Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2169778	01/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care - Lockport Laboratroy	1206 E 9th St, Lockport, 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 observation, review of laboratory records, and interviews with technical supervisor #1; Dupage Medical Group - Lockport (DMG-L, CLIA ID# 14D2169778) failed to follow the laboratory's policy and notify CMS of the receipt of hematology proficiency testing samples received on 11-25-2019 from Dupage Medical Group - Tinley Park (DMG-TP, CLIA ID# 14D0420182) for the third American Proficiency Institute (API) proficiency testing (PT) event of 2019 for hematology and ran the samples (XE-11, XE-12, XE-13, XE-14, and XE-15) on 11-27-2019 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 observation, review of laboratory records and interviews with technical supervisor #1; Dupage Medical Group - Lockport (DMG-L, CLIA ID# 14D2169778) failed to follow the laboratory's policy and notify CMS of the receipt of hematology proficiency testing samples received on 11-25-2019 from Dupage Medical Group - Tinley Park (DMG-TP, CLIA ID# 14D0420182) for the third American Proficiency Institute (API) proficiency testing (PT) event of 2019 for hematology and ran the samples (XE-11, XE-12, XE-13, XE-14, and XE-15) on 11-27-2019 prior to the submission deadline of 12-02-2019. Findings Include: 1. During a tour of the laboratory facility at 9:10 am on 1-15-2020, the surveyor observed patients' specimens being testing on a Sysmex XN-1000, Serial Number 39108. 2. Interview with technical supervisor #1 (TS1) on 1-15-2020, at 9:20 am, confirmed the Sysmex XN-1000 analyzer was used to perform the following tests: complete blood counts (CBC) with and without a differential, reticulocyte counts, and nucleated red blood cell counts (NRBCs). 3. Proficiency testing (PT) records for 2019 and 2020 were reviewed. 4. Review of PT records revealed a letter from the API that documented API was unable to fulfill the DMG-L request for Hematology-5S PT samples because the item was no longer available for 2019. 5. The DMG form, "Proficiency Testing Evaluation", documented the following information: Date Received: From TP 11-25-19 Kit Description: Heme 3rd Date Survey Submitted: "Blank" Explanation & Corrective Action "Lockport was unable to order API for Heme 3rd event. The lab missed the cut off date. Lockport recieved Tinley Park's survey material after the submission date. The lab ran the survey and evaluated the results when the survey answers were posted online." 6. Review of the API 2019 PT schedule revealed that the PT submission due date for Hematology event 3 was 12-02-2019 and DMG-L had received the PT samples prior to the submission due date on 11-25-2019. 7. Review of PT documentation revealed the laboratory ran the PT samples XE-11, XE-12, XE-13, XE-14, and XE-15, they received from DMG-TP on 11-27-2019. 8. Review of the policy, "Proficiency Testing", stated under the heading, "general compliance", on page 1 the following: "7. Not communicate with any other laboratory regarding PT results prior to the date the lab must report PT results to the program. 8. Not submit PT specimen to an outside lab for testing for any reason, even if patient samples are routinely sent out for additional or confirmatory testing 9. Notify CMS or accrediting agency if any lab refers PT specimens to this lab for testing." Additionally, on page 6 of 7 the PT policy stated the following: "1) No proficiency testing specimen shall ever be referred to another laboratory for analysis under any circumstances. 2) There will not be any communication of any type with this laboratory and another laboratory, or another laboratory's employee, to discuss or compare results of proficiency testing events. 3) If any other laboratory submits a proficiency testing specimen to our laboratory for analysis, that laboratory's manager and director will b immediately notified. Violation of this policy may be grounds for immediate dismissal." 9. TS1

	provided PT documentation from DMG-TP for API Hematology Event 3 which revealed DMG-TP ran the hematology PT samples XE-11, XE-12, XE-13, XE-14, and XE-15 on 11-19-2019 and submitted their results to API on 11-29-2019. 10. Interview with TS1 at 6:00 pm on 1-15-2020 confirmed the above findings that DMG-L received API PT samples on 11-25-2019 for API PT event 3 for hematology from DMG-TP prior to the submission deadline of 12-02-2019 and failed to follow the DMG proficiency testing policy and ran the samples on 11-27-2019.