Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2081180	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clearfield Jefferson Primary Care Assoc	1464 N Main Street, Punxsutawney, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP) #1, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests were performed from 09/20/2022 to the date of survey. Findings include: 1. The PA regulations (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. Review of the application for Exception to Section 5.22 (f) form signed by the laboratory director (LD) on 02/07/2022 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. On the day of the survey, 04/24/2024 at 11:50 am, interview with TP #1 confirmed that the laboratory failed to ensure that the PA regulations were met regarding having a qualified supervisor on site during all hours of patient testing from 09/20/2022 to 04/24/2024.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on lack of maintenance records and interview with testing personnel (TP) #1, the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 ThermoPro thermometer/humidity monitor used in the Toxicology laboratory from 09/20/2022 to the day of survey. Findings Include: 1. On the day of survey, 04/24/2024 at 11:30 am the laboratory could not provide maintenance/function check records for 1 of 1 ThermoPro thermometer/humidity monitor. 2. Interview with TP #1 on 04/24/2024 at 11:50 am confirmed the 1 of 1 ThermoPro thermometer/humidity monitor was used to record room temperature and relative humidity in the Toxicology laboratory from 09/20/2022 to 04/24/2024. 3. The Thermo Fisher Scientific Indiko Plus analyzer used in the Toxicology laboratory requires an operating temperature range of 18 - 30 degrees Celsius and 40-80 % relative humidity.