

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 29D2087718 | (X3) Date Survey Completed 08/28/2024 |
| Name of Provider or Supplier Keith Mark Gross Md Inc | Street Address, City, State 240 Us Hwy 95a Suite A, Fernley, NV | |
| 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 | This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 28, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws. |
| D5781 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's "Temperature Monitor Log" and an interview with the office manager, the laboratory failed to perform and document corrective action when the cryostat temperature results were outside of the acceptable range. Findings include: 1. A review of the laboratory's "Temperature Monitor Log" from October 2023 through August 2024 found that the laboratory failed to document corrective action when the cryostat temperature was outside of the acceptable range of -20 degrees Celsius to -24 degrees Celsius for the one monthly working day for the following months: December 2023, January 2024, May 2024, June 2024 and August 2024. 2. An interview with the office manager on August 28, 2024 at approximately 2:</p> |

30 PM, confirmed these findings. The laboratory performs approximately 500 Histopathology tests annually.