Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2292280	03/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Honorbridge	7000 Millhouse Road, Chapel Hill, NC	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance summary records for 3 EPOC chemistry analyzers, performance summary records for the Wasserman chemistry analyzer, installation records for the DxH 520 hematology analyzer, lack of documentation, and interviews with laboratory director (LD), testing personnel (TP) #1 and TP #2 03/12/25, the laboratory failed to define reportable ranges for the testing performed on 2 of 2 EPOC chemistry analyzers, #43946 and #43878, and the ACE Axcel chemistry analyzer, failed to verify and establish the performance specifications of EPOC chemistry analyzer #54654, failed to ensure the precision verification of 2 of 2 EPOC chemistry analyzers, #43946 and #43878, and the DxH 520 hematology analyzer included day to day and operator variances, failed to verify the performance of the EPOC chemistry analyzer when moved to another location to perform off-site testing, approximately 36 donors were tested and approximately 15-20 normothermic regional perfusion (NRP) donors were tested since testing began in January of 2024. . 1. The laboratory failed to define the reportable ranges for the testing performed on 2 of 2 EPOC chemistry analyzers, #43946 and #43878, and the ACE Axcel chemistry analyzer. Findings: Review of performance summary records for both EPOC chemistry analyzers revealed an "analytical range" and a "test range" for each analyte tested on the EPOC chemistry analyzers. For example: a. EPOC #43946, analyte Lactate; the "analytical

	range" is 2.70 - 180.20, the "test range" is 0.46 - 16.99. EPOC #43878, analyte Lactate; the "analytical range" is 0.30 - 20.00, the "test range" is 0.44 - 17.10. b. EPOC #43946, analyte Carbon Dioxide; "analytical range" is 5.0 - 250.0, the "test range" is 3.1 - 107.0. EPOC #43878, analyte Carbon Dioxide; "analytical range" is 5.0 - 250.0, the "test range" is 3.3 - 110.0. There was no documentation of the reportable range established from the performance summary data. Review of performance summary records for the ACE Axcel chemistry analyzer revealed an "analytical range" and a "test range" for each analyte tested on the Ace Axcel chemistry analyzer. There was no documentation of the reportable range established from the performance summary data. Interview with LD at approximately 11:45 a.m. confirmed the performance summary records did not define the reportable range for each analyte tested on the 2 EPOC and the ACE Axcel chemistry analyzers. They stated they were unfamiliar with the summary computer program used and did not realize it did not define what reportable range was established for each analyte. 2. The laboratory failed to verify and establish the performance specifications of EPOC chemistry analyzer #54654 since patient testing began in October of 2024. Two tests were performed on this analyzer since October of 2024. Review of performance summary records for the EPOC chemistry analyzers revealed no documentation of a performance verification for EPOC chemistry analyzer #54654. Interview with TP #2 at approximately 11:30 a.m. confirmed performance specifications were not verified and established for EPOC chemistry analyzer #54654 prior to performing patient testing. They stated the analyzer was put into use in October of 2024 and confirmed two tests were performed. 3. The laboratory failed to ensure the precision verification of 2 of 2 EPOC chemistry analyzers, #43946 and #43878, and the DxH hematology analyzer included day to day and operator variances. Findings: a. Review of performance summary records for EPOC chemistry analyzer #43946 and #43878 revealed all performance verification testing was performed on October 11, 2023. There was no documentation available to indicate that any additional samples were tested on different days by the laboratory testing personnel. Interview with TP #2 at approximately 11:30 a.m. confirmed all testing for the precision verification was performed on October 11, 2023. They also confirmed the precision verification was performed by the service representative only. b. Review of installation records for the DxH 520 hematology analyzer revealed the analyzer was installed 10/19/23, and all precision verification testing was performed the same day by the service representative. There was no documentation available to indicate that any additional samples were tested on different days by the laboratory testing personnel. 4. The laboratory failed to verify the performance of 2 of 2 EPOC chemistry analyzers, #43946 and #43878, when moved to another location to perform off-site testing, approximately 36 donors were tested since testing began in January of 2024. Findings: Review of laboratory records revealed no documentation indicating the performance of quality control (QC) when the EPOC chemistry analyzer was moved to another location to perform off-site testing. During interview with TP #1 at approximately 10:00 a.m., they stated QC is performed in-house prior to the transportation of an EPOC chemistry analyzer and was not performed at the new location after transportation and prior to performing patient testing. Interview with TP #2 at approximately 9:00 a.m. confirmed approximately 36 donors were tested since testing began in January of 2024. Phone interview 03/24/25 at approximately 12:00 p.m. confirmed 15 - 20 NRP donors were tested since testing began in January of 2024.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i)

	Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on absence of documentation and interviews with LD, TP #1 and TP #2, 03/12 /25, the laboratory failed to perform calibration verifications on 2 of 2 EPOC chemistry analyzers at least once every 6 months since testing began in January of 2024, at period of approximately 14 months in which calibration verifications were not performed. Approximately 36 donors were tested since January of 2024. Findings: Review of 2024 and 2025 laboratory records revealed no documentation of calibration verifications for 2 of 2 EPOC chemistry analyzers, #43946 and #43878, since testing began in January of 2024. Interviews with TP #1 and TP # 2 at approximately 9:00 a. m. confirmed testing began on the 2 EPOC chemistry analyzers, #43946 and #43878, in January of 2024. TP #2 also confirmed approximately 36 donors were tested since January of 2024. Interview with LD at approximately 12:45 p.m. confirmed the laboratory had not performed calibration verifications on EPOC chemistry analyzer #43946 and #43878 since testing began in January of 2024.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the ACE Axcel chemistry analyzer, review of the laboratory's policies and procedures, and random review of remote humidity monitoring system records 03/12/25, the laboratory failed to ensure corrective action was taken and documented for humidity readings outside the acceptable limits on 2 of 5 days of testing in December 2024 (12/3/24, 12/4/24). Findings: Review of manufacturer's instructions for the ACE Axcel chemistry analyzer revealed the manufacturer specifies operation of the analyzer in an

	environment with a relative humidity of 20-80% (non-condensing). Review of the laboratory's "GENERAL LABORATORY CONDITIONS" policy revealed "... If any readings are not within acceptable limits, appropriate remedial action will be taken and documented. ..." Random review of remote humidity monitoring system records revealed all hourly recorded humidity readings were below 20% on 12/3/24 and 12/4 /24 when patients were tested. There was no documentation of corrective action for the humidity readings below acceptable limits.