

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0665170	(X3) Date Survey Completed 09/09/2024
Name of Provider or Supplier Western Diversey Surgical Center	Street Address, City, State 2744 N Western Ave, Chicago, 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the laboratory representative and testing personnel (TP) #1 and #2; the laboratory failed to ensure no inter-laboratory communications pertaining to the results of PT samples took place for five of six PT events reviewed for the years of 2022 through 2024 for the analyte of D Rho Type (0875). See D2011.</p>
D2011	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to</p>

the program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the laboratory representative and testing personnel (TP)s #1 and #2; the laboratory failed to ensure no inter-laboratory communications pertaining to the results of PT samples took place for five of six immunohematology Rhesus (Rh) factor testing PT events reviewed for the years of 2022 through 2024 for the analyte of D Rho Type (0875). Findings include: 1. Upon review of laboratory records, onsite at Laboratory A on 09/05/2024, two PT binders were discovered in the laboratory containing PT documentation: a. A binder labeled as "College of American Pathologists [CAP]2013 Surveys" containing Laboratory A's API PT events. b. A blue unlabeled binder containing Laboratory B's API PT events. 2. Review of API PT records for immunohematology Rh factor testing for both laboratories (Laboratory A and Laboratory B) revealed TP #2 performed events at both laboratory locations for four of six immunohematology Rh factor PT events reviewed (2022 - Event 3, 2023 - Event 1, 2023 - Event 3, and 2024 - Event 1). PT Year and Event Lab A Submission Date 2022 - Event 3 12/12/2022 2023 - Event 1 04/03/2023 2023 - Event 3 12/11/2023 2024 - Event 1 04/01/2024 PT Year and Event Lab B Submission Date 2022 - Event 3 12/14/2022 2023 - Event 1 04/10/2023 2023 - Event 3 12/13/2023 2024 - Event 1 04/10/2024 PT Year and Event Submission Deadline 2022 - Event 3 12/14/2022 2023 - Event 1 04/10/2023 2023 - Event 3 12/13/2023 2024 - Event 1 04/10/2024 3. Interview with the laboratory representative on 09/05/2024, at 12:21 pm, revealed that the binder for Laboratory B was stored at Laboratory A because Laboratory A staff are the only ones performing the Rh factor at Laboratory B when they travel there one day a week. 4. Review of API PT records for immunohematology Rh factor testing for both laboratories (Laboratory A and Laboratory B) revealed TP #2 performed events at both laboratory locations for four of six immunohematology Rh factor PT events reviewed (2022 - Event 3, 2023 - Event 1, 2023 - Event 3, and 2024 - Event 1). PT Year and Event Lab A Submission Date 2022 - Event 3 12/12/2022 2023 - Event 1 04/03/2023 2023 - Event 3 12/11/2023 2024 - Event 1 04/01/2024 PT Year and Event Lab B Submission Date 2022 - Event 3 12/14/2022 2023 - Event 1 04/10/2023 2023 - Event 3 12/13/2023 2024 - Event 1 04/10/2024 PT Year and Event Submission Deadline 2022 - Event 3 12/14/2022 2023 - Event 1 04/10/2023 2023 - Event 3 12/13/2023 2024 - Event 1 04/10/2024 5. Interview with TP #2 on 09/09/24, via telephone, at 3:50 pm, confirmed that TP #2 performed the above-mentioned immunohematology Rh factor PT Events at both laboratories (Laboratory A and Laboratory B). 6. Interview with TP #1 on 09/05/2024, at 1:48 pm, revealed that TP #1 had performed the most recent immunohematology Rh factor PT event (2024 - Event 2) at both laboratories (Laboratory A and Laboratory B). PT Year and Event Lab A Submission Date 2024 - Event 2 08/05/2024 PT Year and Event Lab B Submission Date 2024 - Event 2 08/07/2024 PT Year and Event Submission Deadline 2024 - Event 2 08/14/2024 7. Interview with the laboratory representative on 09/05/2024, at 3:20 pm, confirmed that the same TP had performed five of six immunohematology Rh factor PT events (2022 - Event 3, 2023 - Event 1, 2023 - Event 3, 2024 - Event 1, and 2024 - Event 2) at both Laboratory A and Laboratory B.