

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0420182	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Duly Health And Care - Tinley Pk Lab	Street Address, City, State 17495 S Lagrange Rd, Tinley Park, IL	
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 review of laboratory records, lack of documentation, and interview with the technical supervisor (TS); the laboratory failed to perform and document twice a year evaluations of group A Streptococcus (Strep A) bacteriology analyte and SARS-CoV-2 (COVID-19), Influenza A (Flu A), and Respiratory Syncytial Virus (RSV) virology analytes on four of four Cepheid GeneXpert instruments in 2022 through the date of survey 03/06/2024. Findings include: 1. Review of laboratory records revealed four Cepheid GeneXpert instruments in use for Strep A bacteriology patient testing; COVID-19, Flu A, and RSV virology patient testing on the following instruments in 2022, 2023, and 2024: A. Cepheid GeneXpert Instrument S/N: 814223 B. Cepheid GeneXpert Instrument S/N: 835626 C. Cepheid GeneXpert Instrument S/N: 110019365 D. Cepheid GeneXpert Instrument S/N: 110019366. 2. Review of laboratory records revealed no documentation of the twice a year evaluation of analytes (Strep A, COVID-19, Flu A, and RSV) performed on each of the four instruments listed in Finding 1. 3. On 03/06/2024, at 2:38 p.m., the TS confirmed the above findings.</p>