

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0618990	(X3) Date Survey Completed 06/29/2022
Name of Provider or Supplier Diagnostic Laboratory Services Inc - Hilo	Street Address, City, State 1248 Kinoole Street Ste 102, Hilo, HI	
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
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 a review of laboratory personnel records and an interview with testing personnel on 06/29/2022 at 1:00 PM, it was determined that the laboratory failed to follow written policies and procedures to assess employee competency to ensure personnel maintain the required competency for accurate and reliable testing and reporting. The findings include: 1. Testing personnel were unable to retrieve the 2021 annual competency assessment for the individual who served as the laboratory technical supervisor/general supervisor/testing personnel. 2. The field Operations Manager confirmed on 07/05/2022 at 7:44 AM that a 2021 annual competency assessment for the laboratory technical supervisor/general supervisor/testing personnel was not performed. The areas of competency assessment include: a. Abnormal/unusual findings b. Amending of results, manual and automated c. PT urine cell identification d. Manual differential e. CAP interpretations f. QA Proficiency testing g. QA review h. Siemens Clinitek Adventus/Status i. Sysmex XS1000i j. Stago Satellite (Protime) k. Urinalysis Manual/macro/micro l. STAT documentation /reporting 3. The laboratory performed 4,732 routine chemistry and urinalysis tests, and 94,412 hematology tests in 2021.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical</p>

phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on a review of laboratory personnel records and an interview with the testing personnel on 06/29/2022 at 1:00 PM, and confirmation by the Field Operations Manager on 07/05/2022 at 7:44 AM, it was determined that the laboratory director failed to ensure the policies and procedures established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of testing were followed to ensure employee competency for accurate and reliable testing and reporting. See CFR 493.1235, D tag D5209.