

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657443	(X3) Date Survey Completed 04/24/2020
Name of Provider or Supplier Amz Laboratory	Street Address, City, State 105 North Delaware Avenue, Minersville, PA	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a review of the CASPER Report 155 report and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analytes: Triiodothyronine (TT3), Thyroxine (TT4) and the subspecialty Endocrinology. The laboratory had unsatisfactory scores for the 3rd event of 2019 and the 1st event of 2020. See D2107 and 2108.
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 review of the CASPER Report 155 report and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analytes: Triiodothyronine (TT3) and Thyroxine (TT4). The laboratory had unsatisfactory scores for the 3rd event of 2019 and the 1st event of 2020. Findings Include: AAB - TT3: Event 3 in 2019 = 0%. AAB - TT3: Event 1 in 2020 = 0%. AAB - TT4: Event 3 in 2019 = 0%. AAB - TT4: Event 1 in 2020 = 0%.

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 the CASPER Report 155 report and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance in the subspecialty Endocrinology and has sustained a subsequent occurrence of unsuccessful participation scores for the 3rd event of 2019 and the 1st event of 2020. Findings Include: AAB Endocrinology - 2019 Event #3- 50%. AAB Endocrinology - 2020 Event #1- 50%. subspecialty Failure PT Desk Audit