

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2163672	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier The Occupational Health Center - East Side	Street Address, City, State 4950 Buffalo Road, 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	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on lack for records and interview with the laboratory director (LD) and an R.T., 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 R.T. 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 - 96 MedTox Profile II tests were analyzed. 3. From 01/01/2020 to 12/31/2020 - 337 MedTox Profile II tests were analyzed. 4. From 01/01/2021 to 08/17/2021 - 192 MedTox Profile II tests were analyzed. 5. The LD and the R.T. confirmed the finding above on 08/17/2021 around 10:15 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the testing personnel laboratory director (LD) and an R.T., the laboratory failed perform maintenance/</p>

function checks on 1 of 1 Accu ID refrigerator thermometer from 11/6/2020 to the day of survey. Findings Include: 1. On the day of survey, 08/17/2021, observation of the laboratory revealed the following thermometer was due for a function check /maintenance from 11/06/2020 to 08/17/2021: - 1 of 1 Accu ID thermometer. - Serial Number: TT003652. - Due: 11/06/2020. 2. The LD and R.T. confirmed the findings above on 08/17/2021 around 10:35 am.

D8103

BASIC INSPECTION REQUIREMENTS
CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the laboratory director (LD) and an R.T., the laboratory did not have the required records available during the inspection on 08/17/2021. Findings Include: 1. On the day of survey 08/17/2021, the laboratory could not provide the following records: - Monthly quality assessment (QA) records from October, November and December of 2019. - Monthly QA records from June and July of 2021. - Room temperature logs from October and December of 2019. - Room temperature logs from January, February, March, July, September, October, November and December of 2020. - Refrigerator temperature logs from October and December of 2019. - Refrigerator temperature logs from January, February, March, July, September, October, November and December of 2020. 2. The LD and the R.T. confirmed the findings above on 08/17/2021 at 10:30 am.