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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D0724352 | (X3) Date Survey Completed 06/23/2020 |
| Name of Provider or Supplier Hale County Hospital | Street Address, City, State 508 Green Street, Greensboro, 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 |
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| 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 the CMS CASPER Reports (#153 and #155) for Proficiency Testing (PT) and API (American Proficiency Institute) PT evaluations, the surveyor determined the laboratory failed to successfully participate in ImmunoHematology for compatibility testing for two consecutive testing events, Event #3, 2019 and Event #1, 2020. The failures of compatibility testing for these two consecutive testing events resulted in an initial unsuccessful participation. The findings include: 1. A review of the CASPER reports revealed the laboratory scored sixty percent (60 %) for compatibility testing for Event #3, 2019, and 80 % for Event #1, 2020, two consecutive testing events. 2. The surveyor confirmed the above noted findings with</p> |

the review of the API PT evaluations: the 60 % score for Event #3, 2019 and 80 % for Event #1, 2020. 3. These two consecutive failures resulted in the laboratory's initial unsuccessful PT participation.

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 the CMS CASPER Reports (#153 and #155) for Proficiency Testing (PT) and API (American Proficiency Institute) PT evaluations, the surveyor determined the laboratory failed to satisfactorily perform in ImmunoHematology for compatibility testing for two consecutive testing events, Event #3, 2019 and Event #1, 2020. The failures of compatibility testing for these two consecutive testing events resulted in an initial unsuccessful participation. The findings include: Refer to D2016.