

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305141	<b>(X3) Date Survey Completed</b>  01/30/2019
<b>Name of Provider or Supplier</b>  Mizell Memorial Hospital	<b>Street Address, City, State</b>  702 N Main Street, Opp, 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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 CASPER reports (#153 and #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the laboratory's testing personnel on January 30, 2019, the surveyor determined the laboratory failed to successfully participate in Immunohematology proficiency testing for two consecutive testing events, Events #2 and #3 of 2018. The two failures resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. A review of the CASPER reports and API proficiency testing evaluations revealed the laboratory scored 80 % (percent) for compatibility testing for Event #2, 2018 and zero percent for Event #3. The zero</p>

percent resulted from a failure to submit the results by the submission deadline, resulting in a "Failure to Participate." 2. In a telephone interview on January 30, 2019 at 2:57 PM, the testing personnel confirmed the laboratory failed to submit the results to API by the submission deadline for Event #3, and confirmed the unsuccessful participation.

**D2178**

**COMPATIBILITY TESTING**  
CFR(s): 493.863(c)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:  
Based on a review of CMS CASPER reports (#153 and #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the laboratory's testing personnel on January 30, 2019, the surveyor determined the laboratory scored a zero percent (%) for Immunohematology testing for Event #3, 2018, due to a "Failure to Participate" (unsatisfactory performance). The findings include: 1. A review of the CASPER reports and API proficiency testing evaluations revealed the laboratory scored zero percent for Immunohematology testing (second failure for compatibility testing) for Event #3, 2018, graded as a "Failure to Participate" by API. 2. The testing personnel confirmed the above noted findings, in a telephone interview on January 30, 2019 at 2:57 PM. The testing personnel stated the laboratory manager failed to submit the results by the submission deadline.

**D2181**

**COMPATIBILITY TESTING**  
CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory 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 review of CMS CASPER reports (#153 and #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the laboratory's testing personnel on January 30, 2019, the surveyor determined the laboratory failed to perform satisfactorily in compatibility testing (Immunohematology) for two consecutive testing events, Events #2 and #3 of 2018. The two failures resulted in the laboratory's initial unsuccessful proficiency testing participation. The findings include: 1. Refer to D2016.

**D6090**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of CMS CASPER reports (#153 and #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the laboratory's testing personnel on January 30, 2019, the surveyor determined the laboratory director failed to ensure the results for Immunohematology testing Event #3, 2018 were submitted by the submission deadline. As a result of this failure, the laboratory scored a zero percent (%), due to a "Failure to Participate" (unsatisfactory performance). The findings include: 1. A review of the CASPER reports and API proficiency testing evaluations revealed the laboratory scored zero percent for Immunohematology testing for Event #3, 2018, graded as a "Failure to Participate" by API. 2. The testing personnel confirmed the above noted findings, in a telephone interview on January 30, 2019 at 2:57 PM. The testing personnel stated the laboratory manager failed to submit the results by the submission deadline. 22378  
Licensure and Certification Supervisor