Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0724352	06/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hale County Hospital	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 Centers for Medicare and Medicaid (CMS) CASPER 155 reports, American Proficiency Institute (API) Proficiency Testing (PT) reports, and an interview with the interim Laboratory Manager, the laboratory failed to maintain successful PT participation for the White Blood Cell (WBC) Differential for three consecutive events, Events #2 and #3, 2022, and Event #1, 2023. These failures result in a non-initial unsuccessful PT participation. Refer to D2130.
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 the Centers for Medicare and Medicaid (CMS) CASPER 155 report, American Proficiency Institute (API) Proficiency Testing (PT) reports, and an interview with the interim Laboratory Manager, the laboratory failed to maintain successful performance in three consecutive events (2nd and 3rd events of 2022, 1st event of 2023), resulting in unsuccessful performance for White Blood Cell Differential (WBC Diff). The findings include: 1. A review of the CASPER 155 report revealed the following scores: a) Event #2, 2022 WBC Differential 60 % b) Event #3, 2022 WBC Differential 4 % c) Event #1, 2023 WBC Differential 0 % 2. The API PT reports confirmed the above mentioned scores, and indicated the laboratory failed to participate in Event #1, 2023. 3. In an interview on 6/27/2023 at 9: 22 AM, the interim Laboratory Manager confirmed the above noted PT failures. At 11: 15 AM, during a follow-up interview, the interim Laboratory Manager agreed to voluntarily cease testing of the WBC Differential.
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 Centers for Medicare and Medicaid (CMS) CASPER 155 report and American Proficiency Institute (API) Proficiency Testing (PT) reports, the laboratory director failed to provide overall management and direction for proficiency testing performance. The laboratory director failed to ensure proficiency testing samples were tested as required.
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 the Centers for Medicare and Medicaid (CMS) CASPER 155 report and American Proficiency Institute (API) Proficiency Testing (PT) reports, and an interview with the interim Laboratory Manager, the Laboratory Director failed to ensure the testing personnel timely submitted the PT results of the Hematology, Event #1, 2023. The untimely submission of the PT values resulted in a "Failure to Participate." The findings include: 1. A review of the CASPER 155 report revealed the following score: a) Event #1, 2023 Hematology = 0 % 2. The API PT reports confirmed the above mentioned score, and indicated the laboratory failed to

	participate in Event #1, 2023. 3. In an interview on 6/27/2023 at 9:22 AM, the interim Laboratory Manager confirmed the former Laboratory Manager did not submit the results by the grading time-lines for Event #1, 2023.