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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D2071973 | (X3) Date Survey Completed 09/24/2019 |
| Name of Provider or Supplier Noms - Dermatology | Street Address, City, State 2500 West Strub Road, Suite 350, Sandusky, 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 |
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| D5429 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interviews with the Histopathology Processor and Manager, the laboratory failed to have the cryostat and stainer, utilized for MOHS testing, serviced annually. All patients tested under the subspecialty of histopathology have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures, found the following statements: "Maintenance and Function Checks, Policy...The...cryostat will be serviced professionally each year." "Cryostat Maintenance, Purpose/Policy Statement: An outside company performs annual maintenance." "Cryostat Maintenance...Steps and Key Points: 10. Preventative Maintenance and grounding check done annually." "Automated Stainer Maintenance...Steps and Key Points: 5. Grounding check is performed annually." 2. Review of the laboratory's equipment service records found the following evidence of preventative maintenance: Leica Cryostat Serviced on 11/8/2017 Leica Cryostat Serviced on 5/15/2019 Leica Stainer Serviced on 11/8/2017 Leica Stainer Serviced on 5/15/2019 3. Surveyor requested the 2018 preventative maintenance records for the cryostat and stainer. 4. The Histopathology Processor and Manager confirmed, on 9/24/19 at 11:20 am, that the lab failed to perform the 2018 preventative maintenance on the cryostat and stainer, as stated in the policy and procedure. Thus, the 2018 preventative maintenance documents for the cryostat and stainer could not be produced.</p> |