

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0706461	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Articularis Healthcare Group, Inc	Street Address, City, State 2015 2nd Ave, Summerville, SC	
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: During a PT desk review performed on 2/27/2018, based on review of CASPER reports 153D, 155D and graded reports from American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for the subspecialty of endocrinology, the analyte thyroid stimulating hormone (TSH) for two consecutive events reviewed (2017, Events 1 and 2). See D2099 and D2107.</p>
D2099	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p>

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

During a PT desk review performed on 2/27/2018, based on review of CASPER report 155D and graded reports from API, the laboratory failed to attain an overall test event score 80 percent for the subspecialty of endocrinology, for two consecutive events reviewed (2017, Events 1 and 2). Findings include: 1. Review of the CASPER report 155D revealed the following event scores for endocrinology: a. 2017, Event 1: 50% b. 2017, Event 2: 50% 2. The scores were confirmed upon review of the graded PT report from API.

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:

During a PT desk review performed on 2/27/2018, based on review of CASPER report 155D and graded reports from API, the laboratory failed to achieve satisfactory performance for the regulated analyte TSH in two consecutive testing events reviewed (2017, Events 1 and 2). Findings include: 1. Review of the CASPER report 155D revealed the following event scores for TSH: a. 2017, Event 1: 0% b. 2017, Event 2: 0% 2. The scores were confirmed upon review of the graded PT report from API.