Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0724352	(X3) Date Survey Completed 03/15/2021
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
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 review of the CMS CASPER Report (#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 three out of four consecutive events Event #3 2019, Event #1 2020, and Event #3 2020. The failures of compatibility testing for these three out of four consecutive events resulted in a noninitial 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, eighty percent (80%) for Event #1 2020, and eighty percent (80%) for Event #3 2020, three out of four

	consecutive events. 2. The surveyor confirmed the above noted findings with the review of the API PT evaluations: 60% for Event #3 2019, 80% for Event #1 2020, and 80% for Event #3 2020. 3. An initial unsuccessful PT participation for Event #3 2019 and Event #1 2020 for compatibility testing was cited on 06/23/2020. These three out of four consecutive events resulted in the laboratory's noninitial 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 satisfactory perform in ImmunoHematology for compatibility testing for three out of four consecutive testing events, Event #3 2019, Event #1 2020, and Event #3 2020. The failure of compatibility testing for these three out of four consecutive testing events resulted in a noninitial unsuccessful participation. The findings include: Refer to D2016.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the CMS CASPER Report (#153 and #155) for Proficiency Testing (PT) and API (American Proficiency Institute) PT evaluations, the surveyor determined the Laboratory Director failed to ensure the laboratory successfully participated in ImmunoHematology for compatibility testing for three out of four consecutive events Event #3 2019, Event #1 2020, and Event #3 2020. The failures of compatibility testing for these three out of four consecutive events resulted in a noninitial unsuccessful participation. The findings include: Refer to D2016. 1. A review of the CASPER reports revealed the laboratory scored sixty percent (60%) for compatibility testing for Event #3 2019, eighty percent (80%) for Event #1 2020, and eighty percent (80%) for Event #3 2020, three out of four consecutive events. 2. The surveyor confirmed the above noted findings with the review of the API PT evaluations: 60% for Event #3 2019, 80% for Event #1 2020, and 80% for Event #3 2020. 3. An initial unsuccessful PT participation for Event #3 2019 and Event #1 2020 for compatibility testing was cited on 06/23/2020. These three out of four consecutive events resulted in the laboratory's noninitial unsuccessful PT participation.