Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0955652	08/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
National Institutes Of Health	9000 Rockville Pike, Bldg 10 Rm 8n252, Bethesda, 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 recertification onsite survey was conducted 08/29/2024 and standard level deficiencies were cited.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, client specimen handling instructions, patient log sheet, final test reports, patient information sheets, and interview with testing person 1, the laboratory failed to ensure documentation of the integrity (frozen) of 5 of 5 specimens when collected and received for catecholamines testing (04/27/2023 through 07/23/2024). Findings included: 1. Review of the laboratory's procedure "PART I: Sampling and Shipping of Samples ...3. Sample Processing: ... The plasma should be separated into plastic tubes clearly marked with the date and patient ID and frozen immediately (e.g., dry ice). The sample should be stored at -70C or colder. Catechols in plasma stored at -20C are not stable." Further review stated, "4. Specimen Shipping: ...Samples of plasma should be shipped frozen (e.g., on dry ice in a Styrofoam container) to the NIH." The above instructions were provided to the laboratory's clients via electronic mail (email) along with a "Patient Information Sheet." The information sheet included at the bottom right, "Stored at -70C? __." 2. Review of the laboratory's patient log sheet included 5 patients that had been received and tested for plasma catecholamines on high performance liquid chromatography (HPLC) method. The log sheet did not include whether the specimens were received on dry ice and patient information sheets did not include how clients/collectors stored

	the specimens, as follows: Patient Log #1736 (one tube of plasma) collected 04/25 /2023 and analyzed 04/27/2023 Patient Log #1737 (four tubes of plasma) collected 05 /18/2023 and analyzed 05/23/2023 The above two patients did not include patient information sheets because it had not been created yet. There was no documentation of how the specimens were stored by the collectors. Patient Log #1741 (two tubes of plasma) collected 08/02/2023 and analyzed 08/09/2023 and 08/10/2023 Patient Log #1743 (one tube of plasma) collected 12/18/2023 and analyzed 12/19/2023 Patient Log #1745 (one tube plasma) collected 07/22/2024 and analyzed 07/29/2024 The above three patients included patient information sheets and the question, "Stored at -70C? __" was not checked off. 3. During an interview on 08/29/2024 at 2:30 pm, testing person 1 reviewed and confirmed the above information. She stated all specimens come with dry ice but did not have documentation of ensuring those conditions.
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, direct observation, and interview with testing person 1, the laboratory failed to monitor and document room temperature and humidity for 3 of 3 stored reagents and 4 of 4 analyzers according to manufacturer's requirements. Findings included: 1. Review of Waters 2707 Autosampler manufacturer's instructions stated on page 73, "General specifications ...Working temperature 10 to 40C ...Humidity 20 to 80%" Review of Water 515 HPLC Pump manufacturer's instructions stated on page B-1, "Environmental specifications ... Operating temperature 4 to 40C; Humidity 20 to 80%, noncondensing." Review of Coulochem III manufacturer's instructions stated on page A-4, "Environmental: Operating Temperature: 10-35C; Humidity: Maximum 80% RH (35C), non-condensing." (RH - Relative Humidity) 2. During a tour of the laboratory on 08/29 /2024 at 11:30 am, two Waters 2707 Autosamplers, one Waters 515 HPLC Pump, and one Coulochem III electrochemical detector were observed on the countertop. The Waters with the Coulochem were used for plasma catecholamine testing. In addition, the following sampling of reagents were observed stored on shelves: Supelco Buffer, reference standard B5020-500 mL, expiration date 02/01/2026, manufacturer's storage requirements: 15C to 25C. Supelco Buffer, reference standard B4770-500 mL, expiration date 11/24/2024, manufacturer's storage requirements: 25C. Sigma-Aldrich LiChropur Octane-1-sulfonic acid sodium salt, manufacturer's storage requirements: 15C to 25C. 3. During an interview on 08/29/2024 at 11:30 am, testing person 1 was asked whether room temperature and humidity was monitored and documented, she stated no.
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of HPLC analyzer patient results, final test reports, and interview with testing person 1, the laboratory failed to ensure catecholamine test results were entered accurately for 1 of 5 patient final reports (from 04/27/2023 through 07/23 /2024). Findings included: 1. Review of Patient Log #1742 "upright" position results from the HPLC analyzer were analyzed 08/09/2023 and included catecholamines dihydroxypheylglycol (DHPG) value of 1683 pg/ml and norepinephrine (NE) value of 2744 pg/ml. Review of the final test report for Patient Log #1742 "upright" position results included a DHPG value of 2428 pg/ml and NE value of 3379 pg/ml. 2. During an interview on 08/29/2024 at 2:11 pm, testing person 1 was asked how results were transmitted from the HPLC analyzer to the final test report. She explained results are entered manually into a final test report template by the laboratory director. Testing person 1 was unable to locate HPLC analyzer results that were consistent with the final test report results (DHPG value of 2428 pg/ml and NE value of 3379 pg/ml). The laboratory failed to ensure catecholamine test results were entered accurately for 1 of 5 patient final reports.