

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0932456	<b>(X3) Date Survey Completed</b>  01/25/2018
<b>Name of Provider or Supplier</b>  Robert A Woodbury Md	<b>Street Address, City, State</b>  1200 E Putnam Ave, Riverside, CT	
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>D0000</b>	The laboratory of Robert Woodbury, M.D. was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on 1/25/18.
<b>D5413</b>	<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 record review, observation and director interview, the laboratory failed to ensure proper function checks of the cryostat instrument in the specialty of histopathology. Findings include: 1. Record review of the cryostat temperature logs on 1/25/18 revealed: a) Acceptable temperature ranges were not listed on the logs for 2016 and 2017. b) Actual temperature values were not being recorded on the logs, only check marks for 2016 and 2017. 2. Observation of the temperature reading on the Leica cryostat on 1/25/18 at 10:15 AM was -18C. 3. Record review of the laboratory's cryostat maintenance procedure on 1/25/18 revealed the cryostat acceptable temperature range is -20C to -30C. 4. Interview with director on 1/25/18 at 10:30 AM confirmed: a) Temperature ranges not were listed on the cryostat log sheets for 2016 and 2017. b) Actual temperatures were not being documented on the cryostat log sheets for 2016 and 2017. c) Procedure states the acceptable range is -20C to -30C and the instrument temperature reading was -18C which was out of range and no corrective action was documented. 5. The laboratory performs 293 histopathology tests annually.</p>