

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2142369	(X3) Date Survey Completed 09/01/2021
Name of Provider or Supplier Mission Dermatopathology Laboratory Pllc	Street Address, City, State 2620 Mccullough Avenue, San Antonio, TX	
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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6168 - 42 C.F.R. 493.1487 Condition: Testing Personnel ; high complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 the laboratory's test menu, review of the laboratory's records from 2019 and 2020, and staff interview, it was revealed the laboratory failed to have documentation performing twice annual accuracy assessments in 2019 and 2020 for grossing, special stains, and immunohistochemistry staining. The findings include: 1. A review of the laboratory's test menu revealed the laboratory performed the following tests: a) grossing of histology specimens b) special stains: congo red colloidal iron Verhoeff's Van Gieson Giemsa Von Kossa PAS-F Gram GMS Fontana Masson Warthin-Starry AFB Fite AFB Perl's (Iron) Steiner Trichrome c) immunohistochemistry stains BCL-2 BCL-6 BER-EP4 CAM 5.2 34Be12 CD1a CD3 CD4 CD5 CD7 CD8 CD10 CD20 CD30 CD31 CD34 CD43 CD68 CD117 CEA</p>

Chromogranin CK7 CK20 D2-40 Desmin EMA Factor XIIIa HHV8 HMB45 HPV HSV1&2 Ki67 Mart-1 MLH 1 MSA MSH2 MHS6 MITF Negative CT P16 P63 PCKAE1/AE3 PHH3 PMS 2 S100 SMA Spirochete Synaptophysin TTF-1 VZV Vimentin 2. The laboratory was asked to provide documentation of performing twice annual accuracy assessments for the identified tests in 2019 and 2020. No documentation was provided. 3. An interview with the laboratory manager on 09/01 /2021 at 1030 hours in the conference room revealed the facility only performed twice annual accuracy assessment for H&E stains. She stated the other tests and grossing were not included. This confirmed the findings.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 3 testing personnel who performed grossing of histology specimens (refer to 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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 3 testing personnel who performed grossing of histology specimens. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 4 testing personnel who performed grossing of histology specimens. 2. A review of the laboratory's personnel records revealed testing personnel number 3 (as listed on Form CMS 209) had an associates degree in nursing the thus, did not qualify to perform grossing of histology specimens. 3. The laboratory was asked to provide additional education records to quality testing personnel number to to perform the high complexity testing. No documentation was provided. 4. An interview with the manager on 09/01/2021 at 1040 hours in the conference room - after her review of the records- confirmed the findings.