Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D0420182	**(X3) Date Survey Completed** 01/28/2020
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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records and interviews with the general supervisor (GS) #1 and the technical supervisor (TS); Dupage Medical Group - Tinley Park (DMG-TP, CLIA ID# 14D0420182) failed to follow the laboratory's policy and sent American Proficiency Institute (API) hematology proficiency testing (PT) samples XE-11, XE-12, XE-13, XE-14, and XE-15 to Dupage Medical Group - Lockport (DMG-L, CLIA ID# 14D2169778) for the third hematology PT event of 2019 prior to the submission deadline of 12-02-2019. See D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested

	testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with the general supervisor (GS) #1 and the technical supervisor (TS); Dupage Medical Group - Tinley Park (DMG-TP, CLIA ID# 14D0420182) failed to follow the laboratory's policy and sent American Proficiency Institute (API) hematology proficiency testing (PT) samples XE-11, XE-12, XE-13, XE-14, and XE-15 to Dupage Medical Group - Lockport (DMG-L, CLIA ID# 14D2169778) for the third hematology PT event of 2019 prior to the submission deadline of 12-02-2019. Findings Include: 1. Proficiency testing (PT) records for 2019 were reviewed. 2. Review of instrument print outs from the Sysmex XN-1000, serial number 30201, confirmed API PT event 3 samples (XE-11, XE-12, XE-13, XE-14, and XE-15) were ran on 11-19-2019 by TP#7 at DMG-TP. 3. Interview with GS#1 at 4:05pm, on 1-28-2020, confirmed that once the hematology samples (XE-11, XE-12, XE-13, XE-14, and XE-15) had been ran by DMG-TP and then they were shipped by a third party courier to DMG-L. 4. PT documentation from DMG-L confirmed receipt of the API event 3 hematology PT samples XE-11, XE-12, XE-13, XE-14, and XE-15 on 11-25-2019 from DMG-TP. 5. DMG-L PT documentation revealed the samples (XE-11, XE-12, XE-13, XE-14, and XE-15) were ran at DMG-L on their Sysmex XN-1000 analyzer, serial number 39108, on 11-27-2019. 6. The DMG-TP API attestation statement for 2019 hematology event 3 confirmed results for samples XE-11, XE-12, XE-13, XE-14, and XE-15 were submitted electronically to API on 11-29-2019 which was after the date those same samples had been ran at DMG-L (11-27-2019). 7. Review of the API 2019 PT schedule revealed that the PT submission due date for 2019 hematology event 3 was 12-02-2019 and DMG-TP had sent the PT samples to DMG-L prior to the submission due date of 12-02-2019. 8. Review of the policy, "Proficiency Testing", revealed the laboratory failed to follow the policy as outlined on page 1 of 8 that stated "no proficiency testing specimen shall ever be referred to another laboratory for analysis under any circumstances." 9. Interview with the TS at 5:30 pm, on 1-28-2020, confirmed the above findings that DMG-TP sent 2019 API PT event 3 hematology samples to DMG-L for analysis prior to the submission deadline of 12-02-2019.