

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1041929	<b>(X3) Date Survey Completed</b>  11/04/2020
<b>Name of Provider or Supplier</b>  Dermath Diagnostics Bay Area	<b>Street Address, City, State</b>  10500 University Center Dr Ste 200, Tampa, 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>	An announced CLIA recertification survey was conducted at Dermath Diagnostics Bay Area on 11/02/20 to 11/04/20. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6076-Laboratory Director 493.1441 D6168-Testing Personnel 493.1487
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Histology Supervisor the laboratory failed to retain logs from 2019. Findings Included: Review of daily logs for Cryostat temperature, humidity, and room temperature revealed no logs for 2019. Review of the "QC Log For Technical Evaluation of Frozen Section Tissue Slides" which included stain quality control and reagent lot numbers revealed no logs prior to 10/02 /19. Interview on 11/02/20 at 1:58 PM with the Histology Supervisor confirmed that the aforementioned logs were not available for review.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on record review and interview with the Operations Director the laboratory failed to perform competency evaluations on 2 (#A and #B) out of 2 Testing Personnel for 2 (2019 and 2020) out of 2 years reviewed. Findings Included: Review of employee records revealed no competency evaluations for Testing Personnel #A or #B. Interview on 11/02/20 at 3:30 PM with the Operation Director revealed that the mobile unit was being rented out and confirmed that there was no competency evaluations for Testing Person #A or #B.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assurance peer review and interview with the Operations Director the laboratory failed to ensure the accuracy of testing at least twice a year for 2 (#A and #B) out of 2 Dermatologists who were performing MOHS testing for 2 (2019-2020) out of 2 years reviewed. Findings Included: Review of QC (Quality Control) logs from 10/02/19 to 03/25/20 revealed 2 Dermatologists (#A and #B) were reading MOHS slides. The laboratory did not have any Quality Assurance peer review on either Dermatologist. Interview on 11/02/20 at 2:30 PM with the Operations Director revealed that they rented the mobile unit out and did not have any peer reviews on the 2 Dermatologists.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Dermatology Clinic Practice Administrator the laboratory failed to include the name and address of the laboratory location where the testing was performed for 4 out of 4 reports reviewed. Findings Included: Review of Patient reports pulled on 10/16/19, 12/18/19, 02/20/20, and 03/25/20 revealed none of the reports included the name or address of where the testing was performed. Interview on 11/04/20 at 1:15 PM with the Dermatology Clinic Practice Administrator confirmed that these were the Patient reports and the information for testing was not present.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

	<p>1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the Laboratory Director failed to ensure Testing Personnel were qualified prior to patient testing (See D6102) and failed to have oversight of the Laboratory (See D6082).</p>
<p><b>D6082</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Histology Supervisor and Operations Director the Laboratory Director failed to have oversight of the laboratory for analytic and postanalytic phases of testing for 2 (2018-2020) out of 2 years reviewed. Findings Included: The Laboratory Director failed to have oversight of the laboratory due to: not ensuring retention of records (See D3031), failure to ensure competencies were performed (See D5209), failure to ensure the accuracy of testing of the Testing Personnel (See D5217), failure to ensure Patient reports were correct (See D5805), and failure to ensure Testing Personnel were qualified (see D6171).</p>
<p><b>D6102</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Histology Supervisor and Operations Director the Laboratory Director failed to ensure Testing Personnel met the education and experience requirements prior to patient testing for 2 (2019-2020) out of 2 years reviewed. Findings Included: Review of personnel records revealed no verification of education for 2 (#A and #B) out of 2 Testing Personnel prior to them reporting patient results. There was no competency records in 2019 or 2020 for either Testing Person. Neither Testing person performed quality assurance peer review to verify the accuracy of testing for 2019 or 2020. Interview on 11/02/20 at 3:30 PM with the Operations Director confirmed that since the mobile unit was rented out, they did not have any of the aforementioned documents.</p>
<p><b>D6168</b></p>	<p><b>TESTING PERSONNEL</b> CFR(s): 493.1487</p>

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Operations Director the laboratory failed to verify the education and licensure of 2 (#A and #B) out of 2 Testing Personnel prior to performing patient testing (See D6171).

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the

factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Operations Director the laboratory failed to verify the education and licensure of 2 (#A and #B) out of 2 Testing Personnel prior to performing patient testing. Findings Included: Review of Staff credentials revealed no documentation of Testing Person #A or #B. Interview on 11/02/20 at 3:30 PM with the Operations Director revealed that the mobile unit was rented out and the credentials were not verified prior to patient testing. Testing Personnel #B's medical license and board certification was provided on 11/02/20.