Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0692393	03/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nc State Laboratory Of Public Health	4312 District Drive, Raleigh, NC	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on surveyor record review and interview the laboratory failed to document the evaluation of the comparison studies for multiple instruments in accordance with laboratory Quality Assessment Plan. Findings include: 1. The laboratory review revealed the laboratory comparison study in Newborn Screening for MSMS test did not show documentation that the comparison study was evaluated and approved by the Techncal Supervisor. Comparison studies performed in Blood Lead were not evaluated or signed each time peformed. The laboratory Quality Assessment Plan states comparison must be performed twice a year and evaluated. The policy was not being followed by the laboratory staff consistently. Two laboratory sections were found to perform the comparison studies but did not document their evalutaion in accordance with the laboratory policy. 2. The laboratory has specific guidance in the Quality Assessment Plan on page 19 of 20, which states"For applicable clinical test procedures that are performed on multiple instruments, or when there is more than one method for producing the same test result (i.e. manual vs. automated methods), at least twice a year, the Unit must perform and document a comparison study between the methods or instruments. This study will evaluate and define the relationship between methodologies or instruments that perform the same test". Two laboratory sections were not following the laboratory requirements. 3. The laboratory Technical Supervisor confirmed during the interview on March 7, 2019 at 2:00pm, the laboratory did not document comparison evaluation as required in the laboratory Quality Assessment Plan.