Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1050390	01/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kidney Care Center	812 Campus Dr, Joliet, 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
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 review of the laboratory records and interview with testing personnel (TP) #1; the laboratory failed to establish policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's quality assessment plan on page 2 of 10 under the heading of "Personnel" stated the following: "We will establish and follow written policies and procedures, as described in the CLIA personnel requirements, to evaluate employee competency (and consultant competency, if applicable)." 2. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209. 3. On survey date 01-23-2018 at 03:15 pm, TP#1 confirmed the laboratory failed to establish a competency assessment policy.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen

	processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory director failed to identify the responsibilities and duties of each person engaged in all phases of testing. Findings Include: 1. No duties and responsibilities were specified in writing for 2 of 2 testing personnel listed on the CMS-209. 2. No duties and responsibilities were specified in writing for the laboratory director, clinical consultant, and technical consultant. 3. On survey date 01-23-2018, at 3:15 pm, TP#1 confirmed that there were no documents specifying the duties and responsibilities for each person engaged in testing process.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory's technical consultant failed to ensure annual competency assessments were completed for 1 of 1 testing personnel. Findings Include: 1. Review of competency assessment records for testing personnel (TP) #1 from 2016 through 2017 found no competency assessments were completed for chemistry and hematology testing. 2. During survey date 01-23-2018, at 3:15 pm, TP#1 confirmed no competency assessments had been completed by the technical consultant in 2016 and 2017 for moderate complexity chemistry and hematology testing performed by TP#1.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. TP#2, as listed on the CMS-209, failed to have documented training prior to analyzing patient specimens for moderate complexity hematology and chemistry testing. See D6066.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to have training documentation for 1 of 1 new TP listed on the CMS-209. Findings Include: 1. Interview with TP#1 on 1-28-2018 at 2:10 pm, confirmed TP#2 started patient testing in November of 2017. 2. Review of laboratory personnel records found no training documentation for TP#2 prior to analyzing patient specimens. 3. On survey date 01-28-2018, at 3:15 pm, TP#1 confirmed the laboratory failed to have training documentation for moderate complexity hematology and chemistry testing for TP#2 prior to analyzing patient specimens.