

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2141868	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Urgent Family Clinic Llc	Street Address, City, State 301 North John Young Parkway, Kissimmee, FL	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory used expired reagents on their Beckman Coulter Access 2 Immunoassay Analyzer and calibrators on their Beckman Coulter AU480 Chemistry Analyzer. Findings: 1. During examination of the laboratory's refrigerator on 11/13/19, an expired bottle of Access System Check Solution lot number 123452 expiration date 2019-09-30 was found. The bottle label contained a handwritten date of "11/04." During an interview on 11/13/19 at 1:02 PM, Testing Personnel A verified that the bottle was opened on 11/04/19 and that was the first date the expired reagent was used. 2. During examination of the laboratory's refrigerator on 11/13/19, an expired bottle of Lyophilized Chemistry Calibrator Level 1 lot number 9610161 expiration date 2019-08-31 and Lyophilized Chemistry Calibrator Level 2 lot number 9610261 expiration date 2019-08-31 was found. The bottle label contained a handwritten date of "11/04." Review of calibration records showed that the Creatinine calibration was performed on 10/16/19. No other calibrators for Serum Creatinine were located. During an interview on 11/13/19 at 1:3 PM, Testing Personnel B stated that they stopped testing patients the last day of October, 2019. During an interview on 11/13/19 at 2:44 PM, Testing Personnel B stated that the calibrators were only used for the Serum Creatinine, and acknowledged that the calibration for Serum Creatinine was performed on 10/16/19.</p>