

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0619283	<b>(X3) Date Survey Completed</b>  06/15/2022
<b>Name of Provider or Supplier</b>  Diagnostic Laboratory Services Kona 2	<b>Street Address, City, State</b>  75-170 Hualalai St B200-201, Kailua Kona, HI	
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>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 a review of laboratory personnel records and an interview with the testing personnel on 06/15/2022 at 2:00 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. The testing personnel was unable to retrieve the 2021 annual competency assessment for the individual who served as laboratory technical supervisor/general supervisor/testing personnel 2. The Field Operations Manager confirmed on 06/17/2022 at 11:28 AM that a 2021 annual competency assessment for the laboratory technical supervisor/general supervisor/testing personnel was not performed 2. The laboratory performed 3730 routine chemistry and urinalysis tests, and 44598 hematology tests in 2021</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 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.</p>

This STANDARD is not met as evidenced by:  
Based on a review of laboratory personnel records and an interview with the testing personnel on 06/15/2022 at 2:00 PM, and confirmation by the Field Operations Manager on 06/17/2022 at 11:28 AM, it was determined that the laboratory director failed to ensure that 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.