

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2064013	(X3) Date Survey Completed 10/09/2019
Name of Provider or Supplier Medipath Llc	Street Address, City, State 4665 Ponce De Leon Blvd, Coral Gables, FL	
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	A recertification survey conducted on 10/09/2019 found that the Medipath Llc clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on record review and interview with laboratory director (LD), the laboratory failed to perform the semi-annual competency assessment for 1 out of 3 testing personnel (TP) (TP # A, TP # B and TP # C); during 1 out of 2 years reviewed. Findings include: Review of staff files revealed that TP # A had initial evaluation on 10/31/2018 in that position. There was no 6 months assessment documented for this TP During an interview on 10/09/2019 at 11:00 AM, with the LD, she confirmed that there was no documentation of the semi-annual competency assessment for the TP # A for the period of reference.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory director (LD), the laboratory failed to have negative control slides for recording the negative reactivity for each immunohistochemical (IHC) stains for the 6 out of 6 patients reports reviewed. The findings include: Only the microscopic examination of the slides is performed at the laboratory. A review of the following patients IHC slides and reports, revealed that the laboratory failed to have a negative control for IHC stains used: -MPS2019-007740, immunohistochemical stain for biomarker p16. - MPS2019-007617, immunohistochemical stain for biomarker p16 - MPS2019-007811, immunohistochemical stain for biomarker p16 - VM19-15285, immunohistochemical stain for CD138 -VM19-14560, immunohistochemical stain for biomarker p16 - VM19-15451, immunohistochemical stain for PIN4 and J PIN4 During an Interview on 10/09/2019 at 12.30 pm, the LD confirmed the laboratory did not have negative controls for the IHC stained slide cases of the above-reference.

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:
Based on patient reports review and interview with laboratory director (LD), the laboratory failed to list the correct address for the laboratory in final patient reports for 3 out of 3 patients reports reviewed. Findings include: A review of the following final patient reports MPS2019-007759, VM19-13610, MPS29019-006775, revealed that the reports had incorrect laboratory address listed. During an interview on 10/09/19 at 11:00 a.m., the laboratory director confirmed that the final report did not include the correct laboratory address.