

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305645	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier Mobile Bay Ob/Gyn	Street Address, City, State 3 Mobile Infirmery Circle, Suite 201, Mobile, 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 CMS (Centers for Medicare and Medicaid Services) CASPER reports and MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) evaluations, and a review of the Recertification Notes from 4/06/2021, the surveyor determined the laboratory failed to successfully participate in PT testing for RBC (Red Blood Cell Count) and HCT (Hematocrit) for two of three consecutive testing events (Event #1 and #3, 2021). These failures result in an initial unsuccessful PT participation. The findings include: 1. A review of the CASPER reports revealed the laboratory scored zero percent (%) for all analytes of the CBC (Complete Blood Count) for Event #1, 2021, due to a "Failure to Participate," and 60 % for the RBC</p>

and Hematocrit for Event #3, 2021. 2. The surveyor confirmed the above noted findings with a review of the detailed PT evaluations from MLE. 3. The surveyor conducted a recertification survey on 4/7/2021 and noted the laboratory received a "Failure to Participate" for Event #1, 2021, due to illness of staff. None performed the PT testing, prior to the submission deadline. The laboratory performed a self-evaluation. The laboratory staff stated they notified MLE via email. Additionally, CLIA has no record the laboratory ceased patient testing during this time. Note: In the event the laboratory ceases patient testing for a time, it is not required to perform the PT. However, the lab is responsible and must notify the PT provider as well as the CLIA State Agency. .

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 review of CMS CASPER reports and MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) evaluations, and a review of the Recertification Notes from 4/06/2021, the surveyor determined the laboratory failed to satisfactorily perform in PT testing for RBC (Red Blood Cell Count) and HCT (Hematocrit) for two of three consecutive testing events (Event #1 and #3, 2021). These failures result in an initial unsuccessful PT participation. The findings include: Refer to D2016.