

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2155189	(X3) Date Survey Completed 04/07/2021
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
D3035	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii)</p> <p>In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the testing personnel (TP2), the laboratory failed to retain the quality control (QC) records for the Immunohematology testing performed, for at least 2 years. Findings include: 1. The laboratory's procedures manual and control logs from the months of August and December of 2019, March and September of 2020, and February of 2021 were reviewed. 2. The laboratory used ELDON RhD visual agglutination test card for Rhesus (RH) factor D antigen testing. 3. The Control logs revealed the quality control (QC) test cards were not retained for the 5 out of 5 months selected for review. 4. Further review showed the laboratory recorded QC results but had never retained the QC test cards. 5. The laboratory failed to include, when establishing its patients' test card retention policy, to include the retention of its QC test cards as required. 6. On a Recertification survey conducted on 04/07/2021 at 11:45 AM, the TP2 confirmed the above findings.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the testing</p>

personnel (TP2), the laboratory failed to retain all proficiency testing (PT) records for the Immunohematology testing performed, for at least 2 years. Findings include: 1. The laboratory's procedures manual and American Proficiency Institute (API) PT records for 2019 through 2021 were reviewed. 2. The laboratory participated in the API-PT program for the Rhesus (RH) Factor D Antigen visual agglutination test performed in the laboratory . 3. Review of the API-PT documents revealed the PT sample test cards were not retained for 6 out of 6 PT testing events. 4. Further review showed the laboratory recorded PT results but had never retained the PT test cards. 5. The laboratory failed to include, when establishing it's patients' test card retention policy, to also include the retention of its PT sample test cards as required. 6. On a Recertification survey conducted on 04/07/2021 at 11:45 AM, the TP2 confirmed the above findings.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on record review, the Laboratory Personnel Report (CMS 209), and an interview with the testing personnel (TP2); the laboratory failed to establish written procedures to include the assessment of individual's test performance who are performing Immunohematology testing, affecting 2 out of 2 TP. Findings: 1. The CMS 209, personnel records, and procedures manual were reviewed. 2. The laboratory failed to have a written competency procedure which included one of the following: *The assessment of test performance through testing previously analyzed specimens, *Through internal blind testing samples or *Through external proficiency testing (PT) samples, to evaluate the TP performing Rhesus (RH) factor D antigen testing. 3. The CMS 209 listed 2 TP (TP1 and TP2) performing Rh factor D testing. 4. The personnel documents for TP1 and TP2 did not include test performance training and evaluation. 5. On a Recertification survey conducted on 04/07/2021 at 11:45 AM, the TP2 confirmed the above findings.