

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0942607	(X3) Date Survey Completed 04/14/2021
Name of Provider or Supplier Natl Ctr For Hlth Statistics Nhanes Iv	Street Address, City, State 3311 Toledo Road, Hyattsville, MD	
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
D0000	A federal surveyor from the Division of Clinical Laboratory Improvement & Quality CLIA Operations, Centers for Medicare and Medicaid Services (CMS) - Philadelphia CMS Office conducted an announced CLIA Recertification survey at the NATL CTR FOR HLTH STATISTICS NHANES IV laboratory on April 14 , 2021. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. Specific deficiencies cited are as follows:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory equipment QC records, lack of corrective action policy in laboratory procedures and staff interview the laboratory failed to document corrective action for out of range humidity readings during the months of May 2019- June 2019 at the 404 stand located in Chicago, IL. Findings Include: National Health and Nutrition Examination Survey: MEC (Mobile Examination Center) Equipment QC Report- Report #303 From May 22, 2019 -June 27, 2019 there were 23 QC daily reports tracked. Seven (7) of 23 days the humidity reading was greater 79 ; 80 or more is out of range according to the "Humidity Monitoring" Laboratory Procedures. 1.05 /25/2019- 84% 2.05/27/2019- 84% 3.05/28/2019- 84% 4.06/08/2019- 81% 5.06/09</p>

/2019- 81% 6.06/16/2019- 80% 7.06/27/2019- 80% MEC Laboratory Procedures
2020- "10.9.4: Humidity Monitoring" revealed the lack of corrective action policy for
a laboratory humidity reading stating acceptable humidity range below 80%. On 04/04
/2021, during interview with the laboratory director and clinical consultant at 2:30 pm,
the staff confirmed the laboratory does not document corrective actions the laboratory
staff performs nor does the laboratory procedures define the corrective action
necessary.