Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1063733	09/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
First Surgical Hospital	4801 Bissonnet Street, Bellaire, 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 compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey completed on 09/16/2025 and recertification is recommended. Standard level deficiencies were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of instructions on Proficiency Testing Performance Evaluation from American Proficiency Institute (API), the laboratory's proficiency testing results from 2024 to 2025, and confirmed in an interview, the laboratory failed to have review documentation of self-evaluation of "Not Graded" results for 3 of 9 events reviewed. The findings were: 1. Review of the instructions from American Proficiency Institute (API) revealed "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the laboratory's API proficiency testing events from 2024 to 2025 revealed no documentation of self-evaluation of "not graded" results for 3 of 9 events reviewed. 2025 Chemistry Core 2nd Event 2025 Hematology 2nd Event 2025 Immunology/Immunohematology 2nd Event 3. Further review of the API proficiency testing events for 2025 2nd events revealed, 2025 Chemistry Core 2nd Event Analyte: CK-MB Sample: CM-06 Reported Result: 99.8 Expected Result: 80.7-134.6 Performance: Not Graded Analyte: Bilirubin, Total Sample: CM-07 Reported Result: 2.3 Expected Result: 1.8-2.9 Performance: Not Graded Analyte: Bilirubin, Total Sample: CM-09 Reported Result: 1.6 Expected Result: 1.3-2.2 Performance: Not Graded Analyte: Bilirubin, Total Sample: CM-10 Reported Result: 3.0 Expected Result: 2.4-3.7 Performance: Not Graded 2025 Hematology 2nd Event Educational

	Blood Cell Identification Analyte: Eosinophil (DIF)(%) Sample: DIF-02 Reported Result: 6 Expected Result: 0-14 Performance: Not Graded Analyte: Lymphocyte (DIF)(%) Sample: DIF-02 Reported Result: 13 Expected Result: 0-12 Performance: Not Graded Analyte: Monocyte (DIF)(%) Sample: DIF-02 Reported Result: 4 Expected Result: 0-7 Performance: Not Graded Analyte: Myelocyte (DIF)(%) Sample: DIF-02 Reported Result: 2 Expected Result: 0-2 Performance: Not Graded Analyte: Neutrophil, seg or band (DIF)(%) Sample: DIF-02 Reported Result: 75 Expected Result: 67-96 Performance: Not Graded Analyte: Platelet estimate (DIF) Sample: DIF-02 Reported Result: Increased Expected Result: Increased Performance: Not Graded Analyte: RBC Morphology (DIF) Sample: DIF-02 Reported Result: Hypochromic RBC Anisocytosis Expected Result: See Data Summary Performance: Not Graded Analyte: Blood Cell ID Sample: ECI-06 Reported Result: Basophil, all stages Expected Result: Basophil, all stages Performance: Not Graded Analyte: Blood Cell ID Sample: ECI-07 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Neutrophil, seg or band Performance: Not Graded Analyte: Blood Cell ID Sample: ECI-08 Reported Result: Dacryocyte (tear-drop cell) Expected Result: Dacryocyte (tear-drop cell) Performance: Not Graded Analyte: Blood Cell ID Sample: ECI-09 Reported Result: Eosinophil, all stages Expected Result: Eosinophil, all stages Performance: Not Graded Analyte: Blood Cell ID Sample: ECI-10 Reported Result: Platelet(s), giant/large Expected Result: Platelet(s), giant/large Performance: Not Graded 2025 Immunology/Immunohematology 2nd Event Analyte: Crossmatch Type (SER) Sample: SER-06, SER-07, SER-08, SER-09, and SER-10 Reported Result: Immediate Spin only Expected Result: See Data Summary Performance: Not Graded Analyte: Xmatch Reaction Strength (SER) Sample: SER-06 Reported Result: Negative Expected Result: Negative Performance: Not Graded Analyte: Xmatch Reaction Strength (SER) Sample: SER-07 Reported Result: Negative Expected Result: See Data Summary Performance: Not Graded Analyte: Xmatch Reaction Strength (SER) Sample: SER-08 Reported Result: Negative Expected Result: See Data Summary Performance: Not Graded Analyte: Xmatch Reaction Strength (SER) Sample: SER-09 Reported Result: Negative Expected Result: Negative Performance: Not Graded Analyte: Xmatch Reaction Strength (SER) Sample: SER-10 Reported Result: Negative Expected Result: Negative Performance: Not Graded 4. An interview on 09/15/2025 at 11:00 am in a conference room, the general supervisor (as listed on CMS 209 form) confirmed the above findings. Key: API=American Proficiency Institute CMS=Center for Medicare and Medicaid Services
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory's Pentra C 400 ISE maintenance logs from January 2025 to August 2025, and confirmed in an interview, the laboratory failed to have documentation of required monthly maintenance for 5 of 8 months reviewed for Horiba Pentra C 400 Chemistry analyzer. The findings were: 1. Review of the manufacturer's instruction titled ABX Pentra 400 User Manual (P/n: RAB125EEN) under Maintenance and Troubleshooting in Table 9-1: Maintenance procedures revealed "Maintenance procedures: 1.4 Wash tower cleaning 1.5 Syringe plunger tips replacement 1.6 Qualitest 1.7 Cooling unit filter cleaning" 2. Review of the laboratory's Pentra C 400 (SN: 907C40812) ISE

	maintenance logs from January 2025 to August 2025 revealed no documentation of required monthly maintenance for 5 of 8 months reviewed. March 2025 April 2025 May 2025 July 2025 August 2025 3. An interview on 09/16/2025 at 10:36 am in a conference room, the general supervisor (as listed on CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, calibration verification records from January, 2024 to September, 2025, and confirmed in an interview, the laboratory failed to have documentation for 1 of 2 calibration verification records in 2024 on Horiba Pentra C 400 Chemistry Analyzer. The findings were: 1. Review of the laboratory's policy titled ABX PENTRA 400 (CHEMISTRY), effective date October 2016, under calibration verification revealed "Calibration Verification is required every 6 months." 2. Review of the laboratory's calibration verification records from January, 2024 to September, 2025 revealed the laboratory failed to have documentation for 1 of 2 calibration verification records for May, 2024 on Horiba Pentra C 400 Chemistry Analyzer (SN: 907C40812). 3. An interview on 09/16/2025 at 10:33 am in a conference room, the general supervisor (as listed on CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, transfusion service testing records from 05/23/2025 to 09/18/2025, patient records, confirmed in an interview, the laboratory failed to document Rh (D) quality control for 25 of 25 days reviewed.

	The findings were: 1. Review of the laboratory's policies/procedures revealed no policy/procedure written for Rh(D) typing quality control. 2. Review of the laboratory's transfusion service records under Rh Typing revealed "Test Method with 2 columns: CAT /Tube. Cells with anti-D/D Control." 3. Further review of transfusion service testing from 05/23/2025 to 09/18/2025 revealed the laboratory failed to document Rh (D) quality control for 25 of 25 days reviewed. 05/23/2025 05/27/2025 05/28/2025 05/29/2025 06/05/2025 06/10/2025 06/12/2025 06/17/2025 06/23/2025 06 /25/2025 06/26/2025 06/27/2025 06/30/2025 07/24/2025 07/31/2025 08/04/2025 08/07 /2025 08/12/2025 08/14/2025 08/18/2025 08/19/2025 08/20/2025 08/29/2025 09/02 /2025 09/04/2025 4. Review of the patient records for the above dates revealed 34 patients having Rh (D) typing testing. 05/23/2025 Accession#: 2505230001 Patient Rh (D) result: D POS 05/23/2025 Accession#: 2505230003 Patient Rh(D) result: D NEG 05/27/2025 Accession#: 2505270005 Patient Rh(D) result: D POS 05/28/2025 Accession#: 2505280002 Patient Rh(D) result: D POS 05/29/2025 Accession#: 2505290001 Patient Rh(D) result: D POS 05/29/2025 Accession#: 2505290007 Patient Rh(D) result: D POS 05/29/2025 Accession#: 2505290011 Patient Rh(D) result: D POS 05/29/2025 Accession#: 2505290020 Patient Rh(D) result: D POS 06/05 /2025 Accession#: 2506050002 Patient Rh(D) result: D POS 06/05/2025 Accession#: 2506050011 Patient Rh(D) result: D POS 06/10/2025 Accession#: 2506100002 Patient Rh(D) result: D POS 06/12/2025 Accession#: 2506120001 Patient Rh(D) result: D NEG 06/17/2025 Accession#: 2506170001 Patient Rh(D) result: D POS 06 /23/2025 Accession#: 2506230002 Patient Rh(D) result: D POS 06/25/2025 Accession#: 2506250001 Patient Rh(D) result: D POS 06/26/2025 Accession#: 2506260001 Patient Rh(D) result: D POS 06/27/2025 Accession#: 2506270001 Patient Rh(D) result: D POS 06/30/2025 Accession#: 2506300001 Patient Rh(D) result: D POS 06/30/2025 Accession#: 2506300003 Patient Rh(D) result: D POS 07/24 /2025 Accession#: 2507240006 Patient Rh(D) result: D POS 07/31/2025 Accession#: 2507310001 Patient Rh(D) result: D POS 08/04/2025 Accession#: 2508040004 Patient Rh(D) result: D NEG 08/07/2025 Accession#: HW58729 Patient Rh(D) result: D POS 08/12/2025 Accession#: 2508120001 Patient Rh(D) result: D POS 08/14/2025 Accession#: 2508140002 Patient Rh(D) result: D POS 08/18/2025 Accession#: 2508180003 Patient Rh(D) result: D POS 08/18/2025 Accession#: 2508180005 Patient Rh(D) result: D POS 08/18/2025 Accession#: 2508180012 Patient Rh(D) result: D POS 08/19/2025 Accession#: 2508190001 Patient Rh(D) result: D POS 08/20 /2025 Accession#: 2508200003 Patient Rh(D) result: D POS 08/20/2025 Accession#: 2508200009 Patient Rh(D) result: D POS 08/29/2025 Accession#: 2508290016 Patient Rh(D) result: D POS 09/02/2025 Accession#: 2509020007 Patient Rh(D) result: D NEG 09/04/2025 Accession#: 2509030006 Patient Rh(D) result: D NEG 5. An interview on 09/16/2025 at 11:33 am in a conference room, the general supervisor (as listed on CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services