

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0704074	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Hamilton Hospital/Respiratory Therapy	Street Address, City, State 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	An entrance conference was held with the laboratory representative. 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 representative at the exit conference. The laboratory representative was 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 CMS Southern Operations Branch-Dallas 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.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT)</p>

records, and staff interview, the laboratory failed to test chemistry blood gas proficiency samples in the same manner as it tests patient specimens for 3 of 3 testing events in 2021 (1st, 2nd, and 3rd events). Findings included: 1. Review of the CMS 209 form revealed 2 Testing Persons (TP-1 and TP-2) performed moderate complexity testing on the Nova Stat Profile CCS blood gas analyzer. 2. Review of the laboratory policy titled, "Arterial Blood Gas Analysis" (Revised August 28,2009), stated the following: "Staff Qualifications ...Proficiency testing will be completed per federal regulations." 3. Review of the API proficiency testing records from 2021 (1st, 2nd, and 3rd events) revealed TP-2 performed the proficiency testing for blood gas analytes for 3 of 3 testing events. 4. In an interview on 09/29/2021 at 12:41 pm in the chapel, Testing Person -1, after review of the proficiency testing documents, confirmed the above findings.

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 reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of Nova Stat Profile CCS blood gas analyzer operator's manual, laboratory environmental records (01/2021 through 04/2021), and staff interview, the laboratory failed to ensure humidity readings were within manufacturer's specifications for the Nova Stat Profile CCS blood gas analyzer for 68 of 119 days. Findings included: 1. The Nova Stat Profile CCS blood gas analyzer operator's manual (REF 52920E1 2018-12) stated the following: "1.4 Requirements ...Ambient Operating Temperature: 15C to 32C (59F to 89.6F. Operate at Humidity: 20 to 85% without condensation ..." 2. A random review of the laboratory environmental records (01/2021 through 04/2021), revealed an acceptable humidity range of 20 - 85%. Further review of the laboratory environmental logs revealed the following days when the humidity was recorded as "LO": January 2021 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 26, 27, 28, 29, 31 February 2021 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 28, 29 March 2021 1, 2, 3, 5, 6, 7, 8, 15, 16, 18, 19 April 2021 1, 2, 3, 21, 22 No documentation of corrective action for the unacceptable humidity readings was provided. The laboratory failed to ensure humidity readings were within manufacturer's specifications for the Nova Stat Profile 4. During an interview on 09/29 /2021 at 01:00 pm in the chapel, Testing Person-1, after review of the records, 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 a random review of patient test records, laboratory's verification studies for the Nova Stat Profile CCS blood gas analyzer (Serial Number P07320120C) and staff interview, it was revealed the laboratory failed to ensure the reference ranges for 3 of 3 analytes measured in venous blood specimens and cord blood specimens were verified by the laboratory's verification studies. Findings included: 1. A random review of patient test records from the Nova Stat Profile CCS blood gas analyzer revealed the laboratory tested arterial, venous, and cord blood specimens for pH, pCO₂, and pO₂. The following patients were tested using venous or cord blood specimen types: a. Date: 10/13/2020; Patient 00554833; Specimen Type Venous pH=7.431; pCO₂=90.3; pO₂=41.5 b. Date: 11/06/2020; Patient 00556873; Specimen Type Venous pH=6.945; pCO₂=40.4; pO₂=44.9 c. Date: 11/09/2020; Patient 00557063; Specimen Type Venous pH=7.429; pCO₂=21.0; pO₂=119.8 d. Date: 11/30/2020; Patient 00554833; Specimen Type Venous pH=7.420; pCO₂=57.3; pO₂=18.4 e. Date: 09/09/2021; Patient 00587056; Specimen Type Venous pH=7.482; pCO₂=32.4; pO₂=49.9 f. Date: 09/14/2021; Patient 00587951; Specimen Type Cord blood pH=7.353; pCO₂=39.9; pO₂=27.1 2. Review of the verification studies for the Nova Stat Profile CCS blood gas analyzer (Serial Number P07320120C), approved by the laboratory director 04/2020, revealed the laboratory failed to ensure reference ranges for the 3 analytes measured in venous blood specimens and cord blood specimens were verified by the laboratory's verification studies. 3. During an interview on 09/29/2021 at 01:00 pm in the chapel, Testing Person-1 was asked to provide documentation of verification of reference ranges for pH, pCO₂, and pO₂ analytes measured in venous and cord blood specimens. No documentation was provided. This confirmed the above findings. Word Key: PCO₂= Partial pressure of carbon dioxide PO₂= Partial pressure of oxygen

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 random review of patient reports for tests performed on the Nova Stat Profile CCS blood gas analyzer from 10/13/2020 through 09/22/2021 and interview with staff, it was revealed that the laboratory failed to ensure the specimen source was documented on the final patient reports for 13 of 14 patients. Findings Included: 1. Review of the patient test records from 10/13/2020 through 09/22/2021 revealed the laboratory failed to include the specimen source for the following final patient reports: Date: 10/13/2020: Patient 00554833 Date: 11/06/2020: Patient 00556873 Date: 11/09/2020: Patient 00557063 Date: 11/30/2020: Patient 00558410 Date: 09/06/2021:

Patient 00586804 Date: 09/09/2021: Patient 00587056 Date: 09/13/2021: Patient 00587768 Date: 09/15/2021: Patient 00587954 Date: 09/20/2021: Patient 00588400 Date: 09/21/2021: Patient 00588540 Date: 09/22/2021: Patient 00588541/14:00 Date: 09/22/2021: Patient 00588541/18:05 Date: 09/22/2021: Patient 00588541 2. During an interview on 09/29 /2021 at 01:00 pm in the chapel, Testing Person-1, after review of the records, confirmed the above findings

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on random review patient reports for tests performed on the Nova Stat Profile CCS blood gas analyzer from 10/13/2020 through 09/22/2021, and staff interview, it was revealed the laboratory failed to ensure reference intervals were available for 6 of 14 result evaluations. Findings included: 1. A review of patient test reports from 10/13 /2020 through 09/22/2021 revealed the laboratory listed reference ranges for arterial blood gas specimens on the final report form. A review of laboratory arterial blood gas patient log revealed the laboratory also tested venous and cord blood specimens for blood gases. A review of patient test reports from 10/13/2020 through 09/22/2021 revealed the following 6 of 14 blood gas test reports that failed to ensure reference intervals for venous and cord blood specimens were available for test result evaluation: a. Date: 10/13/2020; Patient 00554833; Specimen Type Venous pH=7.431; pCO2=90.3; pO2=41.5 The final report failed to include reference ranges for venous specimens. b. Date: 11/06/2020; Patient 00556873; Specimen Type Venous pH=6.945; pCO2=40.4; pO2=44.9 The final report failed to include reference ranges for venous specimens. c. Date: 11/09/2020; Patient 00557063; Specimen Type Venous pH=7.429; pCO2=21.0; pO2=119.8 The final report failed to include reference ranges for venous specimens. d. Date: 11/30/2020; Patient 00554833; Specimen Type Venous pH=7.420; pCO2=57.3; pO2=18.4 The final report failed to include reference ranges for venous specimens. e. Date: 09/09/2021; Patient 00587056; Specimen Type Venous pH=7.482; pCO2=32.4; pO2=49.9 The final report failed to include reference ranges for venous specimens. f. Date: 09/14/2021; Patient 00587951; Specimen Type Cord blood pH=7.353; pCO2=39.9; pO2=27.1 The final report failed to include reference ranges for cord blood specimens. 2. During an interview on 09/29 /2021 at 01:00 pm in the chapel, Testing Person-1, after review of the records, confirmed the above findings.