

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0302673	(X3) Date Survey Completed 08/07/2019
Name of Provider or Supplier Oncology Specialties, Pc	Street Address, City, State 101 Dr W H Blake Jr Drive, Muscle Shoals, 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 the Casper reports (#153 and #155) for proficiency testing and a review of the MLE (Medical Laboratory Evaluation) proficiency testing reports, the surveyor determined the laboratory failed Chloride testing (Chemistry) for two of three consecutive testing events, 2018 MLE M3 and 2019 MLE M2. These failures resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. A review of the Casper reports revealed the laboratory failed Chloride testing for Event 2018 MLE M3 and 2019 MLE M2, two of three consecutive testing events. 2. A review of the MLE proficiency testing records revealed the laboratory scored 40 % (percent) for Chloride for 2018 MLE M3 and 60</p>

% for 2019 MLE M2. 3. These failures resulted in the laboratory's initial unsuccessful proficiency testing participation.

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 review of the Casper reports (#153 and #155) for proficiency testing and a review of the MLE (Medical Laboratory Evaluation) proficiency testing reports, the surveyor determined the laboratory failed to perform satisfactorily in Chloride testing (Chemistry) for two of three consecutive testing events, 2018 MLE M3 and 2019 MLE M2. These failures resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. A review of the Casper reports revealed the laboratory failed Chloride testing for Event 2018 MLE M3 and 2019 MLE M2, two of three consecutive testing events. 2. A review of the MLE proficiency testing records revealed the laboratory scored 40 % (percent) for Chloride for 2018 MLE M3 and 60 % for 2019 MLE M2. 3. These unsatisfactory scores in Chloride testing resulted in the laboratory's initial unsuccessful proficiency testing participation.