

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1009929	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Kansas Nephrology Physicians	Street Address, City, State 1035 N Emporia Street, Wichita, KS	
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 upon direct observation during a tour of the laboratory, review of BIO-RAD manufacturer's control sheet and interview with testing personnel #1 and #2 (refer to the Laboratory Personnel Report (CMS-209)) at 10:40 AM on November 6, 2018, the laboratory failed to ensure that controls in use had not exceeded their stability expiration date. Findings were: 1. During a tour of the lab, the surveyor observed the following BIO-RAD Control bottles stored in the refrigerator currently in use had the following open dates. Liquichek Unassayed Chemistry Control --- level 2; lot 31872, unopened frozen expiration date 1/31/2020. Open date: 10/25/2018. Liquichek Urine Chemistry Control --- level 1; lot 66791, unopened refrigerator expiration date 12/31/2018. Open date: 10/3/2018. --- level 2; lot 66792, unopened refrigerator expiration date 12/31/2018. Open date: 10/2/2018. Liquichek Immunoassay Plus Control, unopened frozen expiration date 6/30/2020. --- level 1; lot 40971, level 2; lot 40972, level 3; lot 40973. Open date for all: 9/27/2018. Liquichek Specialty Immunoassay Control, unopened frozen expiration date 1/21/2020. --- level 1; lot 60231, level 2; lot 60232, level 3; lot 60233. Open date for all: 9/27/2018 2. Review of the BIO-RAD manufacturer's control sheets stated the following stability listed below once thawed and opened or just opened for the urine chemistry controls. Liquichek Unassayed Chemistry Control: this control will be stable thawed and stored refrigerated as follows: Bilirubin (Total), Triglycerides and Phosphorus: 6 days. Liquichek Urine Chemistry Control: this control will be stable stored refrigerated for all analytes for 30 days. Liquichek Immunoassay Plus Control: this control will be stable thawed and stored refrigerated as follows for all analytes tested at this lab for 14 days. Liquichek</p>

Specialty Immunoassay Control: this control will be stable thawed and stored refrigerated for Parathyroid Intact (PTH intact) for 7 days. 3. Testing personnel #1 and 2 confirmed that the expired control vials were were all used for quality control on November 5, 2018.