

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2155189	(X3) Date Survey Completed 03/19/2019
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 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 technical consultant (TC1), the laboratory failed to retain the patient test records for the Rhesus (RhD) testing performed for at least 2 years for 17 out of 17 patients. Findings include: 1. The laboratory's standard operating procedures (SOP) manual and patient test logs were reviewed. 2. The ELDON RhD card test kits were used for Rhesus factor testing. 3. Review of the patient test logs revealed 17 patients were tested with the above test cards. 4. The laboratory failed to retain the test cards for 17 out of 17 patients. 5. The laboratory SOP failed to require the retention of patients' RhD test cards. 6. TC1 confirmed on 03/19/2019 at 1:00 PM, that the laboratory did not keep the patient test cards.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and an interview with the technical consultant (TC1), the laboratory failed to monitor and document manufacturer's required conditions essential for proper storage of test kits to ensure accurate and reliable test system operations for 17 out of 17 patients. Findings include: 1. The laboratory's standard operating procedures (SOP) manual, manufacturer's package insert, kit and quality control (QC) logs were reviewed. 2. The ELDON RhD card package insert stated the ELDON RhD tests cards must be stored between 5 to 37 degrees Celsius. 3. The kit and QC logs showed no documentation of room temperatures in the location where ELDON RhD cards are stored. 4. The SOP failed to include a policy and procedure for ensuring the storage room for the test cards is monitored. 5. On 03/19/2019 at 1:00 PM, the TC1 confirmed the above findings.

D5800

POSTANALYTIC SYSTEMS
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of laboratory logs, test records and an interview with the technical consultant (TC1); 1. The laboratory failed to accurately and reliably transcribe test results into the patient electronic medical records (EMR). See D5801. 2. The laboratory failed to establish written quality assurance policies and procedures for the post-analytic phase of the Rhesus (RhD) factor testing performed. See D5891.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the technical consultant (TC1), the laboratory failed to accurately and reliably enter test results into the patient electronic medical records (EMR), for 1 (Patient-CX3) out of 8 patients. Findings include: 1. The laboratory's standard operating procedures (SOP) manual, patient electronic records, and patient test logs were reviewed. 2. The review of 8 patients' Rhesus (RhD) test results from the test log showed the following: Patient-CX3's result for RhD factor recorded on the test log was negative(-); Patient-CX3's result for RhD

factor recorded in the patient's EMR was positive(+). 3. On 03/19/2019 at 1:00 PM, the TC1 confirmed the above findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the technical consultant (TC1), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in transcribing patients' results, for 1 (Patient-CX3) out of 8 patients. Findings include: 1. The laboratory's standard operating procedures (SOP) manual, patient electronic records, and patient test logs were reviewed. 2. Review of 8 patients' test results revealed 1 out of 8 patients' test results were transcribed into the electronic medical record (EMR) incorrectly (See D5801). 3. The SOP failed to include a policy and procedure for monitoring and preventing transcription errors when reporting patient results in their EMR. 4. On 03/19/2019 at 1:00 PM, the TC1 confirmed the above findings.