

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1026830	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Saline Heart Group Pa	Street Address, City, State 1000 Hwy 35 North, Suite 8, Benton, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Observation and interview determined that the laboratory failed to label two of two bottles of wash solution with identity, storage requirements, and preparation and expiration dates. Findings follow: A) During a tour of the laboratory on 8/13/24 at 02:17 p.m. two plastic white colored bottles were observed partially filled with clear liquid. One bottle was labeled "Alfa Wassermann System Diluent lot 605522 expiration 2024-08-31" the second was labeled "Alfa Wassermann System Diluent lot 481716 expiration 2023-12-31". Both bottles were uncapped. B) During an interview on 8/13/24 at 02:17 p.m., testing personnel identified as number 4 on the CMS 209 form, when asked what the bottle contained, said one bottle contained water and the second contained alcohol and they were used to rinse instrument probe and verified that the bottles were mislabeled as to contents, storage requirements, and preparation and expiration dates.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the</p>

laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Review of the laboratory policy and procedure "Quality Control (QC) of Patient Test Systems", Levey-Jennings (LJ) Report September 2023 for Serum Glutamic Pyruvate Transaminase (ALT), and Aspartate Transaminase (AST) analysis, and through interviews with laboratory staff, determined the laboratory failed to monitor, over time, the accuracy of chemistry test results for those analytes. Survey findings include: A) A review of the general policy and procedure manual revealed a quality control policy stating " Review previous data points on LJ plots for scatter, shifts, or trends. A shift is defined as the following: when five data points in a row have fallen on one side of the mean. Remedial action is to be taken if this situation is found, to include: changing reagent packs; re-calibration of assays; adjustment of means if instructed by technical support or the lab consultant." B) A review of the September 2023 LJ report for Alfa Wassermann Chemistry Controls Level 1 and Level 2 lot numbers 1501 UNCM and 1166 UECM respectively for ALT and AST analysis revealed that QC results for ALT analysis were recorded as below the mean for 16 of 16 times for both levels and QC results for AST analysis were recorded as below the mean for 12 of 13 times for level 1 and 15 of 15 times for level 2. C) A review of the technical consultant quality assurance reports for 2023 found no mention of shifts in ALT or AST analysis. D) Upon request, the laboratory was unable to provide documentation of corrective action taken to address shifts in the September 2023 LJ charts for ALT and AST analysis. E) In an interview, at 2:37 p.m. on 8/13/24, laboratory staff member #2 (as listed on the CMS-209 form) confirmed the shifts were present without documented corrective actions.

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:

Review of policies and procedures for quality control of patient test systems, a review of the Alfa Wassermann level 1 and level 2 manufacturer's requirements for assignment of values, and a review of the Alfa Wassermann ACE chemistry system quality

control (QC) documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for eight of eight tests reviewed in which Alfa Wassermann were the quality control material used. Survey findings include: A) A review of the laboratory policy and procedure "Quality Control of Patient Test Systems" determined the policies and procedures stated: "Laboratory personnel conduct parallel testing of new lot numbers of controls using replicate files. A replicate file is created for each new lot number of control, and controls are tested once a day for 20 days, or twice a day (once in the am, once before closing) for 10 consecutive days. A mean is calculated from the 20 data points. Once a new lot number of controls is put into use, historical SDs are used to calculate new ranges." B) The manufacturer's package inserts for Alfa Wassermann Chemistry Control Level 1 lot # 1501 UNCM and Alfa Wassermann Chemistry Control Level 2 lot # 1166 UECM stated "each laboratory should establish its own mean and precision parameters". C) Through a review of quality control documentation for ten analytes recorded in September 2023, the surveyor observed the mean and acceptable quality control ranges the laboratory employed were identical to the mean and ranges provided by the manufacturer of Alfa Wassermann Chemistry Controls Level 1 and Level 2 lot numbers 1501 UNCM and 1166 UECM for the analytes of Albumin (ALB), Serum Glutamic Pyruvate Transaminase (ALT), Aspartate Transaminase (AST), Carbon Dioxide (CO2), Creatinine (CR), Sodium (Na) Total Protein (TProt) , and total Cholesterol (Chol). D) In an interview, at 12:00 p.m. on 8/13/24, laboratory staff member #2 (as listed on the form CMS-209) stated "I don't think they ran 20 replicates to set the mean for new lot of control material" and confirmed that the target and ranges for the analytes identified above were identical. .

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Review of the "Saline Heart Group Laboratory Policy", quality control (QC) results for September 2023, corrective action documentation, patient results, and interview determined that patient results were not evaluated to the last successful QC performance when QC failed and corrective action made changes in the test system operation for one of six instances reviewed. Findings follow: A) Review of the laboratory's "Saline Heart Group Laboratory Policy" revealed that under the heading "Quality Control Corrective Actions" paragraph 3 stated "For failed quality control which requires instrument intervention(i.e. calibration, instrument maintenance /troubleshooting) after corrected QC will be run and found acceptable. Several patient results will be reviewed from the time of the last successful QC. The clinical consultant will determine by looking at the results if additional measures are necessary". B) Through a review of creatinine (CR) QC results for September 2023 it was determined that on 9/05/23 Alfa Wassermann Chemistry Controls Level 1 and Level 2, lot numbers 1501 UNCM and 1166 UECM respectively, were both outside of

acceptable range on three attempts before acceptable results were obtained on the fourth attempt . C) Review of corrective action documentation for CR analysis on that date revealed for the first instance of QC failure corrective action consisted of repeating the QC procedure but on the second instance corrective action stated "calibrate and rerun on new sample" which indicated a change in the testing system. D) Review of chemistry QC results for CR analysis revealed that the most recent successful QC for CR analysis prior to 9/5/23 was performed at 8:42 a.m. on 8/30/23. E) Review of patient results revealed that 11 CR tests were performed and reported on 8/30/24 (patient identified as numbers 1 through 11 on the separate patient identification list). F) In an interview on 8/13/24 at 11:17 a.m., the laboratory staff member (# 2 on hte CMS 209 form) confirmed that the CR results reported on 8/30/23 had not been evaluated.