

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1026830	(X3) Date Survey Completed 01/09/2023
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: Through review of package inserts, observation, and interview it was determined that the laboratory did not change expiration dates on control materials after opening as required by manufacturer. Finding follow: A) Review of the package insert for Liquichek Hematology Controls (A) revealed that the product expires in twenty-one days after vial is opened and the expiration dates should be changed as required after opening. B) On 1/9/2023 at 1:00pm the surveyor observed, Liquichek Hematology Controls (A) in use , that did not have new expiration dates indicated on the testing materials. C) In an interview on 1/09/2023 at 1:10pm laboratory staff member (number 4 on form CMS 209) confirmed that no dates were written on the vials when the controls were put into use and, when asked when the control material was put into use, stated that she did not know.</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 laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

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:

Through a review of the Individualized Quality Control Plans (IQCP) for the D-Dimer assay performed on the PathFast immuno analyzer, and through interviews with laboratory staff, it was determined the laboratory failed to establish the number and type of control materials used for D-Dimer assays. Survey findings follow: A) Through review of the IQCP for D-Dimer assays performed on the PathFast immunoanalyzer it was determined the Quality Control Plan failed to state the number and frequency of controls to be run or the specific type of control which would be used in the D-Dimer assay. B) In an interview at 12:20 p.m. on 1/9/2023, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of specific type of control in the Quality Control Plan for D-Dimer assay.

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 review of quality control records, control manufacturer ' s product inserts, and interview, it was determined that the laboratory did not follow established statistical parameters (standard deviation) in establishing acceptable range for complete blood cell (CBC) analysis control materials in one of three months reviewed. Findings follow: A) In an interview conducted on 1/9/23 at 09:15 a.m. , the laboratory staff member (# 2 on the CMS 209 form) stated that acceptable ranges for three levels of Cell-Dyne 18 Plus Control material used for quality control for all parameters of CBC analysis were established by using "historical standard deviations (SD)" determined by the laboratory and provided a list of those SD's to the surveyor. B) Review of the manufacturer's package insert for Cell-Dyne 18 Plus Control revealed " the recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus, they are wider than the +/- 2 SD range for one instrument". C) Review of quality control results for September 2022 for Cell-Dyne 18 Plus Control, lot numbers L2234, N2234 and H2234 used by the laboratory

revealed that acceptable ranges in use for all parameters of CBC analysis matched those provided by the manufacturer and not the historical SD's on the list provided by the laboratory.