

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2026498	(X3) Date Survey Completed 06/19/2019
Name of Provider or Supplier Easton Dermatology Associates Llc	Street Address, City, State 403 Marvel Court, Easton, 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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: A. Based on record review and interview, the laboratory director did not ensure that review of laboratory worksheets identified problems such as incomplete entries. Findings: 1. The laboratory did not have a written policy that stated how to conduct reviews of the cryostat preventive maintenance worksheet to ensure that the maintenance performed by the laboratory is documented; 2. The cryostat preventive maintenance worksheet is a document that is completed each day of testing (MOHS surgery) and the daily tasks on the worksheet ensure that the cryostat is performing as expected for the processing of patient tissue for histology testing. The worksheet is designed so that three months of maintenance are recorded on one sheet and in the bottom right corner of the worksheet is a space to document review of the completed record; 3. The written procedure did not identify the person responsible for the review and did not identify how to conduct the review to identify problems; 4. From January 2019 to May 2019, one out of twentytwo days reviewed, the cryostat preventive maintenance was not documented for MOHS surgery conducted 5/24/19; 5. From January 2018 to June of 2018, three out of forty days reviewed , the cryostat preventive maintenance was not documented for MOHS surgery conducted February 23, 2018; March 30, 2018 and June 29, 2018; 6. On the December 2017 cryostat preventive maintenance worksheet, maintenance was not documented for surgery performed December 15, 2017; 7. On the November 2017 cryostat preventive</p>

maintenance worksheet, the maintenance was not documented for surgery performed November 3, 10 and 17, 2017; 8. On the October 2017 cryostat preventive maintenance worksheet, the maintenance was not documented for surgery performed October 13, 20 and 27, 2017; and 9. On the September 2017 cryostat preventive maintenance worksheet, the maintenance was not documented for surgery performed September 8, 15 and 29, 2017. B. Based on record review and interview, the laboratory (lab) director did not ensure that October, November, December 2017 slide quality control results were available for review at the time of survey. Findings: 1. The worksheet for the stain quality control was not in the labs records; and 2. this was confirmed with the histology technician during interview on the day of survey.