

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0140865	(X3) Date Survey Completed 08/20/2018
Name of Provider or Supplier Larry P Roberts Md Pc	Street Address, City, State 175 Memorial Highway Suite 3-2, New Rochelle, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory quality control (QC) records and an interview with the laboratory director, the laboratory failed to test QC material when a new bottle of Siemens' 10 SG Urine reagent strips are opened for use on the Clinitek Status. Findings Include: It was confirmed by the laboratory director on August 20, 2018, at approximately 12:30 pm that the laboratory failed to follow the manufacturer's instruction for the Siemens' 10 SG Urine reagent strips and the Clinitek Status instrument and test positive and negative controls prior to patient testing for year 2017. The testing person stated "I am unable to find those records" Approximately 600 patient tests were performed for urinalysis and results reported from.</p>