

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0309672	(X3) Date Survey Completed 11/29/2022
Name of Provider or Supplier Coffee Medical Group Llc	Street Address, City, State 1615 McMinnville Hwy, Manchester, TN	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a desk review of the Center for Medicare and Medicaid Services CASPER Report 0155D (CMS 155), the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing records, and staff interview, the laboratory failed to successfully participate in the specialty of Hematology for the analytes automated white blood cell differential (WBC Diff), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), and Platelet (PLT) for two consecutive events, resulting in initial unsuccessful PT participation (refer to D2130 and D2131).
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 a desk review survey of the CMS 155 report, the laboratory's 2022 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records, and phone interview with the nurse manager, the laboratory failed to maintain satisfactory performance in two consecutive PT events for the WBC Diff, RBC, HCT, HGB, WBC, and PLT analytes, resulting in initial unsuccessful PT participation. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores for the WBC Diff, RBC, HCT, HGB, WBC, and PLT analytes: 2022 Event two: WBC Diff: 0% RBC: 0% HCT: 0% HGB: 0% WBC: 0% PLT: 0% 2022 Event three: WBC Diff: 0% RBC: 0% HCT: 0% HGB: 0% WBC: 0% PLT: 0% 2. Review of the laboratory's MLE PT performance evaluation records revealed the following unsatisfactory scores for WBC Diff, RBC, HCT, HGB, WBC, and PLT analytes: 2022 Event two: WBC Diff: 0% RBC: 0% HCT: 0% HGB: 0% WBC: 0% PLT: 0% 2022 Event three: WBC Diff: 0% RBC: 0% HCT: 0% HGB: 0% WBC: 0% PLT: 0% 3. Phone interview with the nurse manager on December 1, 2022 at approximately 11:00 am confirmed the survey findings.

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 a desk review survey of the CMS 155 report, the laboratory's 2022 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records, and interview with the nurse manager, the laboratory failed to achieve satisfactory performance for the overall specialty of Hematology in two consecutive PT events in 2022 (event 2 and event 3). The findings include: 1. Review of CASPER CMS 155 report, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in two consecutive events: 2022 Event 2: 0% 2022 Event 3: 0% 2. Review of the Medical Laboratory Evaluation (MLE) performance evaluation records revealed the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in two consecutive events: 2022 Event 2: 0% 2022 Event 3: 0% 3. Phone interview with the nurse manager on December 1, 2022 at approximately 11:00 am confirmed the survey findings.