Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2200388	06/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Houston Healthcare Bonaire Med Stop	520 Ga Highway 247 South, Suite 501, Bonaire, GA	

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
D0000	A proficiency testing desk review was completed on June 16, 2025. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
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 review of the Centers for Medicare and Medicaid Services (CMS) CASPER 155 report and review of the laboratory 's AAB -MLE proficiency testing (PT)

	reports, the laboratory failed to maintain satisfactory participation in PT in the specialty of Hematology for the analyte of White Blood Cell Count (WBC) for 3 out of 4 events for events 1 & 3 of 2024, and event 1 of 2025. Refer to D 2130
D2130	HEMATOLOGY CFR(s): 493.851(f) (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 review of the CMS CASPER 155 report and review of the laboratory 's AAB -MLE proficiency testing (PT)reports, the laboratory failed to maintain satisfactory participation in PT in 3 out of 4 events in the specialty of Hematology for the analyte of White Blood Cell Count (WBC) . Findings include: 1. Desk review of the CMS CASPER 155 report revealed the laboratory failed WBC count on: 2024 Event 1 score: 60% 2024 Event 3 score: 40% 2025 Event 1 score: 20% 2. Desk review of the laboratory's proficiency testing reports from AAB-MLE confirms the laboratory failed WBC count on the aforementioned events resulting in the non-initial unsuccessful performance.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of the laboratory 's AAB -MLE PT reports, the laboratory director failed to provide overall management and direction for proficiency testing to ensure successful participation in PT for the specialty of Hematology. Refer to D6016 and D6019.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the CMS CASPER Report 155 and the AAB-MLE 2024 events 1 & 3 and 2025 event 1 PT evaluation reports, the laboratory director failed to ensure successful proficiency testing performance in WBC count in three of four testing events, resulting in the non-initial unsuccessful participation for WBC count. Refer to D2130
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)

	(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the CMS CASPER 155 report and the laboratory's AAB-MLE proficiency testing records on 6/16/2025, the laboratory director failed to ensure an approved corrective action plan was followed to ensure successful participation in PT. Refer to D2130