

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1015603	<b>(X3) Date Survey Completed</b> 05/09/2023
<b>Name of Provider or Supplier</b> Avero Diagnostics	<b>Street Address, City, State</b> 4642 N Loop 289 Suite 205, Lubbock, TX	
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>	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and certification is recommended.
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of quality control (QC) records, patient testing logs, and interview, the laboratory failed to document the performance of the Hematoxylin and Eosin quality control, including the intended reactivity to ensure predictable staining characteristics, used to stain specimens for dermatopathology/histopathology interpretations for 14 out of 16 months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled, Laboratory Quality Assurance Plan, effective 07/16/2022, under 7.8 Quality Control stated, "Avero Diagnostics Laboratory must establish and maintain a QC system that ensures accurate reporting of results and optimal specimen integrity and identification throughout the testing process. The QC policy and procedure described in this section will in general be the basis for quality control in the laboratory. However, for tests that require specific and different QC procedures, these will be outlined in the written test SOP or a sectional QC policy." B. On May 9, 2023 at 1130 hours QC records were requested for 2022 and 2023. Records from Feb 19, 2022 - current were not provided. C. Review of the FrozenSection Turn- Around-Time Log from 02/19/2022 - 05/08/2023 showed 23 patients were tested, as listed by collection date and case #: 1.</p>

05/09/2022 SP22-001401 2. 04/25/2022 not listed 3. 05/09/2022 SP22-001860 4. 06/15/2022 SP22-002228 5. 09/20/2022 SP22-003547 6. 09/27/2022 SP22-003634 7. 10/05/2022 SP22-003758 8. 10/19/2022 SP22-904378 9. 10/19/2022 SP22-904379 10. 10/24/2022 SP22-904464 11. 12/01/2022 SP22-905019 12. 12/20/2022 SP22-905343 13. 12/28/2022 SP22-905448 14. 01/05/2023 SP23-900037 15. 01/18/2023 SP23-000226 16. 02/15/2023 SP23-900689 17. 01/23/2023 SP23-000306 18. 02/21/2023 SP23-000717 19. 02/24/2023 SP23-000788 20. 03/09/2023 SP23-901039 21. 04/03/2023 SP23-001317 22. 04/10/2023 SP23-001527 23. 04/17/2023 SP23-001527 D. Interview with the former supervisor on May 9, 2023 at 1130 hours in the office acknowledged the QC was performed for surgicals, but had never done QC specifically for frozens.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

I. Based on review of the patient test reports and interview, the laboratory failed to specify where the frozen section grossing and dermatopathology/histopathology interpretations, and the permanent section grossing and dermatopathology/histopathology interpretations were performed for 10 of 10 test reports reviewed. A. Review of the ten patient test reports from 08/13/2021 - 04/03/2023 showed two laboratory addresses in the header; however, the report did not specify where the frozen section grossing and dermatopathology/histopathology interpretations and the permanent section grossing and dermatopathology/histopathology interpretations were performed, as listed by date collected and accession number: 1. 04/03/2023 SP23-001317 2. 03/09/2023 SP23-000965 3. 02/21/2023 SP23-000717 4. 02/15/2023 SP23-000626 5. 09/19/2022 SP22-003547 6. 04/14/2022 SP22-001401 7. 01/07/2022 SP22-000070 8. 12/01/2021 SP-21-005615 9. 09/10/2021 SP21-004299 10. 08/13/2021 SP21-003888 B. Interview with the former supervisor on May 9, 2023 at 1355 hours in the office confirmed the location where frozens and permanents were performed was not specified in the report. II. Based on review of patient test reports and interview, the laboratory failed to include the address of the facility where the frozen section biopsies were performed for four of ten reports reviewed. Findings follow. A. Review of ten test reports from 08/13/2021 - 04/03/2023 showed four had the wrong address for the frozen section biopsy, as listed by date collected and accession number: 1. 04/03/2023 SP23-001317 2. 03/09/2023 SP23-000965 3. 02/21/2023 SP23-000717 4. 02/15/2023 SP23-000626 B. Interview with the Director of Client Services on May 9, 2023 at 1345 hours in the office confirmed the laboratory moved to a new location on 12/12/2022 and they needed to update the address on the test reports.