Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0894962	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Surgery Of Southern Ohio	1213 Nilles Road, Fairfield, OH	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Item I: Based on record review and an interview, the laboratory failed to blindly verify the accuracy of the Mohs grossing procedures, that is not listed in Subpart I, at least twice annually. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's Mohs Surgery policies and procedures, on 719/18, found no instructions to blindly verify the Mohs grossing and procedures performed, at least twice annually. 2. An interview with the Office Manager, on 7/19/18 at 9:39 am, confirmed that the lab did not verify the accuracy of the Mohs grossing procedures, at least twice annually. Item II: Based on record review and an interview, the laboratory failed to verify the accuracy of the potassium hydroxide (KOH) testing procedures, not listed in Subpart I, at least twice annually. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's KOH policies and procedures, on 7/19/18, found no instructions to blindly verify the accuracy of the KOH procedures performed, at least twice annually. 2. Review of records, on 7/19/18 found no evidence that the lab participated in proficiency testing to verify the accuracy of KOH testing. 3. An interview with the Office Manager on 7/19/18 at 9:53 am, confirmed that the lab did not participate in proficiency testing through API to verify the accuracy of KOH testing.
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 an interview, the lab failed to check immunohistochemical stains for negative reactivity each time of use. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of policy and procedure found the following: "1. Both a positive and negative piece of tissue for IHC QC slides are provided by the doctor. 2. A negative piece of tissue is cut at 4 microns and placed in the middle of a positive charged slide. 3. A positive piece of tissue is cut at 4 microns and placed at the bottom of the same slide..." 2. Review of quality control records found that a negative control was documented for time of use. 3. Direct observation of the control slides, on 7/23/18 at 10:25 am, found no physical evidence of a negative control in the middle of the slide for the immunohistochemical stains performed at the laboratory. 4. An interview of a lab assistant, on 7/23/18 at 10:25 am, confirmed that although a negative control was documented each time of use, no negative control was performed for immunohistochemical stains at the laboratory.