

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2024612	(X3) Date Survey Completed 02/01/2018
Name of Provider or Supplier Kan-Di-Ki, Llc DbA Diagnostic Laboratories	Street Address, City, State 3230 E Broadway, Ste A-100, Phoenix, AZ	
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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on lack of test comparison results from 2016 and 2017 and interview with the facility personnel, the laboratory failed to document test comparison results twice a year that evaluates and defines the relationship between test results using two separate test methods for testing performed in the (A) specialty of hematology and (B) sub-specialty of urinalysis. Findings include: A1. The laboratory performs complete blood count (CBC) testing on the Sysmex XN1000-R analyzer in the specialty of hematology, which includes the test results from an automated differential. If the specimen meets certain criteria outlined in laboratory policy then the laboratory performs and reports the results from a manual differential instead of using the results of the automated differential. A2. The laboratory's established policy titled, "Method Comparison Study Procedure and Template" indicates the laboratory has a system in place to perform a comparison between (3) automated hematology differentials and manual differentials by lab techs every 6 months. A3. No documentation was presented for review during the survey conducted on February 1, 2018 to indicate the laboratory performed and documented test method comparison activities during 2016 and 2017 between automated and manual differentials as indicated above. B1. The laboratory performs automated urine microscopy testing on patient specimens using the Iris Urinalysis analyzer. If warranted, the laboratory performs a manual urine microscopic. B2. The laboratory's established policy titled, "Method Comparison Study Procedure and Template" indicates the laboratory has a system in place to</p>

perform a comparison between (3) automated urine microscopies and manual slide microscopy by lab techs every 6 months. B3. No documentation was presented for review during the survey conducted on February 1, 2018 to indicate the laboratory performed and documented test method comparison activities during 2016 and 2017 between automated and manual urine microscopies as indicated above. 4. The facility personnel confirmed that the laboratory did not document test method comparisons for CBC differentials and microscopic urine testing during 2016 and 2017 as stated above.