Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2032238	07/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Daniel D Cohen Md Pa	315 N Lakemont, Winter Park, 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 was conducted on July 24, 2019. Daniel D Cohen MD PA was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain histopathology slides for at least 10 years from the date of examination for 1 out of 6 patient slides examined (#2). Findings: Review of patients slides revealed that the slides for patient #2 where not available. During an interview on 7/24/19 at 1 PM, the Administrator acknowledged she was unable to locate the slides for patient #2.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain

	and Immunohistochemical (IHC) stains in 2018 at least twice annually. Findings: The laboratory uses peer review to verify the accuracy of the reading and interpretation H&E stain and IHC stains. Review of the laboratory's records showed that peer review on the Laboratory Director was performed only once in 2018, on 11/06/18. The laboratory evaluates the following IHC stains: CK5 (Cytokeratin 5 IHC stain), Cytokeratin 14 (carcinoma IHC stain), CK 903 (Prostate Carcinoma IHC stain), P504S (prostate adenocarcinoma IHC stain), P63 (P63 gene IHC stain), PIN3 (prostatic adenocarcinoma cocktail IHC stain), PIN4 (prostatic adenocarcinoma cocktail IHC stain), and Racemase (prostate carcinoma IHC stain). During an interview on 7/24/19 at 11:20 AM, the Laboratory Director acknowledged that peer review was sent out only once in 2018.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (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 interview, the laboratory failed to have negative control slides for recording the negative reactivity for each for Immunohistochemical (IHC) stains from 7/24/17 to 7/24/19. Findings: Only the microscopic examination of the slides is performed at the laboratory. A review of the procedure titled "Quality Control Slides for Histology Case" showed that procedure states "For IHC stains: positive and negative control slides are stained and distributed to the pathologist with each accession stained slide." Review of patient slides showed that there was no negative control slides for 1 (#6) out of 6 (#1, 2, 3, 4, 5, 6) patient slides reviewed. Patient #6 each had a PIN4 (prostatic adenocarcinoma cocktail IHC stain) stained slide. The laboratory evaluates the following IHC stains: CK5 (Cytokeratin 5 IHC stain), Cytokeratin 14 (carcinoma IHC stain), CK 903 (Prostate Carcinoma IHC stain), P504S (prostate adenocarcinoma IHC stain), P63 (P63 gene IHC stain), PIN3 (prostatic adenocarcinoma cocktail IHC stain), PIN4 (prostatic adenocarcinoma cocktail IHC stain), and Racemase (prostate carcinoma IHC stain). During an interview on 7/24/19 at 12:45 PM, the Laboratory Director confirmed they don't have separate negative control slides for IHC stained slides.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document and maintain

	records of the number of hours spent examining cytology slides during each 24 hour period. Findings: Review of the laboratory's log titled "Manifest for Technical only Clients" showed that the laboratory failed to record the amount to time spent examining cytology slides during each 24 hour period from 7/24/17 through 7/24/19. During an interview on 7/24/19 at 10:28 AM, the Laboratory Director acknowledged that the she did not record the amount to time spent examining cytology slides.