Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0297371	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Douglas K Pierce Md Pa	Street Address, City, State 8787 Bryan Dairy Rd Ste 360, Largo, FL	

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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when the room temperature was out of range for 19 events during the time period of December 2016 - November 2016) Findings included: 1. Record review of the QC record logs showed the acceptable "In Use" room temperature is 75 +/- degree Fahrenheit. The following dates had temperatures out of range with no corrective action documented: 1. January 4, 2017: documented temperature of 69.7 2. January 5, 2017: documented temperature of 66.9 3. January 13, 2017: documented temperature of 67.2 4. January 18, 2017: documented temperature of 62.2 5. January 19, 2017: documented temperature of 62.2 6. February 23, 2017: documented temperature of 69.6 7. February 24, 2017: documented temperature of 62.7 8. March 10, 2017: documented temperature of 68.7 9. April 13, 2017: documented temperature of 62.2 10. April 14, 2017: documented temperature of 62.7 11. April 20, 2017 documented temperature of 67.2 12. April 21, 2018: documented temperature of 62.1 13. May 11, 2017: documented temperature of 68.9 14. June 9, 2017: documented temperature of 68.9 15. April 4, 2018: documented temperature of 66.7 16. May 17, 2018: documented temperature of 68.7 17. August 24, 2018: documented temperature

	of 69.1 18. August 30, 2018: documented temperature of 66.3 19. October 25, 2018: documented temperature of 69.1 2. Interview on 11/06/2018 at 12:30 p.m., the Laboratory Manager confirmed no corrective action was documented for the out of range room temperature requirements for the Cryostat used to cut patient tissue specimens for slide preparation and staining.