Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0888131	07/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bay Shore Dermatology	7550 Assunta Ct, Fairhope, AL	

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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the MOHS Quality Assurance (QA) documentation and an interview with Clinical Consultant #2, the surveyor determined the laboratory failed to document their QA reviews and the corrective actions taken for discrepant diagnoses in the MOHS surgical slide interpretations by outside pathologists. This was noted in four out of forty cases reviewed on six MOHS QA logs. The findings include: 1. A review of laboratory procedures revealed every four months the laboratory sent out ten Histopathology slides from frozen section specimens collected during MOHS surgery cases, to an outside pathologist for review. A review of a policy dated 8/10 /12, entitled "Quality Control Protocol" revealed, "...6. Any disparity in diagnosis between the pathologist and MOHS surgeon will be discussed and resolved. ...". 2. A review of the QA log revealed the laboratory documented the ten Case numbers (#), the diagnoses of the Pathologist, Laboratory Director (LD), and Clinical Consultant (CC) #2 with their signature and the date of their interpretations; the date completed was also recorded on the form. 3. A review of the six 2016-2017 QA logs revealed the following discrepant diagnoses: A) Dated completed: 09/23/2016; Case # BS-299-16; Pathologist-Negative; LD-Negative; CC#2-Positive B) Dated completed: 12/14/2016; Case # BS-462-16; Pathologist-Negative; LD-Negative; CC#2-Positive C) Dated completed: 12/14/2016; Case # BS-531-16; Pathologist-Positive; LD-Negative; CC#2-Positive D) Dated completed: 04/29/2017; Case # BS-150-17; Pathologist-Positive; LD-Negative; CC#2-Positive The laboratory further failed to document their reviews (as indicated by a signature and date) of the pathologist's interpretations when the

	documents were returned. 4. In an interview on 7/18/2018 at 12:10 PM, CC#2 was asked if he and/or the Laboratory Director reviewed the returned MOHS QA logs with the pathologist's diagnoses to determine if any corrective actions were required for any discrepant results identified. CC#2 explained he and the Director always reviewed the results, and discussed all discrepancies to determine if a follow-up with the patient was necessary. When asked how the reviews and corrective actions were documented, CC#2 confirmed they had not been documenting their reviews and resolutions of the discrepant results. Thus the above noted findings were substantiated. SURVEYOR: Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor