Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0659180	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
East Tennessee Reproductive Endocrine Lab	Dogwood Ave, Bldg 119, Rm 328, Mountain Home, TN	

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
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (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. This STANDARD is not met as evidenced by: _____ Based on review of the heat block temperatures for the Illumigene testing platform for Group A and B Strep for 2018, manufacturer's temperature specification and interview with the Laboratory Supervisor, the laboratory failed to document remedial action for temperatures outside the specified range. The finding include: 1. Review of the heat block temperatures for the Illumigne Group A and B Strep testing showed 66 days where maximum temperature range was recorded greater than 100 degrees Celsius with no remedial action documented. 2. Review of the manufacturer's temperature specifications were 95 degrees Celsius plus or minus 5 degrees. 3. An interview at approximately 12:00 p. m. May 3, 2018 with the Laboratory Supervisor confirmed the laboratory failed to document remedial action for the heat block temperatures outside the specified range from January 2 to May 2, 2018. _____