Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2123464	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
The Occupational Health Center - Saint Vincent	2501 W 12th St Suite C7, Erie, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack for records and interview with the laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to provide written or electronic requests from an authorized person, before performing MedTox Profile II testing from 08/17/2019 to the day of survey. Findings include: 1. On the day of survey, 08/17 /2021, interview with the LD and TP#1 and #2 revealed, the laboratory did not receive written or electronic requests from an authorized person, before performing MedTox Profile II testing from 08/17/2019 to 08/17/2021. 2. From 08/17/2019 to 12/31/2019 - 356 MedTox Profile II tests were analyzed. 3. From 01/01/2020 to 12/31/202020 - 1,505 MedTox Profile II tests were analyzed. 4. From 01/01/2021 to 08/17/2021 - 679 MedTox Profile II tests were analyzed. 5. The LD and TP#1 and #2 confirmed the finding above on 08/17/2021 around 12:30 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to monitor the temperature where MedTox Profile II cup were stored from 2019 to the day of survey. Findings Include: 1. The MedTox Profile II cups state to be kept at room temperature (2 - 25 degrees Celsius). 2. On the day of survey, 08/17/2021, review of the laboratory temperature records revealed, the room where the MedTox Profile II cups were store was not being monitored for temperature for 08/17/2019 to 08/17/2021. 3. The LD and TP#1 and #2 confirmed the findings about on 08/17/2021 around 12:15 pm.