Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0666830	01/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Drs Poulton & Smith Llc	5233 King Ave, Suite 204, Baltimore, MD	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the histotech, the laboratory did not ensure that the lot numbers and expiration dates of the dyes used during tissue grossing to orient the tissue position while viewing under the microscope were recorded. Findings: 1. The laboratory records for 2018 and 2019 were reviewed to ensure that there was documentation of the lot numbers and expiration dates of the stains and solutions used during the staining process. The records did not include documentation of the lot numbers and expiration dates of the dyes used during tissue grossing. 2. During the survey on 01/22/18 at 11:15 AM the histotech confirmed that the lot numbers and expiration dates of the dyes used during tissue grossing were not included in the laboratory records.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the autoclave spore log and interview with the office personnel, the laboratory director did not ensure that the quality assurance (QA) plan included

	written instructions for completing the required information on the autoclave spore logs and that the spore check was being performed on a weekly basis. Findings: 1. According the the office personnel the autoclave is checked on a weekly basis using a spore check product to ensure that the autoclave is performing the sterilization properly on the instruments used during procedures and in the laboratory. 2. The autoclave spore logs from 2018 and 2019 were reviewed. The records showed that the spore check was not being performed and documented on a weekly basis as required. The records showed that in 2018 the spore check was only performed 1-2 times a month and month and in June of 2018 there was no spore check performed. In January through March 2019 the spore check was only performed 1-2 times a month; there were no spore checks performed between 03/11/2019 through 08/14/2019; and from 08/14/2019 through September 2019 the spore check was performed 2-3 times a month. The records did not identify why the spore checks were missing. 3. The autoclave spore logs from 2018 and 2019 were reviewed. None of the worksheets included documentation of the spore type used, "BI Lot #" and expiration date, type of sterilization used, and the "Cycle Length/Temperature." 4 During the survey on 01/22 /2020 at 11:15 AM the office personnel and laboratory director confirmed that the records did not identify why the spore checks were not performed weekly and that the worksheets were not completed as required.