Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2033858	**(X3) Date Survey Completed** 07/24/2018
Name of Provider or Supplier Mdx Health Inc	**Street Address, City, State** 15279 Alton Pkwy Ste 100, Irvine, CA	

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**
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory documents and interview with laboratory personnel, it was determined that results of control materials failed to meet the laboratory's criteria for acceptability before reporting patients test results. Findings include: a. The laboratory written procedure document titled, "IR-TSOP-0110 ConfirmMDx for Prostate Cancer Automation LC480 - Diagnostic Assay QC (SecureMDx LIMS)" stated the criteria for assay acceptability: 1) Negative Control - SiHa "Results for the negative control must fall on or within the defined Min-Max ranges to pass." 2) Positive Control - LnCap and Low-ratio Control - LS14 "Results for the positive controls must fall on or within the defined Min-Max ranges to pass." b. Review of laboratory records for Batch C18230075 revealed QC results that failed to meet the laboratory's stated criteria for assay acceptability: Control material lot number 13.0 ---------- LnCap Min - Max Assayed GSTP1 699.70 - 1007.60 689.6 / 0 RASSF1 566.60 - 840.50 0 LS14 Min - Max Assayed ACTB 3216.00 - 9495.00 1800 APC 104.60 - 320.70 0 GSTP1 138.40 - 282.00 0 RASSF1 160.90 - 260.10 0 c. Laboratory records revealed the Controls Summary as "Pass". d. Laboratory personnel affirmed (7/24/18 at 4:30 PM and 8/01/18 at 8:13 AM) that in spite of the aforementioned QC results Failure to meet the laboratory's criteria for acceptability, the assay was accepted and 6 out of 6 results reported anyway. e. Review of laboratory records for Batch C18290071 revealed the Controls Summary "passed" in spite of LS14 results failures for APC, GSTP1, and RASSF1;

	and that results were reported. d. The reliablility and quality of results reported for the "Confirm MDx for Prostate Cancer" test could not be assured when QC fails to qualify assay acceptability.