

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0641761	<b>(X3) Date Survey Completed</b>  05/13/2021
<b>Name of Provider or Supplier</b>  Mobile Division Laboratory	<b>Street Address, City, State</b>  757 Museum Drive, Mobile, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor the laboratory failed to ensure performance of electronic test results verification was sent to the final destination. Findings: 1. The laboratory failed to provide documentation of their completed electronic test verification performed in 2019, 2020 and 2021 on May 13, 2021 at 9:00AM. 2. On May 14, 2021 the Laboratory Director emailed the policy for electronic system verification titled "Senior Micro/Personal Operating Procedure-Laboratory Information Management System (LIMS) Report Verified". The policy stated "The purpose of this Personal Operating Procedure (POP) is to explain the procedure for verifying that Clinical Final Reports are properly generated. This includes both image generated PDF reports (whether delivered via the Web Portal or printed locally and mailed) and HL7 electronically delivered results to EMR (Electronic Medical Record) applications. The goal is to ensure that the data reported within the LIMS is accurately displayed on the final report and delivered to the appropriate ordering provider". The review of the electronic test verification procedure did not provide documentation that the report went to the final report destination. 3. The laboratory provided a copy of their report for electronic test verification that stated "Each month, 5 web portal reports are randomly selected for</p>

proper delivery verification. This is accomplished by checking the Reportable results in LIMS, and comparing this to the "printed" result on the PDF image of the final report. Proper report delivery is accomplished by checking that the report was delivered to the users Lab Online Inbox. The laboratory electronic verification failed to include laboratory verification of test result. 4. An interview with the Technical Supervisor on May 13, 2021 at 9:00AM confirmed that the electronic test verification did not include sending the report to the laboratory for verification.

**D5893**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's quality assurance plan and interview of the Technical Supervisor the laboratory failed to have a quality assessment process /procedure specific to ensure the electronic test results verification is performed. Findings: 1. A review of the laboratory quality assurance plan revealed the laboratory failed to include language on how the laboratory will ensure electronic test system verification. 2. The laboratory QA plan and standard operating procedures did not include the procedure "Senior Micro/Personal Operating Procedure-LIMS", which was provided by the laboratory director. The laboratory director submitted the procedures for several years that did not include her signature of review. 3. An interview with the Technical Supervisor on May 13, 2021 at 9:00 AM confirmed the laboratory did not include electronic test verification process in their QA manual.