Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1063733	02/02/2022
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing for 2020 and 2021, laboratory policies and confirmed with interview, the laboratory failed to test proficiency testing samples it received from the proficiency testing program in the same manner as it tested patient specimens for one of twenty tests reviewed (serum hCG). Findings included: 1. A review of API proficiency testing events from 2020 and 2021 revealed that on three of six events (API 1st event 2021; API 2nd event 2021; API 2nd event 2020) the testing person ran the positive result proficiency specimens in duplicate using their Sure-Vue hCG test cartridges. 2021 API 1st event API-02 - Positive API-03 - Positive API-04 - Positive 2021 API 2nd event API-06 - Positive API-08 - Positive API-10 - Positive 2020 API 2nd event API-06 - Positive API-09 - Positive API-10 - Positive 2. Review of the laboratory policy Critical Values List (policy #01.12) revealed no documentation of a serum hCG as a critical lab result.

	Review of the hCG policy revealed no documentation of a repeat analysis for positive results. 3. An interview with the laboratory manager on 3/1/22 at 1425 hours in the conference room confirmed the above findings. She stated that it's the lab policy to confirm all positive hCG results. However, the laboratory does NOT repeat the testing on their test cartridge, the laboratory sends out for confirmation.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records from 2020 and 2021; laboratory policy and records; and confirmed with interview, the laboratory failed to verify the accuracy of all testing twice annually for one of twenty tests reviewed (urine microscopic) in 2020 and 2021. Findings included: 1. Review of the API test records from 2020 to 2021 revealed no documentation of the laboratory being enrolled in proficiency testing for urine microscopic. 2. Review of the laboratory records available revealed no documentation of a twice annual accuracy assessment for urine microscopic for 2020 or 2021. 3. Review of the laboratory records available revealed no documentation of a policy to determine the accuracy assessment for urine microscopic. 4. Review of the laboratory worksheet Annual Test Volume and Proficiency Testing Programs Worksheet signed by the laboratory director on 1/31/22 revealed an annual volume of 206 for urinalysis. 5. An interview with the laboratory manager on 2/1/22 at 1420 hours in the conference room confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation by surveyor, review of laboratory policies, manufacturer's instructions, and confirmed in interview, the laboratory failed to follow its policy for specimen rejection for one of five specimens observed in the laboratory. The findings included: 1. Surveyor observation on 2/1/22 at 1535 hours in the laboratory revealed one of five purple top tubes for the Pentra 60 C+ hematology analyzer with a short sample (patient ID 9797). 2. An interview with the laboratory manager on 2/1/22 at 1540 hours in the laboratory and after her review of the specimen, she acknowledged that the specimen was 1/4 full and below the fill line for the tube. She stated that the patient was a "hard stick." 3. Review of the laboratory's policy Specimen Rejection revealed under Specimen Rejection Criteria "Improper specimen collection: improper or inadequate venipuncture technique may result in hemolyzed specimens. Inadequate volume of specimen may also inhibit testing." 4. Review of the instructions for use for

	the BD Vacutainer Evacuated Blood Collection System (500030670, 03/2018) under Caution revealed "Overfilling or under filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance." 5. Review of the patient final reports for 2/1/22 revealed the laboratory analyzed and reported the above purple top (Patient ID 9797) for CBC (complete blood count). 6. An interview with the laboratory manager on 2/1/22 at 1540 hours confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from 2021 and confirmed in interview, the laboratory failed to verify manual differential stain quality each day of use for six of ten days reviewed. The findings were: 1. Random review of laboratory patient final reports from March, July, and September of 2021 revealed the laboratory performed manual CBC (complete blood count) differential for the following six patients. 3/11/21: Accession 2103110009 3/16/21: Accession 210316028 9/29/21: Accession 2109290011 9/22/21: Accession 2109220047 7/27/21: Accession 2107270009 7/06/21: Accession 2107060001 2. Review of the laboratory records available for the above days revealed no documentation of the stain quality. 3. An interview with the laboratory manager on 2/1/22 at 1505 hours in the conference room confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records, patient final reports, and confirmed in interview, the laboratory failed to ensure the accuracy and reliability of data for Troponin testing on the iSTAT analyzer for seven of ten patients reviewed. Findings were: 1. Review of the verification studies from 2018 for Troponin on the iSTAT analyzer revealed the lowest reportable range as 0.29 ng/mL. 2. Random review of patient final reports from 2021 revealed seven of ten patient final reports with Troponin results reported outside of its reportable range. Date Patient ID Trop Result (ng/mL) 7/06/21 6315 0.00 9/16/21 8331 0.00 8/16/21 7948 0.00 10/121 7912

	0.00 6/15/21 7158 0.00 9/24/21 7291 0.00 3. An interview with the laboratory manager on 2/2/22 at 1505 hours in the conference room confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel files, and confirmed in interview, the technical supervisor failed to perform semi-annual competency for five of eight testing person (TP) during the first year of testing patient specimens for high complexity testing in immunohematology. Findings were: 1. A review of the facility's personnel files revealed documentation of the initial and second competency within the first year for four of eight testing personnel (TP#16, hire date 10/13/21; TP# 5, hire date 4/22/21; TP #3, hire date 3/29/21; TP #2, hire date 6/7/21) for blood bank testing by the TC #1 who did not meet the requirements as a technical supervisor for immunohematology. The technical consultant has a bachelor's degree. 2. A review of the facility's personnel files revealed documentation of the initial competency of one of eight testing personnel (TP#1, hire date 11/30/20) for blood bank testing by the TP#7 who did not meet the requirements as a technical supervisor for immunohematology. Testing person #7 has a bachelor's degree. 3. An interview with the laboratory manager on 2/1/22 at 1148 hours in the conference room confirmed the above findings.