

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1080427	(X3) Date Survey Completed 08/28/2018
Name of Provider or Supplier Chi St Vincent Medical Group Hot Springs	Street Address, City, State 118 Women'S Center Lane, Ste B, Hot Springs, 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Through a review of laboratory policy and procedures manual, quality control data, patient testing logs, lack of documentation, as well as interview with staff, it was determined the laboratory failed to perform positive and negative controls on days when patients were analyzed. As evidence by: A. A review of the laboratory quality control policy for Stanibo True Serum Pregnancy test revealed "positive and negative controls should be run each day of patient testing. B. A review of quality control data for March, June and July of 2018 revealed on one of sixteen days in June of 2018, the laboratory had no documentation of quality control. C. A review of the Stanibo Serum Pregnancy patient log revealed patient #1402641696 had a serum pregnancy test performed and resulted on 6/22/2018 without documentation of quality controls. D. In an interview on 8/28/2018 at 1330, laboratory personnel #3 (as listed on form CMS 209) confirmed patients were test without documentation of quality controls.</p>
D5551	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by</p>

concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Through a review of laboratory policy and procedure manual, Immunohematology quality control records, patient testing logs, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to perform and document quality control for Immunohematology testing on each day of patient testing. As evidenced by: A. A review of the laboratory Immunohematology quality control policy (QC) revealed " QC will be performed with each run of patient samples." B. A review of quality control data for March, June, and July of 2018 revealed on one of twenty-five days in June 2018, the laboratory had no documentation of quality control. C. A review of the Immunohematology patient log revealed patient #29513514 had an Type and Screen performed and resulted on 6/04 /2018 without documentation of quality controls. D. In an interview on 8/28/2018 at 1130, laboratory personnel #3 (as listed on form CMS 209) confirmed the lack of documented quality control on the day of Immunohematology patient testing.