

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2155189	(X3) Date Survey Completed 09/12/2024
Name of Provider or Supplier Carafem North Shore	Street Address, City, State 4711 Golf Rd - Ste 920, Skokie, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, American Proficiency Institute (API) proficiency testing (PT) records, and interview with testing personnel (TP) #2; the laboratory failed to test PT samples the same number of times as patient samples for three of six PT events between 2022 and 2024 for the specialty of Immunohematology. Findings Include: 1. Review of the laboratory procedure, "Chapter 1: Quality Assessment Plan for Laboratory Testing", stated "We will treat the proficiency testing specimens exactly as we treat patient samples, From accessioning through reporting. We will repeat the tests only if we would repeat patient samples under the same conditions (for example, if the result is a critical value)." 2. Review of API attestation statements found documentation of the PT samples being performed in duplicate by different testing personnel (TP#2, TP#3 and one TP no longer employed (NLE)) on three of six PT records reviewed. A. API 2024 first event had documentation that TP #1 and TP #2 tested samples: RH-01, RH-02, RH-03, RH-04, and RH-05 on 04-15-24. B. API 2023 third event had documentation that TP #1 and TP NLE tested samples: RH-11, RH-12, RH-13, RH-14, and RH-15 on 11-30-23. C. API 2023 second event had documentation that TP #1, TP #2, and TP NLE tested samples: RH-06, RH-07, RH-08, RH-09, and RH-10 on 09-15-23. 3. Interview with TP#2 on survey date 09-12-2024, at 10:04 am, confirmed the PT procedure was not followed and multiple TP had analyzed the PT samples prior to the submission deadline for the PT events identified.</p>