

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2133197	(X3) Date Survey Completed 06/28/2018
Name of Provider or Supplier Precision Toxicology Llc DbA Precision Diagnostics	Street Address, City, State 49 State Road, Nauset Bldg, Suite 103, Dartmouth, MA	
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
D0000	An initial CLIA certification survey was conducted for the Precision Toxicology, LLC dba Precision Diagnostics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 observation, record review and interview, the laboratory failed to ensure that temperature conditions for reliable test system operation met the laboratory's established acceptable criteria as evidenced by the following: a) A review of temperature records for May 2018 (twenty two (22) days of laboratory operation) was performed. b) The review revealed that the temperature of the laboratory refrigerator was above the acceptable temperature range of two (2) to eight (8) degrees Celsius for twenty two (22) out of the twenty two (22) days reviewed (5/1,5/2, 5/3, 5/4, 5/7, 5/8, 5/9, 5/10, 5/11, 5/14, 5/15, 5/16, 5/17, 5/18, 5/21, 5/22, 5/23, 5/24/5/25, 5/29, 5/30 and 5/31/18). c) The review also revealed that the temperature of the laboratory freezer was above the acceptable temperature range of minus 30 degrees Celsius for twenty two (22) out of the twenty two (22) days reviewed (5/1,5/2, 5/3, 5/4, 5/7, 5/8, 5/9, 5/10, 5/11, 5/14, 5/15, 5/16, 5/17, 5/18, 5/21, 5/22, 5/23, 5/24/5/25, 5/29, 5/30 and 5/31/18). d) The temperature of the refrigerator on 6/28/18 at 12:12 PM was observed to be</p>

10.64 degrees Celsius e) For both the refrigerator and freezer there was no corresponding documentation of any remedial or corrective action being taken to correct the out of range temperatures. f) The Director of Quality & Process Improvement confirmed in an interview on 6/28/18 at 12:10 PM that the temperature of the refrigerator was consistently falling out of the acceptable range and could provide no documentation of remedial or corrective action being taken. g) Based on the refrigerator and freezer temperatures falling consistently out of range on an almost daily basis, the stability of reagents and specimens stored in them could not be assured.