| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 33D1035333 | 11/05/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dr Donna A Serure | 327 Middle Country Road, Smithtown, NY | |

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 |
|---|---|
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor review of temperature records an and interview with the Mohs histotechnologist, the laboratory failed to follow the laboratory's temperature policy. Findings Include: It was confirmed by the histotechnologist on November 5, 2018 at approximately 2:00 PM that the laboratory failed to follow the manufacturer's written criteria to monitor and document the temperatures of the cryostat, the room and humidity where Moh's testing is performed on May 7, 8, 21, 2018 and failed to follow the manufacturer's written criteria to monitor and document the humidity of the room where Moh's testing is performed in calendar year 2017. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on a surveyor review of Quality Control (QC) records and an interview with the Mohs histotechnologist, the laboratory failed to have the Mohs surgeon review and sign the quality control acceptability of the Hemotoxlyin and Eosin (H&E) stain used for Mohs surgery slides. Findings include: It was confirmed with the Mohs histotechnologist on November 5, 2018 at approximately 2:00 PM that the laboratory failed to perform and document the acceptability of the Hemotoxlyin an Eosin Stains performed on the following days of testing: 1. July 26, 27, 2017 2. September 5, 7, 12, 19, 21, 26, 28, 2017 3. October 3, 10, 16, 23, 24, 30, 2017 4. Approximately 75 patient slides were tested and results reported for Mohs surgery during the above dates. |