Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0710801	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Madorsky And Pinon Urology Of South Florida Pa	**Street Address, City, State** 7400 Sw 87th Ave Ste 240, Miami, 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
D0000	A recertification survey conducted on 11/05/2019, found that Madorsky Pinon Bruck Mennie Urology Center of South Florida PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209 Laboratory Personnel form, review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Office Consultant (OC), the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Urinalysis sub-specialty for 6 out of 6 events reviewed (2017 3rd event, 2018 1st, 2nd and 3rd event and 2019 1st and 2nd) reviewed. Findings include: 1-Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 11/01/2019 had 4 testing personnel listed (TPA, TP B, TP C and TP D) performing tests in the urinalysis specialty. 2-Review of API PT records for 2018 and 2019, revealed that: -TP A, there was no documentation of PT testing in 2019. -TP D, there was no documentation of PT for 2018 and 2019. During an interview on 11/01/2019 at 11:00 AM, the OC confirmed that TP A and D missed to participate in PT during the years listed above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to perform the annual competency assessment for 4 out of 5 Testing Personnel (TP A, TP B, TP C, TP D and TP E) for 2 out of 2 years reviewed (2018 and 2019). Findings include: - Review of personnel files revealed that there was no documentation of the annual competency assessment for TP A, TP B, TP C and TP D for years 2018 and 2019. During an interview on 11/05/2019 at 11:00 AM, with Office Consultant, he confirmed that there was no documentation of the competency assessment for the TP listed above for the period of reference.