

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0709026	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Center For Advanced Reproductive Services	Street Address, City, State 2 Batterson Park Rd, Farmington, CT	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to follow manufacturer instructions for proper storage of control material in the subspecialty of endocrinology. Findings include: 1. Surveyor observation of the endocrinology laboratory freezer #4 contents on 6/7/18 at 1:45 PM revealed three boxes of Biorad Endocrine Controls. Manufacturer instructions written on these boxes revealed proper storage is -20 to -70C. 2. Record review of the package inserts on 6/7/18 of the BioRad Endocrine controls stored in freezer #4 revealed proper storage range is -20C to -70C. 3. Record review of the endocrinology laboratory freezer #4 temperature logs on 6/7/18 revealed: a. Acceptable freezer temperature range from May 2017 through December 2017 was less than or equal to -20C. b. Acceptable freezer temperature range from January 2018 through February 2018 is Max less than -17C, Min >-23C c. Digital thermometer was replaced with a new thermometer and calibrated on 2/28/18. d. Acceptable freezer temperature range from March 2018 through May 31, 2018 is Max less than or equal to -15C, Min greater than or equal to -25C. e. Temperatures were out of range on 148 of 396 working days from May 2017 through May 2018, based on manufacturer instructions for control proper storage. The laboratory was unaware because the temperature charts had the incorrect temperature range. 4. Staff interview with the technical supervisor (TS) on 6/7/18 at 1:55PM</p>

confirmed the manufacturer instructions for the Biorad Endocrine controls are for storage at a lower freezer temperature. TS stated that he/she was unaware of the storage requirements and was not certain if the freezer can attain the temperature range necessary for proper storage. 5. The laboratory performs 45,200 endocrinology tests annually.

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 take corrective action when the laboratory freezer temperature was out of range. Findings include: 1. Record review of the endocrinology laboratory freezer #4 temperature logs on 6/7/18 revealed: a. Acceptable freezer temperature range from May 2017 through December 2017 was less than or equal to -20C. b. Corrective action was not documented for 7 of 245 working days from May 2017 through December 2017 when temperature was outside of the above range. c. Acceptable freezer temperature range from January 2018 through February 2018 is Max less than -17C, Min >-23C d. Corrective action was not documented for 34 of 49 working days when temperature was outside of the above range. e. Digital thermometer was replaced with a new thermometer and calibrated on 2/28/18. f. Acceptable freezer temperature range from March 2018 through May 31, 2018 is Max less than or equal to -15C, Min greater than or equal to -25C. g. Corrective action was not documented for 91 of 92 days when temperature was outside of the above range. 2. Record review of the package inserts on 6/7/18 of the BioRad Endocrine controls stored in freezer#4 revealed the storage range -20C to -70C. 3. Staff interview with technical supervisor (TS) on 6/7/18 at 1:30 PM confirmed the above findings. TS also stated that the equipment is inconsistent in holding the recommended temperature. TS was unaware of the manufacturer's control storage requirement. 4. The laboratory performs 45,200 endocrinology tests annually. This is a repeat violation.