Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1063733	**(X3) Date Survey Completed** 10/14/2020
Name of Provider or Supplier First Surgical Hospital	**Street Address, City, State** 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**
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagen accurate and reliable test system operation, and test result reporting. The criteria must be consistent w instructions, if provided. These conditions must be monitored and documented and, if applicable, incl Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluc interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 10/12/20 to 10/14/20. I. Based on review of manufacturer' temperature charts, patient reports, and interview, the laboratory failed to ensure the Main Laboratory Temperature met the manufacturer's requirements for PT (Prothrombin time) and APTT (activated Pa Time) performed on the Sysmex CA-600. A. Review of the Sysmex CA-600 Installation Package Re Coagulation Specimen Handling under Specimen Storage stated, "PT *uncentrifuged or centrifuged * degrees C (Celsius)... APTT *uncentrifuged or centrifuged *unopened tube *18-24 degrees C". B. Re laboratory's Main Laboratory temperature chart showed the laboratory's defined room temperature ra C. Review of temperatures from January 2020 - September 2020 showed temperatures exceeded 24 d 28 days in January 2020: 1. Jan 9 (24.1 degrees C), 2. Jan 11 (24.1 degrees C), 3. Jan 13 (24.5 degree degrees C), 5. Jan 15 (24.7 degrees C), 6. Jan 16 (24.7 degrees C), 7. Jan 17 (24.8 degrees C), 8. Jan 1 Jan 19 (24.9 degrees C), 10. Jan 21 (25.0 degrees C), 11. Jan 23 (24.5 degrees C), 12. Jan 24 (24.5 de (24.1 degrees C), and 14. Jan 27 (24.1 degrees C). C. Random review of patient reports for PT and A following patients were tested: patient IDs 1401-0001 on 1/14/20, 1219-0001 on 1/17/20 and 1301-0 Interview with the technical consultant on 10/14/2020 at 1535 hours via phone call from the conferen she could update that to 20-24. II. Based on review of manufacturer's instructions, temperature charts interview, the laboratory failed to ensure the Main Laboratory's established Room Temperature accep manufacturer's requirements for the controls for pH, pCO2 (partial Carbon dioxide), pO2 (partial Oxy (Potassium), Ca (Calcium), Cl (Chloride), TCO2 (total Carbon dioxide), Glu (Glucose), Lac (Lactate

nitrogen) quality control performed on the epoc Blood Analysis System analyzer. A .Review of the E
Metabolites control package insert used for the analysis of pH, pCO2 (partial Carbon dioxide), pO2 (
(Sodium), K (Potassium), Ca (Calcium), Cl (Chloride), TCO2 (total Carbon dioxide), Glu (Glucose),
BUN (Blood urea nitrogen) on the epoc Blood Analysis System analyzer under Procedures stated, "1.
ampule(s) for a minimum of 1 hour to a temperature to as close to 22 degrees C (Celsius)... as possibl
epoc System Procedure Manual, 51008148 Rev 07, under "Supplies and Storage Requirements for Qu
stated, "Follow the Manufacturer's storage and handling instructions. If ampules are taken from cool s
ampules to Room Temperature (20-25 degrees C)." C. Review of the epoc Procedure Manual, 51012
Aqueous Fluid Handling at 9.4.2 Before Use, stated "If ampoules are taken from cool storage, equilib
Room Temperature (20 - 25 degrees C)." D. Review of the laboratory's temperature chart showed the
room temperature range was 16-25 degrees C. Review of temperatures from January 2020 - Septemb
temperatures for 9 of 9 months with the unacceptable room temperature range of 16-25 degrees Celsi
the technical consultant on 10/14/2020 at 1535 hours via phone call from the conference room ackno
update that to 20 to 24. III. Based on observation and interview, the laboratory failed to ensure the ter
manager's office was established and monitored for the storage of laboratory reagents and test kits pe
instructions. A. Surveyor observation on 10/13/2020 at 1445 in the manager's office revealed no mea
temperatures. B. Further observation on 10/13/20 at 1445 revealed the following test kits, reagents, a
tubes: 1. 2 Boxes of Ca Clean II, Lot A0013, exp 2021-05-27 with a manufacturer storage requiremen
printed on the box. 2. 10 Boxes of Sure-Vue Serum/Urine hCG-STAT kits, Lot HCG0022039, exp 20
manufacturer storage requirement of 2-30 degrees C printed on the boxes. 3. 1 Box of NERL Reagent
959427, exp 2021-06 with a manufacturer storage requirement of 15-30 degrees C printed on the box
Vacutainer Buffered Sodium Citrate Blood Collection Tubes, Lot 0167175, exp 2021-03-31 with a m
requirement of 4 - 25 degrees C printed on the box. C. Interview with testing personnel #2 listed on th
/13/2020 at 1455 hours in the laboratory confirmed temperatures were not documented in the manage
aware that reagents or test kits were stored in the office.
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D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(
authorized person ordering the test and, if applicable, the individual using the test results of reporting
corrected reports promptly to the authorized person ordering the test and, if applicable, the individual
(k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:
An unannounced revisit was performed on 10/12/20 to 10/24/20. Based on review of laboratory polic
and confirmed in interview, the laboratory failed to follow its policy to promptly notify the authorize
test when errors in EPOC patient results are detected. Findings were: 1. Review of the laboratory poli
with an effective date of 10/4/2016 revealed "once an error has been discovered or a complaint made,
is initiated by the lab employee in charge at the time..notify ordering physician and/or RN that an erro
the date, time the person was notified, and who is performing the notification on EHR, to the ordering
2. Review of the patient final report of the blood gas specimen observed on 10/12/20 revealed a final
following results and corresponding reference ranges. Patient MR 4297 i-STAT Lactate - 2.87 mg/dL
11.30) iSTAT pH - 7.37 (reference range 7.35-7.45) iSTAT pCO2 - 43 mmHg (reference range 35-45
mmHg (reference range 80-105) iSTAT TCO2 - 24 3. After an interview with the RN Quality Manag
the Patient MR4297 final report on 10/13/20 at 1000 hours in the conference room, he provided the su
final report for the same specimen. Patient MR 4297 EPOC Lac - 2.87 mmol/L (reference range 0.36-
(reference range 7.35-7.45) EPOC pCO2 - 42.5 mmHg (reference range 35-48) EPOC pO2 - 64 mmH
108) EPOC TCO2 - 24 mmol/L (reference range 22-29) 4. Review of the above corrected report reve
of the notification to the ordering physician and/or RN that an error occurred. 5. Review of the electro
/14/20 at 1430 in the laboratory revealed the laboratory canceled the initial order and results for iSTA

	was entered with the corresponding results. 6. An interview with the technical consultant on 10/14/20 phone confirmed the above findings. **********
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism t when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 10/12/20 to 10/14/20. Based on review of the laboratory's interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues systems. The findings were: 1. The laboratory failed to have documentation of the providing the corre final patient test reports (refer to D5801). 2. The laboratory failed to have documentation of providing identifier on patient reports (refer to D5805).