

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D0691228	<b>(X3) Date Survey Completed</b>  10/30/2018
<b>Name of Provider or Supplier</b>  Spanish Fork Clinic Inc	<b>Street Address, City, State</b>  336 W 100 S, Spanish Fork, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5785</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on reagent and specimen storage refrigerator records review, manufacturer's storage temperature recommendations review, and interview with staff, the laboratory failed to document corrective actions taken when storage temperatures exceeded the manufacturer's storage temperature ranges for 5 of 5 test days reviewed. Findings include: 1. Temperature records reviewed for test days 08/31/2018 (18 degrees F), 08/30/2018 (20 degrees F) , 11/29/2017 (20 degrees F), 08/03/2017(30 degrees F) and 11/09/2016 (30 degrees F) included documentation the laboratory recorded refrigerator storage temperatures less than the acceptable range of 2 to 8 degrees Centigrade (approximately 35 to 46 Degrees Fahrenheit). 2. Manufacturer's storage temperature ranges for complete blood count quality control materials and for serum human chorionic gonadotrophin quality control materials review is from 2 to 8 degrees Centigrade (approximately 35 to 46 degrees Fahrenheit). 3. In an interview with staff on 10/30/2018 at approximately 9:30 A.M. and again at 12:30 P.M. staff stated the thermometer was inoperable and had not been replaced prior to the survey on 10/30/2018.</p>