| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>10D1012626 | **(X3) Date Survey Completed**<br><br>12/12/2022 |
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| **Name of Provider or Supplier**<br><br>Fort Myers Dermatopathology Pa | **Street Address, City, State**<br><br>12580 University Dr Ste 200, Fort Myers, FL | |
| 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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| **D0000** | An announced CLIA recertification survey was conducted at Fort Myers Dermatopathology PA on 12/12/22. Fort Myers Dermatopathology PA is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Requirements for Laboratories. The following is description of the Standard-level deficiency. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and staff interview, the laboratory failed to follow their procedure for equipment maintenance for two of two years (2020 - 2022) reviewed. The findings included: On 12/12/22 at 10:30 a.m., tour of the laboratory revealed two Olympus microscopes that had periodic maintenance stickers on them that the date was "12/2020". On 12/12/22 at 10:45 a.m., the histology technologist stated they had periodic maintenance performed on the microscopes every two years. A review of the laboratory's procedure manual signed by the laboratory director on 8 /31/22 revealed the "Equipment Maintenance" procedure that stated "Principle: To have in place a schedule for Preventative Maintenance on an annual basis. Equipment: All laboratory equipment that is in use in the laboratory". On 12/12/22 at 12:00 p.m., the Histology Technologist stated she was unaware that the laboratory's periodic maintenance schedule for the microscope did not agree with the laboratory's "Equipment Maintenance" procedure. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g) |

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review, and interview with the Laboratory Manager, the laboratory failed to ensure quality control (QC) results for hematoxylin and eosin (H&E) stains were documented by Testing Personnel #A and acceptable before reporting patient results from 10/02/20- 12/12/22. The findings included: Record review of the "Quality Control Chart" logs for hematoxylin and eosin stain revealed no documentation to indicate if the control slides were reviewed by the acceptable or not acceptable for 372 days (10/02/20, 10/05/20, 10/07/20, 10/09/20, 10/12/20 - 10/15/20, 10/19/20, 10/21/20, 10/23/20, 10/26/20, 10/28/20, 10/30/20, 11/02/20, 11/04/20, 11/06/20, 11/10/20 - 11/13/20, 11/16/20, 11/18/20, 11/20/20, 11/23/20, 11/25/20, 12/02/20, 12/04/20, 12/09/20, 12/11/20, 12/16/20, 12/18/20, 12/22/20, 12/23/20, 12/30/20, 01/06/21, 01/08/21, 01/11/21, 01/13/21, 01/15/21, 01/18/21, 01/20/21, 01/22/21, 01/25/21, 01/27/21, 01/29/21, 02/01/21, 02/03/21, 02/05/21, 02/08/21, 02/10/21, 02/12/21, 02/15/21 - 02/17/21, 02/22/21, 02/24/21, 02/26/21, 03/03/21 - 03/05/21, 03/10/21 - 03/12/21, 03/15/21, 03/17/21, 03/19.21, 03/22/21, 03/24/21 - 03/26/21, 03/29/21, 03/31/21, 04/01/21, 04/02/21, 04/05/21, 04/07/21, 04/09/21, 04/12/21, 04/14/21, 04/16/21, 04/19/21, 04/21/21, 04/23/21, 04/26/21, 04/28/21, 04/30/21, 05/03/21 - 05/07/21, 05/10/21, 05/12/21 - 05/14/21, 05/17/21, 05/19/21 - 05/21/21, 05/24/21 - 05/28/21, 06/01/21, 06/02/21, 06/04/21, 06/07/21 - 06/11/21, 06/14/21, 06/16/21, 06/18/21, 06/22/21, 06/24/21, 06/29/21, {06/31/21} sic, 07/07/21, 07/13/21, 07/15/21, 07/16/21, 07/20/21, 07/22/21, 07/23/21, 07/27/21, 07/30/21, 08/04/21, 09/14/21 - 09/17/21, 09/20/21 - 09/24/21, 09/27/21, 09/28/21, 10/01/21, 10/04/21 - 10/08/21, 10/12/21, 10/14/21, 10/18/21 - 10/22/21, 10/25/21 - 10/29/21, 11/01/21 - 11/05/21, 11/08/21 - 11/12/21, 11/15/21 - 11/19/21, 11/22/21 - 11/24/21, 11/29/21, 11/30/21, 01/06/22, 01/07/22, 01/10/22 - 01/14/22, 01/17/22 - 01/21/22, 01/24/22 - 01/28/22, 01/31/22, 02/01/22 - 02/04/22, 02/07/22 - 02/11/22, 02/14/22 - 02/18/22, 02/21/22 - 02/25/22, 02/28/22, 03/01/22 - 03/04/22, 03/07/22 - 03/11/22, 03/14/22 - 03/18/22, 03/21/22 - 03/25/22, 03/28/22 - 03/31/22, 4/05/22 - 04/08/22, 04/11/2022, 04/12/2022, 04/14/2022, 04/15/2022, 04/21/2022, 04/22/2022, 04/25/2022 - 04/29/2022, 05/02/22 - 05/06/22, 05/09/22 - 05/13/22, 05/16/22 - 05/20/22, 05/23/22 - 05/27/22, 05/31/22, 06/01/22 - 06/03/22, 06/06/22 - 06/10/22, 06/13/2022 - 06/17/22, 06/20/22, 06/21/22, 06/23/22, 06/24/22, 06/28/22, 06/30/22, 07/06/22, 07/07/22, 07/26/22, 08/02/22, 08/04/22, 08/08/22 - 08/10/22, 08/12/22, 08/16/22 - 08/19/22, 08/22/22 - 08/26/22, 08/29/22 - 08/31/22, 09/01/22, 09/02/22, 09/06/22 - 09/09/22, 09/12/22 - 09/16/22, 09/19/22 - 09/23/22, 09/26/22, 09/27/22, 10/10/22, 10/12/22 - 10/14/22, 10/17/22 - 10/20/22, 10/24/22 - 10/28/22, 10/31/22, 11/01/22 - 11/04/22, 11/07/22 - 11/11/22, 11/16/22 - 11/18/22, 11/21/22 - 11/23/22, 11/28/22 - 11/30/22, 12/01/22, 12/02/2022, 12/05/22 - 12/09/22. Review of the laboratory procedure "MOH'S" (micrographically oriented histographic surgery) H&E ( hematoxylin and eosin) QC (quality control)/QA(quality assurance) revealed "A quality control slide is run on the H&E manual stainer each morning by a technician and the staining is checked for stain adequacy ...The pathologist each day will initial the Moh's H&E Staining QC worksheet." On 12/12/22 at 11:45 a.m., the Histology Technologist stated she completed the QC worksheet and did not know she was to give the QC worksheet to the pathologist.