for Event #3, 2022. The findings include: 1. A review of the CMS CASPER report and the API PT evaluations revealed the laboratory scored the following: a) Event #3, 2022; Endocrinology (TSH) = 0 percent (%) b) Event #3, 2022; Routine Chemistry (Calcium) = 0 % 2. In an interview on 4/03/2023 at 2:17 PM, the testing personnel stated the zero percent scores for Event #3 were due to the failure to submit the results within the timeframe for grading. The laboratory submit the results one day following the deadline.

D2108

ENDOCRINOLOGY

CFR(s): 493.843(g)

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.

This STANDARD is not met as evidenced by:

Based on a review of CMS (Centers for Medicare and Medicaid Services) CASPER report, API (American Proficiency Institute) proficiency testing (PT) evaluations, and an interview with testing personnel, the laboratory failed to perform satisfactorily in Endocrinology testing [Thyroid Stimulating Hormone (TSH)] for two consecutive testing events, Event #3, 2022 and Event #1, 2023. The findings include: 1. A review of the CMS CASPER report revealed the laboratory scored the following: a) Event #3,

2022 Endocrinology (TSH) = 0 percent (%) b) Event #1, 2023 Endocrinology (TSH) = 60 % 2. A review of the API PT evaluations confirmed the above noted findings. 3. In an interview on 4/03/2023 at 2:17 PM, the testing personnel confirmed the two failures; and also stated the zero percent scores for Event #3 were due to the failure to submit the results within the timeframe for grading. The laboratory submit the results one day following the deadline.