Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0704074	02/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hamilton Hospital/Respiratory Therapy	901 West Hamilton, Olney, TX	

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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiency was cited.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, quality control (QC) results, patient final reports, and confirmed in interview, the laboratory failed to document performance of QC prior to patient testing for ten of ten randomly reviewed patients tested in December 2024. Findings Included: 1. During a tour of the facility on 02/05/2025 at 10:16 AM, the surveyor observed one Nova Prime blood gas analyzer available for patient testing (Serial Number: P07320120C). 2. Review of Nova Prime manufacturer's instructions (also serving as the laboratory's policy for blood gas QC), "Nova Biomedical Prime Instructions for Use Manual" (Version: 2014) revealed the following: "Appendix A A.1.1 Quality Control Healthcare facilities should follow federal, state, and local guidelines for testing quality control materials. At a minimum, Nova Biomedical recommends that each laboratory performs the following minimum QC procedures (Auto-Cartridge QC or External Ampule QC) on each analyzer: During each 8 hours of testing, analyze one level of

	Control. Analyze all levels during each day of operation." 3. Review of laboratory QC records in 2024, revealed the laboratory performed all three levels of QC only once every 30 days. The laboratory was asked to provide documentation to support the reduction of QC from every eight hours to every 30 days, and none was provided. 4. Review of patient final reports revealed the following ten patients tested in December 2024, with no documented QC performed prior to patient testing: a. Patient 1 (See attached Patient Alias List) Date Performed: 12/18/2024; 10:28 b. Patient 2 Date Performed: 12/22/2024; 12:36 c. Patient 3 Date Performed: 12/22/2024; 14:47 d. Patient 4 Date Performed: 12/25/2024; 00:09 e. Patient 5 Date Performed: 12/25 /2024; 12:12 f. Patient 6 Date Performed: 12/25/2024; 15:31 g. Patient 7 Date Performed: 12/25/2024; 21:58 h. Patient 8 Date Performed: 12/26/2024; 17:01 i. Patient 9 Date Performed: 12/29/2024; 16:16 j. Patient 10 Date Performed: 12/30 /2024; 23:01 5. In an interview on 02/05/2025 in the facility chapel at 11:35 AM with the technical consultant (TC-1), TC-1 confirmed the laboratory failed to document performance of QC prior to patient testing for ten of ten randomly reviewed patients tested in December 2024.