

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2075815	(X3) Date Survey Completed 03/09/2020
Name of Provider or Supplier Dr Prosper Abitbol Pa	Street Address, City, State 801 Meadows Rd Ste 107, Boca Raton, 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 03/09/2020 found that Dr Prosper Abitbol Pa clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on competency assessment record review and staff interview, the laboratory failed to have annual assessment competency for testing personnel (TP) B for 1 out of 2 years reviewed. The findings include: -A review of personnel competency assessment records for 2018 and 2019 revealed that there was not annual competency for TP B for 2019. During an interview on 03/09/2020 at 11:30 AM, TP B confirmed that the laboratory missed her annual competency for 2019.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the twice a year accuracy verification for histopathology testing during 2019. Findings include: - Review of patient log revealed the laboratory performed testing from January to May</p>

21st 2019. -Review of peer review records revealed that there was no documentation of peer review for histopathology for 2019 -During an interview on 03/09/20 at 11:30 a.m., TP B confirmed that there was no documentation of peer review for histopathology during 2019.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on record review and interview with testing person (TP) B, the laboratory failed to follow their Quality Assurance policy for 3 out of 5 months of 2019. Findings include: -Review of QA policy revealed that the Laboratory Director (LD) will review all quality control and charts on a monthly basis. -Review of the Daily QA/Control log for 2019, revealed that there was no documentation from March to June 2019. - Review of QA laboratory records revealed that the Laboratory Director (LD) failed to sign the monthly QA forms from March to May of 2019. During an interview on 03/09 /2020 at 1:00 PM, with the TP B, she confirmed that the Daily QA log did not have any input from March to May 2019 and that the Monthly QA checklist review records listed above missed to have the LD signature.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to have documentation of the Quality Control Stain Slide review for cases sent out to Mid Florida Laboratory for professional component for 2 out of 2 years reviewed (2018-2019). Findings include: -Review of the retention policy stated to keep quality control records for 2 years. -Review of the binder for the Stain Quality Control/Assurance for cases sent out to Mid Florida Pathology laboratory with CLIA numbers 10D2040413 and 10D2123842, revealed that it missed the records for the Stain Quality review associated with the following cases: Year Case # Accession Date 2018 110-119 4/17 /2018 to 4/24/2018 121-132 4/26/2018 to 5/3/2018 189-201 6/21/2018 to 6/28/2018 206-230 7/10/2018 to 7/24/2018 242-232 8/7/2018 to 7/31/2018 260-263 8/16/2018 289-294 9/20/2018 345-356 11/20/2018 to 11/27/2018 2019 001-003 01/03/2019 004 01/05/2019 005-008, 15-16, 18-33, 38-39, 44-59 not recorded on accession log. During an interview on 03/09/20 at 2:30 PM with the TP B, she stated that due to the laboratory closure for renovation since May 22nd 2019 to March 2020, they moved the records out and the records listed above were misplaced at the time of the survey.