

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2048782	<b>(X3) Date Survey Completed</b>  12/16/2024
<b>Name of Provider or Supplier</b>  Johnny Gurgen Do Pa	<b>Street Address, City, State</b>  1340 Citizens Blvd, Leesburg, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on December 16, 2024. Johnny Gurgen DO PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the Chemical Log, the Tissue Processor Daily Maintenance QC log, and procedure manual; and interview, the laboratory failed to have a step-by-step procedure for the preparation of 80% Alcohol used in the Tissue Tek Vacuum Infiltration Processor (VIP) from June 2024 to November 2024.</p>

Findings: During a tour of the laboratory on 12/16/2024 at 10:20 AM, no 80% Alcohol was observed in the laboratory's two flammable cabinets. Review of the Chemical Log showed four gallons of 80% Alcohol were received on 01/04/2024. Review of the Chemical log showed the four gallons of 80% Alcohol were opened on 01/08/2024, 01/29/2024, 03/05/2024, 04/30/2024. Review of the Tissue Processor Daily Maintenance QC log showed the 80% Alcohol was discarded on the following dates: 05/02/2024, 05/14/2024, 05/29/2024, 06/05/2024, 06/14/2024, 06/27/2024, 07/09/2024, 07/24/2024, 08/08/2024, 08/16/2024, 08/29/2024, 09/06/2024, 09/16/2024, 10/01/2024, 10/15/2024, 10/23/2024, 11/05/2024, 11/13/2024, and 11/21/2024. Review of the procedure manuals signed by the Laboratory Director on 01/09/2024 showed there was no procedure with a step-by-step procedure for the preparation of 80% Alcohol. On 12/16/2024 at 1:05 PM, the Practice Manager stated the Histotechnologist reported she made up the 80% Alcohol after they ran out, and that there was no procedure on making the 80% Alcohol in the procedure manual. On 12/16/2024 at 1:10 PM, the Practice Manager stated no 80% Alcohol was purchased after 01/04/2024 and acknowledged that the Histotechnologist used approximately one gallon per month.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of the Temperature Log / Maintenance Log and interview, the laboratory failed to document corrective action for temperatures and humidity that were not recorded for 1 (January 2024) of 29 months (July 2022 to November 2024)  
Findings: Review of the Temperature Log / Maintenance Log showed temperatures and/or maintenance was recorded for the water bath, oven, embedder, fume hood, microtome, processor, and stainer on the following days for January 2024: 2, 3, 4, 5, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 29, 30, and 31. Review of the Temperature Log / Maintenance Log showed the room temperature for the laboratory was not recorded for the following days in January 2024: 2, 3, 4, 5, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 29, 30, and 31. Review of the Temperature Log / Maintenance Log showed the humidity for the laboratory was not recorded for the following days in January 2024: 2, 3, 4, 5, 8, 10, 12, 15, 16, 17, 18, 19, 22, 24, 26, 29, 30, and 31. On 12/16/2024 at 12:11 PM, the Practice Manager stated she did not know why the room temperature and humidity were not recorded on the above mentioned days.