Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1032489	05/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Paul Herschel Bowman Md Pa D/B/A	5379 Primrose Lake Cir, Tampa, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation during the tour of the laboratory, review of the instrument manual, and interview with the Histology Technician, the laboratory failed to perform manufacturer required periodic maintenance on #2 cryostat. Findings included: During the tour of the laboratory at 9:15 AM, it was observed that #2 cryostat last periodic maintenance was performed 11/08/17. During review of the procedure manual, it was found that the manufacturer instrument manual stated that the cryostat's flywheel and moving components be oiled yearly. During an interview on 05/09/2018 at 10:10 AM, the histology technician stated the manufacturer has not been able to schedule the periodic maintenance for #2 cryostat.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on patient test report record review, interview with the Histology Technician, and corrective action record review, the laboratory failed to document corrective action for the Laboratory Information System. Findings included: During the record review of 4 (#1-11/21/2016, #2 - 04/04/2017, #3 - 11/02/2017, and #4 - 03/07/2018) patient test reports (two out of two years, 2016 -2018), the laboratory was only able to provide patient test reports for patients #1 and #2. During an interview on 05/09/2018 at 10:30 AM, the Histology Technician stated that in the evening the laboratory's Information System's anti-virus program updated. When the anti-virus software updated, it recognized scanned patient's reports as malicious, so the anti-virus software first quarantined all attachments. When quarantined file was full, the anti-virus software started deleting the scanned files. This problem was not discovered until laboratory personnel arrived to the office in the morning. The laboratory was in the process of retrieving the files from the backup cloud. During review of the Laboratory Procedure Manual and review of the Quality Control logs, it was observed that the laboratory had not documented a corrective action for the malfunction of the anti-virus software.
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 Quality Assurance protocol review, laboratory logs record reviews, and interview with the Histology Technician, the laboratory failed to document Quality Assurance staff meetings. Findings included: During the review of the Quality Assurance Protocol, it was found that Quality Assurance staff meetings would be conducted annually. During the laboratory logs record review, it was observed that documentation of Quality Assurance staff meetings were missing from the laboratory's records. During an interview on 05/09/2018 at 10:15 AM, the Histology Technician stated the Quality Assurance staff meetings were being performed and confirmed that the documentation of the Quality Assurance staff meetings was missing.