

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0284441	(X3) Date Survey Completed 08/10/2018
Name of Provider or Supplier Thomas S Breza Md	Street Address, City, State 4341 Bougainvilla Dr, Fort Lauderdale, 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
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 record review and interview with the laboratory director, the laboratory failed to document the room humidity from 2016 to 2018. Findings include: Review of the cryostat manual Leica CM1510 indicated a requirement for room humidity not above 60 %. Quality control records of histopathology room revealed that no documentation of the humidity room done from 2016 to 2018. During an interview on 08/10/18 at 11:30 a.m., the laboratory director confirmed that there was no record of room humidity for the period of 2016-2018.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory director, the laboratory had an</p>

open partially used expired reagent in the flammable cabinet. Findings include:
During tour of the laboratory at approximately 11:00 AM on 08/10/2018 the surveyor found a bottle of Eosin Y, alcoholic lot #39166 expired 11/2016. During an interview on 8/10/2018 at 11:30 AM, with the laboratory director, he confirmed the existence of the expired reagent in the cabinet.