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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D2048782 | <b>(X3) Date Survey Completed</b><br><br>06/22/2022 |
| <b>Name of Provider or Supplier</b><br><br>Johnny Gurgen Do Pa   | <b>Street Address, City, State</b><br><br>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>   |
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| <b>D0000</b>              | A recertification survey was conducted on June 22, 2022. Johnny Gurgen DO PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.  |
| <b>D5609</b>              | <p><b>HISTOPATHOLOGY</b><br/>CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review, observation, and interview, the laboratory failed to document quality control information including the expiration dates, open dates and lot numbers for all reagents used in their Hematoxylin &amp; Eosin (H &amp; E) stains from 03/19/2021 to 06/22/2022. Findings: Review of the procedure titled, "Quality Control Policies and Documentation" noted "Reagent lot numbers and expiration dates must be recorded. The laboratory used the following reagents in their laboratory: Acid Alcohol Solution 0.5%, 100% Reagent Alcohol, 95% Reagent Alcohol, 80% Reagent Alcohol, 70% Reagent Alcohol, Hematoxylin, Eosin, Scott's Tap Water Substitute, 10% Formalin Fixative, Xylene, and Xylene Substitute. Review of the Chemical Log showed the log did not include the opened date or expiration date listed for the following reagents: Received date 03/19/2021 Acid Alcohol Solution 0.5% lot #59975 Received date 03/24/2021 100% Reagent Alcohol lot #2106301 Received date 04/07/2021 Xylene lot #2106206 Received date 05/12/2021 10% Formalin Fixative #2107614 Received date 05/12/2021 100% Reagent Alcohol lot #2107614 Received date 05/12/2021 100% Xylene lot #2108902 Received date 05/12/2021 Hematoxylin lot #120579 Received date 05/12/2021 Eosin lot #108615 Received date 05/12/2021 80% Reagent Alcohol lot #2109216 Received date 05/12/2021 70% Reagent Alcohol lot #2109214 Received date 06/01/2021 Xylene Substitute lot #2112701 Received date 07/06/2021 100%</p> |

Reagent Alcohol lot #2113017 Received date 08/06/2021 100% Reagent Alcohol lot #2117648 Received date 08/06/2021 95% Reagent Alcohol lot #2111110 Received date 08/06/2021 70% Reagent Alcohol lot #2116607 Received date 08/06/2021 Xylene lot #2116537 Received date 08/06/2021 80% Reagent Alcohol lot #2116006 Received date 11/01/2021 Eosin lot #124485 Review of the Chemical Log showed the log did not have the opened date for the following reagents: Received date 08/06/2021 Hematoxylin lot #121679 Received date 09/09/2021 100% Reagent Alcohol lot #2120219 Received date 09/09/2021 95% Reagent Alcohol lot #2119419 Received date 10/13/2021 Xylene lot # 2124209 Received date 10/13/2021 100% Reagent Alcohol lot #2125021 Received date 01/11/2022 Xylene lot #2130021 Received date 03/04/2022 100% Reagent Alcohol lot #2205201 Received date 05/04/2022 100% Reagent Alcohol lot # 2206205 Observations on 06/22/2022 at 10:45 showed the following reagent were in the flammable cabinet and labeled with the following information: 95% Reagent Alcohol lot #2111110 open date 04/22/2022 70% Reagent Alcohol lot #2102109 open date 05/05/2022 Scott's Tap Water Substitute lot #2131703 open date 03/09/2022 Review of the chemical log showed the above mentioned chemical were not listed in the Chemical Log. On 06/22/2022 at 10:58 AM, the Office Manager acknowledged the chemical log did not contain all the required information.