Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0942607	04/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Natl Ctr For Hlth Statistics Nhanes Iv	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	Federal Jurisdictional Survey The laboratory is in compliance with 42 CFR part 493 with standard level deficiencies cited:
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 manufacturer's instructions, temperature charts, and interview, the laboratory failed to have defined the correct criteria conditions for proper storage of reagents at room temperature for hematology (DxH 800) as evidenced by: 1. In review of the manufacturer's instructions for reagents it states for Beckman Coulter DxH 800 analyzer: a. Differential pack store at 2-25 degrees C. b. Cleaner store at 2-25 degrees C. 2. In review of the laboratory's temperature charts the laboratory defined a criteria outside of the proper room temperature storage range: 15-30 degrees C. 3. In review of the room conditions temperature graphs for (all day monitoring) May 25th- 27th and June 1st, 8-10, for three days ,the room temperature was above 25 degrees C at certain periods of the day. The temperature graphs show that they are above 25 degrees without a numeric value. The following dates and times were seen above 25 degrees on the chart : a. 6-10-2018 @ 4pm b. 5-27-2018 @12PM c. 5-26-2018 @4 pm The laboratory did not take any remedial actions and was unaware of the storage requirements by the manufacturer. 4. In interview with the Laboratory Director on 3-18-2019 @1115 am she stated that she was not aware that reagents had a tighter

	storage temperature. She also stated that everything must have changed when they went to the DxH 800 a few years ago.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, manufacturers instructions and interview with staff the laboratory failed to document open vial stability of Coulter 6 C quality control material. as evidenced by: 1. Coulter 6C manufacturers instructions state: " 16 Open Vial days, assumes that the instruction for use section of the package insert is performed a maximum of 18 times within 16 days. 2. Direct observation of current lot of Coulter 6c materiel in the refrigerator(L1 123192490, L2 133182490, L3 143192490) was observed @ 1115 on 0303/18/19 without new expiration date on the vial or documented. 3. In interview with the Director @ 1115 on 03/18/19, she stated : The QC was good for 7 days and they typically run qc 2 times per day during lot rollover and every 4 hours during sessions, , and no means to ensure 18 events in 16 days were not surpassed."
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review, direct observation and interview with staff, the laboratory failed to evaluate all patient obtained since the last acceptable quality control run in 1 of 7 corrective actions from August 2019 corrective action log. As evidenced by: 1. Based on record review, August 22 2018 entry for the 08/22/18 0842 qc run, NHanes Lab DXH 800 troubleshooting log stated Tech Initials LH. Problem/solution WBC Level 3 high ;R flags 3 diff;platelet clump flags and platelet/MPV R flags on SP/ZAP apertures x3, prime sweep flow x 3, clean BSV, unlock DV x3, rinse mixing chamber, nrbcx3 and diffx3; Prime lyse, flush flow cell w/cleaner r0 minutes QC back in 1422 on 08/22/18 . 2. Previous Successful qc run was performed on 08/21/18 @ 1752 with 3 patients run during that shift without patient assessment for out of range qc. a. Patient 616629 run at 1800 on 08/21/18 b. Patient 825165 run at 1819 on 08/21/18 c. Patient 413882 run at 1804 on 08 /21/18 3. In interview with director @1035 on 03/18 /19, she stated :" There is no policy to remidate patients."