

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2108870	(X3) Date Survey Completed 01/02/2018
Name of Provider or Supplier Excel Diagnostics Lab, Inc	Street Address, City, State 2740 Jefferson Street, Suite B, Austell, GA	
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 proficiency testing desk review was completed on January 2, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (2nd and 3rd events of 2017), resulting in the</p>

first unsuccessful occurrence for analyte # 355, chloride (Cl) , analyte # 475 sodium (Na), and the subspecialty of # 525 endocrinology with analyte # 555 human chorionic gonadotropin (HCG) . Findings include: Refer to D 2097 & D 2108

D2097

ROUTINE CHEMISTRY

CFR(s): 493.841(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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from Medical Laboratory Evaluation (MLE), the laboratory failed to maintain satisfactory performance in two consecutive events (2nd and 3rd events of 2017), resulting in the first unsuccessful occurrence for analyte # 355, chloride (Cl) and analyte # 475 sodium (Na). Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analytes #355 Cl and #475 Na on event 2 of 2017 with a score of 40% and event 3 of 2017 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from MLE confirmed the laboratory failed CL and Na on events 2 and 3 of 2017 resulting in the first unsuccessful performance.

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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from Medical Laboratory Evaluation (MLE) , the laboratory failed to maintain satisfactory performance in two consecutive events (2nd and 3rd events of 2017), resulting in the first unsuccessful occurrence for the subspecialty of # 525 endocrinology with analyte # 555 human chorionic gonadotropin (HCG) . Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the subspecialty of endocrinology and analyte # 555 HCG on event 2 of 2017 with a score of 60% and event 3 of 2017 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from MLE confirmed the laboratory failed endocrinology and HCG on events 2 and 3 of 2017 resulting in the first unsuccessful performance.