

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2090673	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Kroll Care	Street Address, City, State 290 Heritage Walk, Ste 102, Woodstock, GA	
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
D0000	Based on an Initial CLIA survey performed on February 22,2018, this facility was found to be noncompliant with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. Findings include: 1. SOP review revealed the laboratory failed to establish and follow written policies and procedures for quality assurance. 2. An interview with Staff #1 (CMS 209) on 2/22/18 in a medical office at approximately 2:30 p.m. confirmed there was not a quality assurance policy and procedure in the laboratory SOP.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and</p>

rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish policies and procedures for preanalytic systems as required. Findings include: 1. SOP review revealed the SOP did not contain a policy and procedure for specimen labeling with two unique identifiers. 2. SOP review revealed the SOP did not contain a policy and procedure for specimen collection. 2. An interview with Staff #1 (CMS 209) in a medical office on 2/22/18 at approximately 2:30 PM confirmed the laboratory SOP did not contain a policy and procedure for specimen labeling with two unique identifiers nor a policy and procedure for specimen collection.