Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2152639	12/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Christ Hospital Physicians Dermatology, The	4440 Red Bank Expressway, Suite 220, Cincinnati, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy and procedure review and an interview with Laboratory Staff (LS), the laboratory failed to follow written policies and procedures for mycology proficiency testing. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, found a "Mycology" policy and procedure which contained the following statement: "This lab has joined a proficiency testing program with The American Proficiency Testing Institute. Membership receipt attached." 2. The Surveyor requested the laboratory's membership receipt from The American Proficiency Testing Institute from LS #2 . The LS #2 confirmed the laboratory was not a member of The American Proficiency Testing Institute, did not have a membership receipt, and was unable to provide the requested document on the date of the inspection. The interviews occurred on 12/19/2018 at 1:41 PM.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

	This STANDARD is not met as evidenced by: Based on policy and procedure review, record review and an interview with Laboratory Staff (LS), the laboratory failed to have an alternative mechanism to detect immediate errors and monitor potassium hydroxide (KOH) performance over time when control material was not available. Findings Include: 1. Review of the laboratory's policies and procedures, did not find any instructions for KOH Quality Control testing procedures. 2. Review of the laboratory's "KOH LOG" did not contain a section for quality control. 2. An interview with LS #2 confirmed the laboratory did not have QC procedures for KOH testing. The interview occurred on 12/19/2018 at 1: 41 PM.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and an interview with Laboratory Staff, (LS), the laboratory failed to have and follow a corrective action policy and procedure to ensure accurate and reliable patient test results and reports. Findings Include: 1. Review of the laboratory's policy and procedure binder titled "Jennifer Cafardi, Mohs Procedure Manual", provided on the date of survey, did not find any mention of a policy and procedure for the hematoxylin and eosin quality control slide corrective action protocols when the quality control slide fails. 3. The Surveyor requested the laboratory's corrective action policy and procedure for hematoxylin and eosin quality control slide failures. The LS #2 confirmed the laboratory does not have a corrective action policy and procedure established, and was unable to provide the requested documentation on the date of survey. The interviews occurred on 12/19/2018 at 1:12 PM.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and an interview with Laboratory Staff (LS), the Laboratory Director failed to ensure that approved policies and procedures were available to all personnel responsible for any aspect of the testing process. Findings Include: 1. Review of the laboratory's "Jennifer Cafardi, Mohs Procedure Manual", did not find any indication the Laboratory Director approved the policies and procedures prior to the implementation of patient testing in 2018, via a signature and date. 2. The Surveyor requested the laboratory's approved policies and procedures from LS #2. The LS #2 confirmed the Laboratory Director did not sign and date the policies and procedures prior to the implementation of patient testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/19/2018 at 1:50 PM.