Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0662473	04/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinic For Special Children,The	20 Community Lane, Gordonville, PA	

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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation and interview with the Laboratory Director (LD), the laboratory failed to establish a maintenance protocol for the Ergo One and Bio Hit pipettes used for High-performance liquid chromatography (HPLC) and ABI 3130 Genetic Analyzer. Findings include: 1. On the day of survey, 04/25/2018, during the tour of the Laboratory, the surveyor observed 10 Ergo One and 2 Bio Hit Pipettes each labeled with a calibration performed date of 12/14/2016 and Due 06/2017. a. Ergo One Pipettes: (# of Pipettes) Volume of Pipette (3) 2-20 ul (2) 0.1-2.5 ul (2) 200 ul (2) 30-300 ul Multi-Channel (1) 100-1000 ul b. Bio Hit Pipettes: (# of Pipettes) Volume of Pipette (1) 0.5-10 ul Multi-channel (1) 100-1000 ul 2. The LD stated "pipettes were normality calibrated every 6 months", but could not provide a procedure stating the maintenance protocol or evidence of recent calibration. 3. The LD confirmed the findings above on 04/25/2018 around 15:45 PM. Note: ul = microliter
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not

	limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on the review of Testing Personnel (TP) competency assessment records and interview with the laboratory director (LD), the laboratory failed to include the assessment of problem solving skills for 3 of 3 TP Competency assessments in 2017. Findings: 1) On the date of survey 04/25/2018, the surveyor reviewed competency assessment records of 3 of 3 TP. The competency assessment did not cover the assessment of problem solving skills which is one of the six requirements for CLIA competency assessment. 2) The LD confirmed the findings above on 04/25/2018 around 13:45 PM.