Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0072589	01/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Howard S Goldberg, Md Inc	990 Paradise Rd, Swampscott, MA	

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 CLIA recertification survey was conducted for the Howard S Goldberg, MD Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 document a control slide of known reactivity with each patient slide or group of patient slides when differential or special staining was performed as evidenced by the following: Surveyors reviewed Mohs histopathology quality control (QC) records for calendar years 2017 and 2018. The review revealed the laboratory failed to document the hematoxylin and eosin (H&E) stain QC for twenty-four (24) out of twenty-seven (27) days of Mohs surgeries in 2017. The practice manager confirmed in an interview on 1 /14/19 at 12:07 PM that H&E stain QC was not documented for twenty-four (24) of twenty-seven (27) days in 2017. The laboratory performs 240 Mohs slide examinations annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to indicate on the test report the name and address of the laboratory location where the test was performed as evidenced by the following: A. The laboratory implemented the professional component of dermatopathology slide interpretations in September 2017. Surveyors reviewed ten (10) test reports between 9/28/17 and 6/1/18. The review revealed the name of the laboratory on the test reports was Cosmetic Dermatology and Aesthetic Laser Center. The laboratory's name is Howard S Goldgerg, MD Inc. The practice manager confirmed on 1/14/19 at 1:13 PM that the test report did not indicate the name of the laboratory where the test was performed. B. Surveyors reviewed eight (8) Mohs test reports between 1/30/17 and 1/11/19. The review revealed that the name and address of the laboratory was not present on three (3) out of eight (8) Mohs test reports. The practice manager stated that laboratory hired a new Mohs surgeon in June 2018. The Mohs surgeon creates his own test reports which are scanned in the practice's EMR. The new test reports did not indicate the name and address of the laboratory where the test was performed . The practice manager confirmed on 1/14/19 at 2:42 PM that the name and address of the laboratory was not present on the three (3) test reports generated by the new Mohs surgeon.