Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2158579	12/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Texas Scottish Rite Hospital For Children	5700 Dallas Parkway, Frisco, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) records (2019 1st, 2nd, and 3rd Events and 2020 1st, 2nd, and 3rd Events) and in interview with staff, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for 3 of 6 chemistry core events in 2019 and 2020. Findings included: 1. Review of laboratory records revealed the laboratory tested blood gas samples for the following analytes on the ABL 90 blood gas analyzer (Serial Number 090R0519N004): Ionized Calcium

	(Blood Gas), Chloride (Blood Gas), Glucose (Blood Gas), pCO2 (Blood Gas), pH (Blood Gas), pO2(Blood Gas), Potassium (Blood Gas), CO2 (Blood Gas) Sodium (Blood Gas), Hemoglobin and Hematocrit. 2. Review of API test records revealed the following statement: "Attestation Statement SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of PT records from 2019 and 2020 revealed the individual performing testing on the PT samples failed to sign the attestation forms for the following events: 2020 Chemistry Core 1st Event Individuals performing the Ionized Calcium (Blood Gas), Chloride (Blood Gas), Glucose (Blood Gas), pCO2 (Blood Gas), pH (Blood Gas), pO2(Blood Gas), Potassium (Blood Gas), and Sodium (Blood Gas) sample sets failed to sign the attestation form. 2020 Chemistry Core 2nd Event Individuals performing the Ionized Calcium (Blood Gas), Chloride (Blood Gas), Glucose (Blood Gas), pCO2 (Blood Gas), pH (Blood Gas), pO2 (Blood Gas), Potassium (Blood Gas), and Sodium (Blood Gas) sample sets failed to sign the attestation form indicating which sample set was tested. 2020 Chemistry Core 2nd Event Individuals performing the Ionized Calcium (Blood Gas), Chloride (Blood Gas), Glucose (Blood Gas), pCO2 (Blood Gas), pH (Blood Gas), pO2(Blood Gas), Potassium (Blood Gas), and Sodium (Blood Gas) sample sets failed to sign the attestation form 4. During an interview on 12/01/2020 at 10:44 am, the Laboratory Administrative Director confirmed the laboratory failed to attest to the routine integration of proficiency samples into the patient workload.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) records (2019 1st, 2nd, and 3rd Events and 2020 1st, 2nd, and 3rd Events) and in interview with staff, it was revealed the laboratory failed to have documentation evaluating proficiency testing results returned as "not graded" by the proficiency testing agency. Findings included: 1. Review of laboratory records revealed the laboratory tested blood gas samples for the following analytes on the ABL 90 blood gas analyzer (Serial Number 090R0519N004): Ionized Calcium (Blood Gas), Chloride (Blood Gas), Glucose (Blood Gas), pCO2 (Blood Gas), pH (Blood Gas), pO2(Blood Gas), Potassium (Blood Gas), CO2 (Blood Gas) Sodium (Blood Gas), Hemoglobin and Hematocrit. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 revealed the laboratory failed to have documentation of evaluating the following results returned as "not graded": API Chemistry Core 1st Event Glucose (Blood Gas) Sample: BG-03 Reported Result: Lab reported test problem Expected Result: 108-133 Performance: Not Graded 3. Further review of the laboratory's API proficiency testing "Performance Evaluation" in the section labeled "Corrective Action" revealed no documentation of corrective action for the ungraded glucose analyte. 4. During an interview on 12/01/2020 at 10:44 am, the Laboratory Administrative Director was

	asked what was the nature of the test problem for the glucose analyte. She then telephoned the Technical Consultant. The Technical Consultant stated that the glucose value was below the measurable range of the blood gas instrument and a result was not provided. 5. Review of the raw data from the ABL 90 Blood gas analyzer in the section labeled "Notes" revealed NO statement that the glucose value was out of measurable range (linearity). Review of the analytical measurable range from the ABL 90 revealed the instrument was programmed to measure glucose values from 0 - 1080. This measurable range was within the limits of API's expected result of 108 - 133. 6. During an interview on 12/01/2020 at 10:44 am, the Laboratory Administrative Director was asked to provide documentation of evaluating proficiency testing or corrective action for the ungraded glucose analyte. No documentation was provided. This confirmed the above finding.
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 laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) records (2019 1st, 2nd, and 3rd Events and 2020 1st, 2nd, and 3rd Events), and in interview with staff, the laboratory failed to verify the accuracy of the unregulated analyte Carbon Dioxide (CO2) twice annually to ensure accurate and reliable test results. Findings included: 1. Review of laboratory records revealed the laboratory tested blood gas samples for the following unregulated analyte on the ABL 90 blood gas analyzer (Serial Number 090R0519N004): CO2 (Blood Gas) 2. Review of API Chemistry Core proficiency testing records from 2019 and 2020 revealed CO2 (Blood Gas) was not part of the API Chemistry Core BG (Blood Gas) sample set. 3. During an interview on 12/01/2020 at 10:44 am, the Laboratory Administrative Director was asked to provide documentation of twice annual accuracy assessment for CO2. No documentation was provided. This confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 direct observation, review of the ABL 90 Blood Gas analyzer laboratory records, and interview with staff, the laboratory failed to ensure verification studies for precision, accuracy, reportable range, and reference intervals were performed for the ABL 90 blood gas analyzer. Findings included: 1. A tour of the laboratory area on 12/01/2010 at 12:30 pm revealed the laboratory performed arterial, venous, and

	capillary blood gas testing on an ABL 90 blood gas analyzer (Serial Number 090R0519N004). Analytes measured were: pH, pCO2, pO2, HCO3, TCO2, ABE, O2 saturation, Sodium, Potassium, Chloride, Carbon dioxide, Glucose, Ionized Calcium and Hematocrit. 2. Review of laboratory records revealed the ABL 90 blood gas analyzer's initial verification studies were performed 09/2014 at another affiliated location. The following reference ranges were approved by the laboratory director on 09/15/2016: pH arterial and capillary: 7.35 - 7.45; Venous 7.35.-7.45 pCO2 arterial and capillary: 35-48 mmHg; Venous 41-54 mmHg pO2 arterial and capillary: 83-108 mmHg; Venous 30-50 mmHg HCO3 arterial and capillary: 22-26 mmol/L; Venous 22-26 mmol/L TCO2 arterial and capillary: 24-30 mmol/L; Venous 24-30 mmol/L ABE arterial and capillary: -5.0 - 5.0 mmol/L; Venous -5.0 - 5.0 mmol/L Saturation (O2sat) arterial and capillary: 94-97%; Venous 50-70% These reference ranges did not include Sodium, Potassium, Chloride, Carbon dioxide, Glucose, Ionized Calcium and Hematocrit. 3. A random review of the initial verification studies revealed a reportable range verification was performed 09/16/2014 at the affiliated location. The following are the proven reportable ranges: pH: 6.776 - 7.836 pCO2: 8.8 - 104.0 pO2: 14.5-580.0 Potassium: 1.0 - 13.5 Sodium: 77.0 - 179.0 Calcium: 0.5 - 3.6 Chloride: 46.0 - 121.0 Glucose: -4.0 - 1239.3 Review of the reportable ranges programmed into the ABL 90 analyzer revealed the following: pH: 6.3 - 8.00 pCO2: 5.1 - 250 pO2: 0.0 - 800 Potassium: 0.5 - 25.0 Sodium: 7.0 -- 350 Calcium: 0.20 -- 999 Chloride: 7 -- 350 Glucose: 0 - 1080 The reportable ranges determined during the initial verification studies DID NOT correspond to the reportable ranges programmed into the analyzer. THE ANALYZER WAS MOVED TO THIS LABORATORY LOCATION 12/2018. 4. During an interview on 12/01/2020 at 12:12 pm, the Laboratory Administrative Director was asked to provide documentation of verification studies performed after the ABL 90 analyzer was moved to the current location that included accuracy, precision, reportable range, and reference ranges. No documentation was provided. The Laboratory Administrative Director was asked to provide raw data for verification of reference ranges for the arterial, venous, and capillary specimen samples that were approved by the laboratory director on 09/15/2016. No documentation was provided. She further stated no patient testing has been performed on the instrument at this laboratory location. The laboratory failed to ensure verification studies for precision, accuracy, reportable range, and reference intervals were performed for the ABL 90 blood gas analyzer. Word Key: PCO2= Partial pressure of carbon dioxide PO2= Partial pressure of oxygen ABE=Arterial Base Excess HCO3=Bicarbonate TCO2=Total Carbon dioxide
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of personnel records, and staff interview, it was revealed the technical consultant failed to identify the need for training for 1 of 10 testing personnel. Refer to D6066
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 Centers for Medicare and Medicaid (CMS-209) form, personnel records, and in interview with staff, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 2 of 10 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS 209 form revealed 10 Testing Persons (TP #1 - TP#10) performing moderate complexity testing on the ABL 90 Blood Gas analyzer. 2. Review of the laboratory's personnel records revealed the following: a. TP# 5; Date of Hire 09/14/2018; Initial Training 10/16/2018: 6-month competency 05/01/2019 No documentation of a second competency assessment in the first year of patient testing. b. TP# 8; Date of Hire 03/17/2019; Initial Training 01/23/2020 Additional competency assessment provided but NO documentation of the date the assessment was performed. 3. During an interview on 12/01/2020 at 11:32 am, the Laboratory Administrative Director was asked to provide documentation of testing personnel competency assessments at least twice the first year of patient testing for TP#5 and TP#8. No documentation was provided. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of the laboratory's personnel records, and in interview with staff, it was revealed the laboratory failed to have documentation of training for the following 1 of 10 testing persons to qualify them to perform moderate complexity testing: Findings included: 1. Review of the CMS 209 form (signed by the laboratory director on 12/01/2020) revealed 10 Testing Persons (TP #1 - TP#10) performing moderate complexity testing on the ABL 90 Blood Gas analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for the following 1 of 10 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the ABL 90 Blood Gas analyzer: Testing person #4; Date of Hire 12/03/2018 No training documentation for the ABL 90 Blood Gas analyzer. 3. During an interview on 12/01/2020 at 11:32 am, the Laboratory Administrative Director was asked to provide documentation of training for TP#4. No documentation was provided. This confirmed the above findings.