Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1085079	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care - Rickert Lab	808 Rickert Dr, Naperville, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, quality control (QC) records, lack of documentation, and interviews with testing personnel (TP) #1; the laboratory failed to perform control procedures on each analyzer in use for both BD Affirm VPIII analyzers and both Cepheid GeneXpert analyzers as required per 493. 1256. Findings include: 1. Upon direct observation on 02/06/2024, at 4:50 pm, surveyors observed two BD Affirm VPIII analyzers (Serial Numbers: A608012 and A605032) and two Cepheid GeneXpert analyzers (Serial Numbers: 821282 and 835922) being utilized for patient testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP)s, for both the Cepheid GeneXpert testing systems and the BD Affirm VPIII testing systems, revealed a lack of documentation to run positive and negative QC on both analyzers every 30 days. 3. On 02/06/2024 at 4:50 pm, an interview with TP #1 confirmed that positive and negative QC was not performed on both the Cepheid GeneXpert analyzers and both the BD Affirm VPIII analyzers. 4. Two of four patients reviewed for Cepheid GeneXpert testing showed the patient test was performed on one Cepheid GeneXpert analyzer while corresponding QC was performed on the other Cepheid GeneXpert analyzer: a. Patient GE12165131 had a Strep test (Reagent Lot Number: 25905) performed on Cepheid GeneXpert A (Serial

	Number: 821282) on 10/30/2023. Corresponding positive and negative QC for Strep Reagent Lot Number 25905 was performed on Cepheid GeneXpert B (Serial Number: 835922) on 10/27/2023. b. Patient GE40628083 had a Covid test (Reagent Lot Number: 04733) performed on Cepheid GeneXpert B on 01/03/2024. Corresponding negative QC for Covid Reagent Lot Number 04733 was performed on Cepheid GeneXpert A on 12/21/2023. 5. Review of QC records revealed a lack of documentation to indicate which BD Affirm VPIII analyzer (A608012 or A605032) was used to perform QC on three of three testing dates reviewed (06/06/2023, 10/31 /2023, 01/03/2024). 6. An additional interview with TP #1 on 02/07/2024 at 2:40 pm, confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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. This STANDARD is not met as evidenced by: Based on lack of documentation, direct observation, and interview with testing personnel (TP) #1, the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between two of two Cepheid GeneXpert instruments used in the years of 2022 and 2023. Findings include: 1. A lack of documentation, including a policy/procedure and documents/results, of instrument-to-instrument test result comparisons as required by 493.1281 for two of two Cepheid GeneXpert instruments. 2. Upon direct observation on 02/06/2024, at 4: 50 pm, two Cepheid GeneXpert instruments were used to perform Strep, Covid, Influenza A and B, and RSV testing in the years of 2022 and 2023: Instrument: Serial Number: A 821282 B 835922 3. An interview with TP #1 on 02/06/2024, at 4:50 pm, confirmed that no policy/procedure or documents/results of instrument-to-instrument test result comparisons were available nor had been performed.