Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1026830	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Saline Heart Group Pa	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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of chemistry quality control results for January, March and April 2018, patient medical records, technical consultant report for March 2018, as well as interviews with staff, it was determined that patients were reported when results of control material failed to meet the laboratory's criteria for acceptability. As evidenced by: A. A review of the ACE Alera Chemistry analyzer daily quality control printouts for 3/7/2018 revealed the Calcium result on the Level 1 Chemistry Control (Lot #1213UNCM) was outside of the acceptable criteria. The control was tested four times with all four results being unacceptable. The acceptable range listed for Calcium is 10.0 to 11.2. Results documented for 3/7/2018 are 0.4, 9.6, 9.5, and 9.4. B. A review of the technical consultant report for March 2018 revealed the laboratory did not have documentation of acceptable quality control result for Level I Calcium (Lot #1213UNCM). C. Through a review of patient chemistry reports it was determined four patients had Calcium results reported on 3/7/2018, when the chemistry control was unacceptable: Patient #3276, patient #7904, patient #15850 and patient #9346. D. In an interview on 06/21/2018 at 1423, technical consultant (as listed on form confirmed there were no acceptable quality control results for Calcium on 3/7/2018, and that patient results were reported.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Through a review of the laboratory policy and procedure manual, review of the instrument validation documentation for the Pathtest Chemistry analyzer, technical consultant reports, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to follow written policies and procedures to assess and correct problems in the analytic systems. As evidenced by: A. The Quality Assurance (QA) Plan in the procedure manual states: "This laboratory has established the following goals for our QA program. We intend to identify problems in our laboratory and apply corrective action." B. A review of the new instrument validation documentation for the Verbatim Americas Pathfast Chemistry Analyzer installed 01/27 /2017 revealed the validation documentation contained another laboratory's name. C. A review of the Technical Consultant report for March 2018 revealed the following "Linearity studies on the Pathtest has the wrong name on the documents. We either have another clinic's forms or the name is just in error." D. The laboratory identified the problem in March 2018 no corrective action was performed to correct the problem until the date of survey on June 21, 2018. E. In an interview June 21, 2018 at 1100 the technical consultant (as listed on form CMS 209) confirmed the validation documentation for Verbatim Pathfast Chemistry analyzer contained another laboratory's named.