| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D0704074 | 07/11/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Hamilton Hospital/Respiratory Therapy | 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 |
|---|---|
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory quality control records (2018 through 06/2019) and confirmed in interview, the laboratory failed to retain package inserts for Stat Profile pHOx Oximeter quality control material for Arterial Blood Gases (ABG) for 17 of 17 lot numbers. The findings included: 1. Review of laboratory quality control records revealed the laboratory failed to retain the lot value assignment datasheets for the following QC (quality control) lot numbers for Stat Profile pHOx quality control material: Lot: 16351017 Lot: 16351018 Lot: 17005010 Lot: 17089034 Lot: 17097061 Lot: 17100084 Lot: 17100094 Lot: 17158033 Lot: 17289034 Lot: 17277013 Lot: 17361067 Lot: 18046030 Lot: 18062002 Lot: 18064054 Lot: 18064055 Lot: 18136029 Lot: 18298040 2. In an interview on 07/10/2019 at 1500 hours in the chapel, the Technical Consultant was asked to provide package inserts for the Stat Profile pHOx quality control material. The TC stated that the laboratory did not kept the package inserts. This confirmed the above findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions for the Nova Stat Profile pHOx Ultra blood gas analyzer (Serial number Z1315090), laboratory environmental records (2018 through 06/2019), and confirmed in interview, the laboratory failed to ensure room temperature and humidity ranges were within the operating specifications for the Nova Stat Profile pHOx Ultra blood gas analyzer for 18 of 18 months. Findings included: 1. The manufacturer's instructions for the Nova Stat Profile pHOx Ultra blood gas analyzer stated the following in the section titled "Working Area Requirements": "Ambient operating temperature is 15C to 30C (59F to 86F). Operate at humidity of 0 to 85% without condensation." 2. Review of the laboratory environmental log titled "Olney-Hamilton Hospital Respiratory Therapy" for 2018 through 06/2019 revealed an acceptable room temperature range of 2C to 25C and humidity range of 0% to 100%. The laboratory failed to ensure room temperature and humidity ranges were within the operating specifications for the Nova Stat Profile pHOx Ultra blood gas analyzer. 3. The above findings were confirmed by the Technical Consultatant on 07/10/2019 at 1500 hours in the hospital chapel. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of the laboratory's Individualized Quality Control Plan (IQCP) for the modification of the frequency of quality control (QC) testing performed for the Nova Stat Profile pHOx Ultra blood gas analyzer, pHOx QC records, and staff interview, it was revealed the laboratory failed to identify risks and the frequency and impact for each risk for 5 of 5 categories for the pHOx Ultra blood gas analyzer. Findings included: 1. During a tour of the laboratory on 07/11/2019 at 0930 hours, a Nova Stat Profile pHOx Ultra blood gas analyzer (Serial Number Z31315090) was observed. The analyzer was used to test pH, PCO2, PO2, O2Sat, HbCO, THb, and OxyHb. 2. Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process. Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components: *Specimen *Test System *Reagent *Environment *Testing Personnel The scope of the risk assessments must encompass the entire testing process - preanalytic, analytic, and post-analytic phases and include, at a minimum, the evaluation of the five risk assessment components listed above for each test for which the laboratory wishes to employ IQCP. To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality. In-house data, established |

| | |
|---|---|
| | by the laboratory in its own environment and by its own personnel, must be utilized to demonstrated that the stability of the test system as it is used in that laboratory supports the number and frequency of the QC documented in the IQCP. 2. Review of the laboratory policy titled "Individualized Quality Control Plan Summary" (Approval date 12/05/2016) and QC records revealed the laboratory failed to identify risk, frequency of occurrence, severity of harm, measures to control risk and supporting documentation of the preanalytic, analytic and post-analytic phases of the five risk assessment components. Examples: For the category of Specimen, the laboratory identified "Written specimen collection procedures with defined acceptability criteria." The laboratory failed to identify the impact of test quality if the specimen collection did not follow procedures or if the specimen was unacceptable for testing. For the category of Test System, the laboratory identified "Two level of external QC every 30 days." The laboratory failed to provide data that supported or proved the rationale for the number, type and frequency of external quality control testing. 3. In an interview on 07/11/2019 at 0930 in the laboratory, testing person#2 was asked to provide documentation of data that supported or proved the rationale for the number, type and frequency of external quality control testing every 30 days and documentation of a more complete IQCP. No documentation was provided. The above findings were confirmed by laboratory representatives during an interview on 07 /11/2019 at 1500 hours in the Chief Operating Officer's office. Word Key: PCO2= Partial pressure of carbon dioxide PO2= Partial pressure of oxygen O2 Sat=Oxygen saturation HbCO=Carboxyhemoglobin THb=Total Hemoglobin OxyHb=Deoxyhemoglobin |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the Technical Consultant (TC) failed to evaluate and document performance for 1 of 1 Testing Persons responsible for moderate complexity testing at least semiannually during the first year testing persons analyze patient specimens in 2017 and 2018. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #3 listed to perform moderate complexity blood gas analysis. 2. Review of personnel records from 2017 through 2019 revealed the following: Testing Person #3; Date of hire-06/22/2017 Training on 06/22/17 Competency Evaluation 05/21/2018 (11 months after initial training) Competency Evaluation 06/19/2019 (2 years after initial training) The TC failed to evaluate and document performance at least semiannually during the first year of patient testing. 3. In an interview on 07/09/2019 at 1000 hours in the hospital chapel, the TC was asked to provide documentation of semiannual competency assessment for Testing Person #3. No documentation was provided. This confirmed the above findings. |