

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1089574	(X3) Date Survey Completed 07/27/2022
Name of Provider or Supplier Affinity Physicians Services	Street Address, City, State 5890 Valley Road Suite 200, Birmingham, 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 reviews of the CMS (Centers for Medicare and Medicaid) CASPER reports and Medical Laboratory Evaluations (MLE), and interviews with a MLE representative on 7/20/2022 at 12:07 PM, and laboratory testing personnel, the surveyor determined the laboratory failed to successfully participate in proficiency testing for WBC (White Blood Cell Differential) for three consecutive events, Event 3, 2021 and Events 1 and 2, 2022. These failures resulted in a non-initial unsuccessful PT participation. Refer to D2130. .</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 reviews of the CMS (Centers for Medicare and Medicaid) CASPER reports and Medical Laboratory Evaluations (MLE), and interviews with a MLE representative on 7/20/2022 at 12:07 PM, and the testing personnel, the surveyor determined the laboratory failed to satisfactorily perform in WBC (White Blood Cell Differential) testing for three consecutive events, Event 3, 2021 and Events 1 and 2, 2022. These failures resulted in a non-initial unsuccessful PT participation. The findings include: 1. A review of the CASPER report revealed the laboratory scored the following for the WBC Differential: a) Event #3, 2021 = 73 % b) Event #1, 2022 = 46 % c) Event #2, 2022 = 66% 2. On 7/20/2022 at 12:07 PM, the surveyor spoke to a MLE representative, who confirmed the laboratory failed PT and provided the following reports: a) MLE M3, 2021 = 73 % b) MLE M1, 2022 = 46 % c) MLE M2, 2022 = 66% 3. On 7/21/2022 at 4:52 PM, the testing personnel left a voicemail message confirming the failures of the WBC differentials, because the absolute numbers were reported instead of the percentages. On 7/26/2022, the testing personnel left another voicemail message, explaining the samples were rerun, and the WBC differential values repeated the same. The error was in the reporting. At 2:43 PM, the testing personnel stated the laboratory would cease testing, until further notice.

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 reviews of the CMS CASPER reports and MLE proficiency testing reports, interviews with a MLE representative and laboratory testing personnel, the laboratory director failed to ensure the testing personnel successfully participated in proficiency testing for White Blood Cell (WBC) Differential (Hematology) for three consecutive testing events, Events #3 2021, and Events #1 and #2, 2022. These failures resulted in a non-initial unsuccessful participation. Refer to 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 reviews of the CMS CASPER reports and MLE proficiency testing reports, interviews with a MLE representative and laboratory testing personnel, the laboratory director failed to ensure the testing personnel successfully participated in proficiency testing for White Blood Cell (WBC) Differential (Hematology) for three consecutive testing events, Events #3 2021, and Events #1 and #2, 2022. These failures resulted in a non-initial unsuccessful participation. The findings include: 1. A review of the CASPER report revealed the laboratory scored the following for the WBC Differential: a) Event #3, 2021 = 73 % b) Event #1, 2022 = 46 % c) Event #2, 2022 = 66% 2. On 7/20/2022 at 12:07 PM, the surveyor spoke to a MLE representative, who confirmed the laboratory failed PT and provided the following reports: a) MLE M3, 2021 = 73 % b) MLE M1, 2022 = 46 % c) MLE M2, 2022 = 66% 3. On 7/21/2022 at 4:52 PM, the testing personnel left a voicemail message confirming the failures of the WBC differentials, because the absolute numbers were reported instead of the percentages. On 7/26/2022, the testing personnel left another voicemail message, explaining the samples were rerun, and the WBC differential values repeated the same. The error was in the reporting. At 2:43 PM, the testing personnel stated the laboratory would cease testing, until further notice.