

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 04D0465641 | (X3) Date Survey Completed 10/19/2018 |
| Name of Provider or Supplier Magnolia Regional Health System Inc | Street Address, City, State 101 Hospital Drive, Magnolia, AR | |
| 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 |
|---------------------------|--|
| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: . Through a review of Respiratory policy and procedure manual, personnel files, a review of proficiency test documentation for 2017 and 2018, as well as interviews with staff, it was determined proficiency testing samples were not tested by all personnel who routinely perform Blood Gas patient testing.. As evidenced by: A. A review of the Respiratory policy and procedure manual revealed the Arterial Blood Gas Proficiency testing policy which states; "The analysis of all proficiency tests samples shall be performed, as closely as practical, in the same manner as regular patient samples." B. A review of eleven of eleven Respiratory personnel records revealed, testing personnel #2, #6,#7, #8, #9, #10 and # 11 (as listed on form CMS-209) were authorized by the Laboratory Director to perform Blood Gas testing. C. A review of 2017 and 2018 Proficiency testing attestation (six of six events) statements revealed Respiratory had no documentation that seven of eleven testing personnel (#2, #6, #7, #8, #9, #10 and #11 as listed on form CMS-209) had not performed proficiency testing in 2017 and 2018. D. A review of six of six Proficiency testing events attestation statements of 2017 and 2018 revealed Respiratory personnel #1(as listed on form CMS 209) participated in all six events. E. In an interview at 14:00 on 10/17/2018, Respiratory personnel #1 (as listed on form CMS -209) confirmed that testing personnel #2, #6, #7, #8, #9, #10 and #11 (as listed on form CMS-209) perform Blood Gas patient testing and had not participated in proficiency testing in 2017 and 2018.</p> |
| 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:

. Through a review of Gem Premier 3500 Blood Gas analyzer user manual, lack of documentation, as well as interviews with staff, it was determined the Respiratory laboratory failed to document humidity conditions that are essential for the operation of the Gem Premier 3500 analyzer. As evidenced by: A. A review of the user manual (Section 11.3 "Specifications") for the Gem Premier 3500 Blood Gas analyzer revealed the Ambient Environmental requirements for the analyzer operations: Relative Humidity 5% to 90%; External Ambient Temperatures 15 to 35 degrees Celsius. B. The surveyor requested daily documentation of humidity. None was provided. C. In an interview on 10/18/2018 at 1330, Respiratory personnel #1 (as listed on form CMS 209) confirmed the Respiratory laboratory has no documentation of humidity on days of testing.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Through a review of Streck Erythrocyte Sedimentation Rate (ESR) Chex package inserts, ESR quality control, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of ESR control. As evidenced by: A. Streck Auto Plus analyzer is utilized by the laboratory to perform ESR assay. The package insert for ESR-CHEX for automated Sedimentation Rate states: "The assay values are derived from replicate analysis on both automated and manual methods. Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits. However, the control means established by the laboratory should fall within the Expected range specified for the control." B. In a review of ESR quality control data, it was determined the mean and acceptable range in three of three months (April, July

and September 2018) reviewed matched the expected range as listed on the ESR-Chex package insert. Level I control range (1-17) and Level II control range (65-101). C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 10/16/2018 at 10:00, general supervisor (as listed on CMS-209) confirmed that the laboratory has not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR control.