

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0645343	<b>(X3) Date Survey Completed</b>  07/09/2020
<b>Name of Provider or Supplier</b>  University Of Miami Immunology And	<b>Street Address, City, State</b>  1600 Nw 10th Ave Rmsb 8149, Miami, 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>	A recertification survey conducted on 07/8-9/2020 found that University Of Miami Immunology and Histocompatibility Laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<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: Based on record review and staff interview, the laboratory failed to follow their employee competency testing policy for testing personnel (TP) for 1 (TP 2) out of 2 (TP1 and TP2) pathologists, acting as TP in the histology specialty. Findings include: 1)Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 07/07/2020 revealed that: -There are 2 pathologist, pathologist 1 (TP 1) is the laboratory director and the second pathologist in the laboratory is TP 2. 2) Record review revealed that the competency assessment provided by the laboratory for TP 2 failed to follow the laboratory employee competency testing policy. During an interview on 07/09/2020 with Laboratory Director at 3:00 pm, he confirmed that the competency for the new pathologist failed to follow the laboratory policy.</p>
<b>D5217</b>	<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>

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to ensure twice a year accuracy verification for Epstein Barr Virus (EBV) Heterophile Antibody detection during 2019 and for the Citrulline quantification in 2018. Findings include: - Review of EBV heterophile antibody detection validation revealed that the completion date was 12/2018. Testing started in January 2019. No record of twice a year accuracy verification was found for 2019. -Review of Citrulline quantification records proficiency testing in the CDC Newborn program, revealed no enrollment in 2018. - During an interview on 07/09/20 at 2:30 p.m., General Supervisor A confirmed that the laboratory failed to perform twice a year accuracy verification for the methods listed above in the years of reference.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(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.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to document the positive and negative control reactivity verification for the immunohistochemical (IHC) stain that the laboratory performed for 3 out of 3 patients reviewed. The findings include: -Test menu for Immunohistochemical revealed that the laboratory performed the following immunohistochemical stains: Single stain: Adenovirus, Fibrinogen, Simian Virus 40 (SV40), BCL-2 gene, B7, Carbonic Anhydrase IX (CAL IX), CD 1 a glycoprotein, Cluster Differentiation 3 (CD3) protein , CD4, CD8, CD15, CD20, CD138, CD68, CD34, CD79a, C4d, C3d, Chromogranin A, Cytokeratin 7 (CK7), Cytomegalovirus (CMV), Epstein Barr Virus (EBV), Glucagon, Hepatitis Surface antigen (HBs), Hepatitis B Core Antigen (HBc), Human Leukocyte Antigen (HLA-Class II) , Helicobacter Pylori, Herpes Simplex Virus (HSV1), Insulin, Ki-67 protein, Multy-Cytokeratine, Myoglobin, Parvovirus B19, S100, SMPDL3B, S100, Synaptophysin, Uromodulin, Renal Cell Carcinoma (RCC), Inhibin Alpha).Double stain (CD4-CD8, CD3-CD68 CM, CD3-CD20). Immunofluorescence Stain: Immunoglobulin IgG, IgA, IgM; Complement C3, C4, C1q, C4d; Albumin, Immunoglobulin chain Kappa, Lambda; Fibrinogen). -Review of patient report 1, 2 and 3, revealed that 3 out of 3 reports had immunohistochemical stains, however, no documentation of the evaluation of the reactivity of the positive and negative control was founded in laboratory logs or patient reports. During an Interview on 07/09/2020 at 11.30 am, the Histology General Supervisor confirmed that the laboratory failed to document the positive and negative control reactivity for the immunohistochemistry stains for the cases of reference.