Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0955652	11/19/2018
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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory relocation verification of assay performance and interview with the technical supervisor, the laboratory failed to ensure all re-establishment characteristics for performance of plasma Catecholamines testing were performed and documented on two esa Coulachem III analyzers prior to patient testing after the laboratory moved into a new location in January 2018. Findings include: 1. The laboratory uses two instruments for analysis of Catecholamines in patient plasma: instrument named 'RED" having Serial No CC6987 and instrument 'YELLOW; having Serial No CC6818. 2. For instrument 'RED' there was no documented evidence the laboratory performed: precision study testing that included assessment of day-to-day, run-to-run and within run variation. 3. For instrument 'YELLOW' there was incomplete documentation of precision study testing as only one run was performed and there was no assessment of day-to-day, run-to-run and within

	run variation. 4. During interview with the technical supervisor at approximately 12: 20pm, there was an admission the laboratory was unaware of these requirements and that is why they were not documented as required under the standard.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, patient reports and interview with the technical supervisor, the laboratory failed to ensure patient plasma catechols reports included appropriate interpretative information related to the how the final interpretation is derived by the laboratory on one of one Menkes patient report reviewed of ten. Findings include: 1. The surveyor reviewed the procedure manual, Section 2 titled 'Reference Ranges for Plasma Catechols', Menkes Reference Range Ratios are listed for 3,4-dihydroxyphenylalamine (DOPA):3,4-dihydroxyphenypenylglycol (DHPG) and 3,4-dihydroxyphenylacetic acid (DOPAC): DHPG ratios for patients with Menkes disease as well as pediatric control sample ranges. 2. In patients with Menkes disease, the DOPA:DHPG ratio range is listed as 6.2-34.2 and for DOPAC:DHPG ratio the range is listed as 4.4-19.7. 3. Pediatric control subject samples without evidence of Menkes disease, the DOPA:DHPG ratio is listed as 1.7-3.3 and the DOPAC:DHPG ratio is listed as 1.5-3.2. 4. For the pediatric patient having DOB 9-27-2017 with an assay date of 5-31-2018; the DOPA: DHPG ratio was listed as 5.3 and the DOPAC:DHPG ratio listed as 1.6, DA:NE ratio listed as 0.01, Interpretation as 'Unaffected' without any interpretative information provided by the laboratory on the report. 5. This information was confimed during interview with the technical supervisor at approximately 1:30pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory quality assurance (QA) manual and interview with the technical supervisor and laboratory director, the laboratory director failed to ensure the facility's quality assessment program monitors were established and maintained to assure the quality of laboratory services in performance of plasma catecholamine testing and identied failures in quality as they occurred. Findings include: 1. The current laboratory QA plan is dated October 2018; 2. Monitors in the General lab systems areas of plasma catecholamine testing were not included in the

	laboratory QA manual; 3. Monitors in the Pre-analytic systems areas of plasma catecholamine testing were not included in the laboratory QA manual; 4. Monitors in the Analytic systems areas of plasma catecholamine testing were not included in the laboratory QA manual; 5. Monitors in the Post-analytic systems areas of plasma catecholamine testing were not included in the laboratory QA manual; 6. These findings were confirmed by interview with the laboratory director at approximately 2: 00pm.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboraotry relocation re-establishment studies and interview with the laboratory director, the lab director failed to ensure verification of accuracy and/or precision of plasma catecholamines on two of two esa Coulachem III analyzers. Findings include: Cross-reference D5423.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the laboraotry procedure manual, patient reports and interview with the laboratory director, the lab director failed to ensure patient Menkes disease reports included appropriate interpretative information. Findings include: Cross-reference D5805.