Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2093330	06/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nih Undiagnosed Diseases Program Clinical Lab	50 South Drive Room 5525, 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 federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey on June 16, 2026. The laboratory was found to not be in compliance with the following condition-level CLIA requirements: 493.1447 - Laboratory Technical supervisor 493.1487 - Testing Personnel The following condition and standard-level deficiencies were found.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of standard operating procedures (SOP), lack of a supervisory competency assessment procedure, and an interview with the laboratory director (LD), the laboratory failed to have a policy or procedure in place to assess the competency of 1 of 1 technical supervisor (TS) for their delegated responsibilities. Findings: 1. Review of the QA program documentation SOP on June 16, 2026, revealed the personnel competency section was for the assessment of competency for testing personnel and not the delegated responsibilities of the TS. 2. The laboratory failed to provide a policy or procedure for the assessment of competency for the TS listed on form CMS 209. 3. By interview on June 16, 2026, at 1:45 pm, the LD confirmed the TS was not assessed for their delegated responsibilities.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or

	procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the lack of proficiency testing (PT) records and an interview with the laboratory director (LD), the laboratory failed to verify the accuracy of blood deoxyribonucleic acid (DNA) isolation at least twice annually for 2 of 2 years (2024 and 2025). Findings: 1. Review of the records on June 16, 2026, revealed that the laboratory failed to perform PT or verify the accuracy of Blood DNA isolation at least twice annually in 2 years (2024 and 2025). 2. By interview on June 16, 2026, at 1:30 pm the LD confirmed no verification of accuracy for Blood DNA isolation has ever been performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 the lack of temperature/humidity records, review of instrument instruction manuals, and an interview with the laboratory director (LD), the laboratory failed to monitor and document room temperature and humidity in the laboratory for 2 of 2 years (June 2024 to June 2026). Findings Include: 1. The Autogen - FlexSTAR manual stated, "Operating Temperature 15C to 30C and 30% to 80% relative humidity (RH), non-condensing". 2. The GE Healthcare NanoVue Plus Product user manual stated, "The instrument is designed for indoor use only, temperatures range 5 Degrees Celsius (C) to 35 C, maximum relative humidity 80% at 31C, decreasing linearity to 50% at 40C are required." 3. The life technologies Qubit 2.0 Fluorometer user guide stated, "product specifications, operating temperature 10-40C and operating humidity 20-80% (non-condensing). 4. The laboratory was unable to provide documentation of the room temperature and humidity monitored in the laboratory. 5. By interview on June 16, 2026 at 1:00 pm, the LD confirmed temperature and humidity were not monitored in the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of laboratory standard operating procedure (SOP), review of centrifuge maintenance documentation, and an interview with the laboratory director (LD), the laboratory failed to perform centrifuge function checks for 1 of 1 Eppendorf

	5810R centrifuge as specified in the test procedure. Findings Included: 1. The Extraction of genomic DNA from the human whole blood (Flexstar) SOP, 4. workflow notes, #3 stated, "....shall be spun down at 1000 g (RCF) for 10 minutes..."). 2. On June 16, 2026, at 12:45 pm, the laboratory provided documentation for function checks performed at 1000g at 5 minutes, but could not provide documentation to show the Eppendorf 5810R centrifuge could centrifuge a specimen at 1000g for 10 minutes. 3. By interview on June 16, 2026, at 1:00 pm, the LD confirmed that the function checked performed did not include the assessment of function at 1000g for 10 minutes.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on observations of the laboratory and an interview with the laboratory director (LD), the laboratory failed to perform the manufacturer-defined function checks for 2 of 2 thermometers in use. Findings: 1. Observation of the laboratory on June 15, 2026, at 1:00 pm revealed the following two thermometers in use, which monitored room temperature, were due for a function check: a. Thomas Scientific Traceable Thermometer S/N: 221612788 - Due: January 23, 2024. b. Lab Rep Co Thermometer, S/N: 240391930 - Due: May 13, 2026. 2. By interview on June 16, 2026, at 1:20 pm, the LD confirmed the 2 thermometers were due for a function check.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of refrigerator temperature records, lack of corrective action documentation, and interview with the laboratory director (LD), the laboratory failed to document corrective actions for when temperatures fall outside acceptable ranges where the Invirogen Qubit dsDNA DR Assay kit was kept for 2 of 10 months (August 2025 - February 2026). Findings: 1. Observations of the laboratory on June 16, 2026, at 10:55 am revealed one box of Invirogen Qubit dsDNA DR Assay kit stored in a refrigerator with the temperature requirement of 2-8 degrees

	Celsius (C). 2. Review of refrigerator temperature records from August 2025 to February 2026 revealed the following days' temperatures were out of range in 2 months (August 2025 and Februray 2026): a. August 13, 2025 - 16.0 C. b. August 14, 2025 - 20.0 C. c. August 15, 2025 - 19.0 C. d. August 18, 2025 - 18.0 C. e. February 04, 2026 - 1.6 C. f. February 09, 2026 - 1.9 C. g. February 12, 2026 - 1.6 C. h. February 13, 2026 - 1.3 C. 3. The laboratory was unable to provide documentation of corrective action performed for the above temperatures out of range. 4. By interview on June 16, 2026 at 1:00 pm, the LD confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 laboratory standard operating procedure (SOP) review of quality assessment records, and interview with the laboratory director (LD), the LD failed to ensure quality assessment programs were maintained for 22 of 22 months. Findings: 1. The QA Program Documentation SOP, 7. General laboratory QA practices stated, "Changes to this QA program occur via discussion through emails, weekly general laboratory meeting, weekly informatics meetings and periodic CLIA lab specific meetings. 2. Review of laboratory months meeting revealed the last documented meeting was on August 5, 2024. 3. The laboratory was unable to provide documentation of the QA meeting performed from September 2024 to June 2026 (22 months). 4. On June 16, 2026, at 1:00 pm, the LD confirmed meetings were held but were not documented.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory personnel records, review of CLIA laboratory personnel report (Form CMS -209) and interview with the laboratory director (LD), 1 of 1 technical supervisor (TS) failed to meet the qualification requirements of 493.1449. Findings: Refer to D6109.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

	This STANDARD is not met as evidenced by: Based on the review of laboratory personnel records, review of CLIA laboratory personnel report (Form CMS -209) and interview with the laboratory director (LD), 1 of 1 technical supervisor (TS) failed to meet the qualification requirements of 493.1449. Findings: 1. On Form CMS 209, digitally signed by the laboratory director on June 15, 2026, at 2:40 pm, listed laboratory personnel number two as the TS. 2. Review of testing personnel records on June 16, 2026, at 10:14 am, revealed that the TS had a translated diploma that stated, "was conferred the degree of Doctor of Medical Sciences on March 23, 2010, from Kyoto University (Kyoto, Japan). 3. By interview with the LD on June 16, 2026, at 1:30 pm, the LD confirmed the TS credentials were not evaluated to determine U.S. equivalency.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the annual personnel competency assessment document and an interview with the laboratory director (LD), the technical supervisor (TS) failed to maintain 1 of 1 testing personnel's (TP)s competency assessment records. Findings Included: 1. The annual personnel competency assessment document stated, "Please attach documentation. 2. Review of the one TP's competency assessment records from 2025 and 2026 revealed a cover sheet with five of the required elements for competency assessment, but no substantiating documentation was provided of the competency assessment activities performed. 3. Further review revealed that the assessment document for the one TP did not include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for the extraction of genomic DNA from human whole blood. 4. By interview on June 16, 2026, at 1:00 pm, the LD confirmed no other documentation was attached to the competency assessment cover page and that the TP was not assessed for test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on the review of laboratory personnel records, review of CLIA laboratory personnel report (Form CMS -209) and interview with the laboratory director (LD), 1

	of 1 testing personnel (TP) failed to meet the qualification requirements of 493.1489. Findings: Refer to 6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on the review of laboratory personnel records, review of CLIA laboratory personnel report (Form CMS -209) and interview with the laboratory director (LD), 1 of 1 testing personnel (TP) failed to meet the qualification requirements of 493.1489. Findings: 1. On Form CMS 209, digitally signed by the laboratory director on June 15, 2026 at 2:40 pm, listed laboratory personnel number one as the TP. 2. Review of testing personnel records on June 16, 2026, at 10:14 am, revealed the TP had a translated diploma that stated, "has completed all the requirements of a doctor of philosophy degree field of study in Biomedical Sciences on February 8, 2011, from the Chulalongkorn University (Bangkok, Thailand). 3. By interview with the LD on June 16, 2026, at 1:30 pm, the LD confirmed the TP credentials were not evaluated to determine U.S. equivalency,