

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2043657	(X3) Date Survey Completed 01/20/2021
Name of Provider or Supplier Southern Oncology Specialists	Street Address, City, State 10320 Mallard Creek Road, Suite 100, Charlotte, NC	
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 desk review of CMS(Centers for Medicare and Medicaid Services) Casper reports 153D and 155D and desk review of 2018, 2019, and 2020 API(American Proficiency Institute) proficiency testing results 1/20/21, the laboratory failed to successfully participate for WBC(White blood cell) differential on five of eight consecutive test events, failed to successfully participate for Platelets on two of three consecutive test events, and failed to successfully participate for the specialty of Hematology on two consecutive test events. See the deficiencies cited at D2130 and D2131.</p>

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on desk review of CMS(Centers for Medicare and Medicaid Services) Casper reports 153D and 155D and desk review of 2018, 2019, and 2020 API(American Proficiency Institute) proficiency testing results 1/20/21, the laboratory failed to achieve satisfactory performance for WBC(white blood cell) differential on five of eight consecutive test events and failed to achieve satisfactory performance for Platelets on two of three consecutive test events, resulting in unsuccessful performance. Findings: 1. WBC Differential: a. Desk review of CMS Casper report 155D and 2018 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 granulocytes % samples, 5 of 5 lymphocytes % samples, and 5 of 5 monocytes % samples and received a score of 0% for WBC differential on the API 2018 2nd Hematology test event. b. Desk review of CMS Casper report 155D and 2018 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 granulocytes % samples, 5 of 5 lymphocytes % samples, and 5 of 5 monocytes % samples and received a score of 0% for WBC differential on the API 2018 3rd Hematology test event. c. Desk review of CMS Casper report 155D and 2019 API proficiency testing results revealed the laboratory provided unacceptable responses for 1 of 5 granulocytes % samples, 2 of 5 lymphocytes % samples, and 3 of 5 monocytes % samples, and received a score of 60% for WBC differential on the API 2019 2nd Hematology test event. d. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 lymphocytes % samples and 5 of 5 monocytes % samples, and received a score of 33% for WBC differential on the API 2020 2nd Hematology test event. e. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 2 of 5 lymphocytes % samples, 5 of 5 basophils % samples, 5 of 5 eosinophils % samples, 5 of 5 monocytes % samples, and 5 of 5 neutrophils % samples, and received a score of 12% for WBC differential on the API 2020 3rd Hematology test event. 2. Platelets: a. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 2 of 5 platelet samples, and received a score of 60% for platelets on the API 2020 1st Hematology test event. b. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 platelet samples, and received a score of 0% for platelets on the API 2020 3rd Hematology test event.

D2131

HEMATOLOGY

CFR(s): 493.851(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 desk review of CMS (Centers for Medicare and Medicaid Services) Casper

reports 153D and 155D and desk review of 2020 API (American Proficiency Institute) proficiency testing results 1/20/21, the laboratory failed to achieve satisfactory performance for the specialty of Hematology on two consecutive test events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory received a score of 33% for White Blood Cell Differential, and a score of 0% for Leukocyte Count, resulting in an overall score of 72% for the specialty of Hematology on the API 2020 2nd Hematology test event. 2. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory received a score of 12% for White Blood Cell Differential, a score of 60% for Erythrocyte Count, a score of 20% for Hematocrit, and a score of 0% for Platelets, resulting in an overall score of 48% for the specialty of Hematology on the API 2020 3rd Hematology test event.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on desk review of CMS(Centers for Medicare and Medicaid Services) Casper reports 153D and 155D and desk review of 2018, 2019, and 2020 API(American Proficiency Institute) proficiency testing results 1/20/21, the laboratory director failed to provide overall management and direction to ensure successful proficiency testing participation. See the deficiency cited at D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D and desk review of 2018, 2019, and 2020 API (American Proficiency Institute) proficiency testing results 1/20/21, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. Findings: 1. WBC Differential: a. Desk review of CMS Casper report 155D and 2018 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 granulocytes % samples, 5 of 5 lymphocytes % samples, and 5 of 5 monocytes % samples and received a score of 0% for WBC differential on the API 2018 2nd Hematology test event. b. Desk review of CMS Casper report 155D and 2018 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 granulocytes % samples, 5 of 5 lymphocytes % samples, and 5 of 5 monocytes % samples and received a score of 0% for WBC differential on the API 2018 3rd Hematology test event. c. Desk review of CMS Casper report 155D and

2019 API proficiency testing results revealed the laboratory provided unacceptable responses for 1 of 5 granulocytes % samples, 2 of 5 lymphocytes % samples, and 3 of 5 monocytes % samples, and received a score of 60% for WBC differential on the API 2019 2nd Hematology test event. d. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 lymphocytes % samples and 5 of 5 monocytes % samples, and received a score of 33% for WBC differential on the API 2020 2nd Hematology test event. e. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 2 of 5 lymphocytes % samples, 5 of 5 basophils % samples, 5 of 5 eosinophils % samples, 5 of 5 monocytes % samples, and 5 of 5 neutrophils % samples, and received a score of 12% for WBC differential on the API 2020 3rd Hematology test event. f. Desk review of CMS Casper reports 153D and 155D revealed the laboratory failed to achieve satisfactory performance for WBC differential on five of eight consecutive proficiency testing events, resulting in non-initial unsuccessful performance.

2. Platelets: a. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 2 of 5 platelet samples, and received a score of 60% for platelets on the API 2020 1st Hematology test event. b. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory provided unacceptable responses for 5 of 5 platelet samples, and received a score of 0% for platelets on the API 2020 3rd Hematology test event.

3. Hematology: a. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory received a score of 33% for White Blood Cell Differential, and a score of 0% for Leukocyte Count, resulting in an overall score of 72% for the specialty of Hematology on the API 2020 2nd Hematology test event. b. Desk review of CMS Casper report 155D and 2020 API proficiency testing results revealed the laboratory received a score of 12% for White Blood Cell Differential, a score of 60% for Erythrocyte Count, a score of 20% for Hematocrit, and a score of 0% for Platelets, resulting in an overall score of 48% for the specialty of Hematology on the API 2020 3rd Hematology test event.