

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0667110	<b>(X3) Date Survey Completed</b>  12/29/2021
<b>Name of Provider or Supplier</b>  Ken C Arakawa Md, Inc	<b>Street Address, City, State</b>  1329 Lusitana St Ste 206, Honolulu, 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 confirmation by the general supervisor on 12/29/2021 at 10:00 AM, 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. 2021 annual competency assessments for the general supervisor and testing personnel were not performed. 2. A 6 month competency assessment was not performed on the testing personnel whose initial assessment was completed on 09/23/2020. 3. A new laboratory director was assigned to the laboratory by the director of operations of a pathology group on 08/01/2021. The director of operations stated on 10/04/2021 that the pathology group was "still working on other documents" necessary for the 2021 annual competency assessments. 4. The general supervisor and testing personnel performed 699 general immunology tests, 41,164 routine chemistry and urinalysis tests, and 34,296 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</p>

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 confirmation by the general supervisor on 12/29/2021 at 10:00 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.