

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1065839	(X3) Date Survey Completed 09/19/2022
Name of Provider or Supplier Will Richardson Md Pa	Street Address, City, State 1120 Bayview Dr, Fort Lauderdale, 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
D0000	A recertification survey was conducted on September 19, 2022. Will Richardson MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document all maintenance activities for six (January 2021, February 2021, April 2021, May 2021, July 2021, and September 2021) of twenty-one months examined. Findings: Review of the "Mohs Daily Quality Control Worksheet," and the "Hematoxylin and Eosin Staining Maintenance Log" (H&E) showed that not all days in which testing was performed were documented. Review of the Mohs Accession Log" listed the dates and the patients who had Mohs surgical procedure. Documentation on the "Mohs Daily Quality Control Worksheet" log showed the H&E stain slide quality was not checked off indicating good quality on the following dates patient testing was performed: 01/07/2021 - 9 patients 01/13/2021 - 3 patients 01/21/2021 - 8 patients 01/28/2021 - 6 patients 02/04/2021 - 7 patients 02/18/2021 - 12 patients 09/23/2021 - 10 patients Documentation on the "Mohs Daily Quality Control Worksheet" log showed the daily records was recorded on the wrong date. The stain quality, microscope and cryostat maintenance, cryostat temperature, room temperature, room humidity, eyewash check,</p>

the Mohs technologists initials, and the doctors initials are recorded on the "Mohs Daily Quality Control Worksheet" log. The laboratory recorded the accession number of the Mohs procedure used for the H&E stain slide quality. The following dates had documentation for the stain quality with an accession number that correlated with a different dates: 02/01/2021 - procedure performed on 02/04/2021 - 7 patients 04/28/2021 - procedure performed on 04/29/2021 - 7 patients 07/28/2021 - procedure performed on 07/29/2021 - 6 patients Documentation on the "Mohs Daily Quality Control Worksheet" log showed there was nothing recorded for maintenance that matched with the accession number of the first patient of the day on the following dates: 07/29/2021 - 6 patients 09/23/2021 - 10 patients Documentation on the "Hematoxylin and Eosin Staining Maintenance Log" log showed the maintenance was recorded on the wrong date. The maintenance was recorded on the following dates: 04/28/2021 - procedure performed on 04/29/2021 - 7 patients 05/24/2021 - procedure performed on 05/27/2021 - 7 patients Documentation on the "Hematoxylin and Eosin Staining Maintenance Log" log showed there was nothing recorded for maintenance for the following dates: 07/28/2021 - 6 patients 09/23/2021 - 10 patients On 09/19/2022 at 4:40 PM, the Mohs Technician acknowledged there was missing information on the logs.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to identify that laboratory staff had not documented quality assessment (QA) for 2021. Findings Included: Review of the policy titled "Quality Assurance for Routine Stains" stated "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist." Review of the QA document showed that the "Monthly Quality Assurance Checklist" was not completed for 2021. On 09/19/2022 at 3:53 PM, the Mohs Technicians stated the checklist was not done in 2021.