

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1080856	(X3) Date Survey Completed 09/01/2021
Name of Provider or Supplier Mark R Kaiser Md Pa	Street Address, City, State 301 E Osceola St, Stuart, 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 September 1, 2021. Mark R Kaiser MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document function checks in the histopathology laboratory from 01/17/20 to 07/30/21. Findings: Review of the quality control and maintenance logs showed the following logs where not filled out completely. 1. The "Mohs Daily Quality Control for the Year 2021" showed for the following dates there was no documentation of the tasks being completed on 01/17/2020, 02/14/2020, 02/20/2020, 08/14/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 04/22/21021, 05/14/2021, and 07/30/2021. 2. The " Mohs Temperature Quality Control Log Daily Quality Control for: Room Temperature" showed for the following dates there was no documentation of the temperature recorded on 02/14/2020, 02/20/2020, 08/14/2020, 09/24/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 4/22/21021, 05/14/2021, and 07/30/2021. 3. " Mohs Temperature Quality Control Log Daily Quality Control for: Room Humidity" showed for the following dates there was no documentation of the humidity recorded on 02/14/2020, 02/20/2020, 08/14/2020, 09/24/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 4/22/21021, 05/14/2021, and 07/30/2021.</p>

/2020, 08/14/2020, 09/24/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 04/22/21021, 05/14/2021, and 07/30/2021. 4. " Mohs Temperature Quality Control Log Daily Quality Control for: Cryostat" showed for the following dates there was no documentation of the temperature recorded on 02/14/2020, 02/20/2020, 08/14/2020, 09/24/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 04/22/21021, 05/14/2021, and 07/30/2021. 5. " The "Mohs Safety Equipment Monitoring Record" showed for the following dates there was no documentation of the tasks being completed on 02/14/2020, 02/20/2020, 08/14/2020, 09/24/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 04/22/21021, 05/14/2021, and 07/30/2021. 6. "The "Mohs Cryostat Maintenance Log" showed for the following dates there was no documentation of the tasks being completed on 02/14/2020, 02/20/2020, 08/14/2020, 09/24/2020, 12/10/2020, 12/18/2020, 02/26/2021, 03/26/2021, 04/22/21021, 05/14/2021, and 07/30/2021. 7. "The "Hematoxylin and Eosin Staining Maintenance Log" showed for the following dates there was no documentation of the tasks being completed on 08/14/2020, and 03/26/21. 8. "The "Hematoxylin and Eosin Staining Quality Control Worksheet" showed for the following dates there was no documentation of the stain quality being evaluated on 08/14/20, 01/29/2021, 03/18/2021, and 03/26/2021. 9. "The "Microscope Verification & Maintenance" showed for the following dates there was no documentation of the tasks being complete on 08/14/20, 01/29/2021, 03/26/2021, and 3/18/2021. The "Mohs Accession Log" showed patients had Mohs surgical procedures performed on the above mentioned dates. On 9/1/21 at 11:30 AM, the Mohs Tech A stated the logs were not always filled out completely.