

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0669049	(X3) Date Survey Completed 06/18/2019
Name of Provider or Supplier University Of Miami Hepatology Diagnostic	Street Address, City, State 1600 Nw 10th Ave Rm 7163, Miami, 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 CLIA recertification survey was conducted at University of Miami Hepatology Diagnostic on 6/18/2019. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 technical supervisor (TS), the laboratory failed to document the annual competency assessment on 1 out of 1 TS and 1 out of 1 general supervisor (GS) for 2 out of 2 years reviewed. Findings include: Review of CMS 209, Laboratory Personnel Report, dated and signed by the Laboratory Director 6/6/2019 revealed that the TS and GS was the same person. Review of employee documentation showed that the laboratory failed to have documentation of annual competency assessment on TS and GS during 2017 and 2018. During an interview on 06/18/2019 at 11:30 AM, with the TS, she confirmed that there was no competency assessment documented for the period of reference for her as TS and GS.</p>