

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2050308	(X3) Date Survey Completed 05/07/2018
Name of Provider or Supplier 7 Hill Gastroenterology Pa	Street Address, City, State 3256 S Pine Ave Bldg 200, Ocala, 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	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to document corrective action when the temperature of the oven used for drying histopathology slides was out of range for 56 days out of four months reviewed in 2017 and 2018. Findings include: The 5/7/18 record review of the "Daily Microtome, Water bath, Slide Dryer Maintenance Log" showed the temperatures documented on 12/4/17, 12/6/17, 12/7/17, 12/11/17, 12/13/17, 12/15/17, 12/18/17, 12/20/17, 12/21/17, 12/26/17, 12/27/17, 12/28/17, 1/3/18, 1/10/18, 1/11/18, 1/15/18, 1/17/18, 1/18/18, 1/22/18, 1/24/18, 1/25/18, 1/29/18, 1/31/18, 2/1/18, 2/5/18, 2/7/18, 2/8/18, 2/12/18, 2/14/18, 2/15/18, 2/19/18, 2/21/18, 2/22/18, 2/26/18, 2/28/18, 3/15/18, 3/19/18, 3/21/18, 3/22/18, 3/26/18, 3/28/18, 3/29/18, 3/30/18, 4/2/18, 4/4/18, 4/5/18, 4/9/18, 4/11/18, 4/12/18, 4/16/18, 4/18/18, 4/19/18, 4/23/18, 4/25/18, 4/26/18 and 4/30/18 at 60C. The acceptable range is 65-70C. There was no indication that the temperature was adjusted into range. The 5/7/18 interview with the technical supervisor at 10:15am confirmed the temperatures were documented out of range and no corrective action took place.</p>