Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2093330	11/19/2020
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	The Centers for Medicare and Medicaid Services (CMS) Philadelphia Regional Office Federal Surveyor conducted an announced routine CLIA recertification survey at NIH Undiagnosed Diseases Program Clinical Laboratory on November 19, 2020. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. Specific deficiencies includes the following:
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on staff interview and lack of documentation ,the laboratory failed to verify accuracy of testing samples with proficiency testing (PT) of a non-regulated analytes. Findings include: 1.On November 19, 2020 at approximately 12:00 pm, a record review of the laboratory's (PT) records revealed an absence of documentation for (PT) for non-regulated analytes. The surveyor asked, "Does the laboratory perform verification of accuracy of test for the Qubit 3.0 Fluorometer with blind testing or split samples or another methodology". The laboratory director (LD) stated, "Nothing is available for our testing. But I'm sure we can come up with something" 2.During the exit interview with the (TS) and (LD) on November 19, 2020 at 1:00 pm confirmed the above findings.
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 the tour of the laboratory and interviews with the technical supervisor (TS) and testing person (TP), the laboratory failed to label reagents currently in use on the Flex Star automated isolation testing system with an open date and expiration date. Findings include: 1.A tour of the laboratory on November 19, 2020 at approximately 10:30 am revealed in-use reagents located on the FlexStar automated isolation testing system: FG3 FlexiGene Hydration Buffer with the no open date and expiration date on the container. 2.During an interview at 10:35 am with (TP), the surveyor asked "Are all in use reagents used for the FlexStar labeled with an open and expiration date?" The (TP) replied, "We could place a label on but we don't, just trust what I'm saying we change it so often." 3.During the exit interview with the (TS) and (LD) on November 19, 2020 at 1:00 pm confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of Thermo-Scientific NanoDrop performance verification procedures, lack of documentation and interview with testing person (TP) & technical supervisor (TS), the laboratory failed to perform and document calibration verification for the Thermo-Scientific NanoDrop One. Finding include: 1.On November 19, 2020 at approximately 11:00 am during a review of the laboratory's Thermo- Scientific NanoDrop protocols titled - S081 - Instructions NanoDrop One- "Performance Verification Check" revealed the following statements "Recommend Schedule: Every 6 months. Section Performance Check Procedure. Line 16 A Results can be exported &printed at this time or at a later time from the Data Viewer" 2.During an interview at 11:52am with the (TP), the surveyor asked for documentation for the NanoDrop performance verification checks. (TP) stated "We were logging it before, we didn't record and don't have those records." 3.During the exit interview with the (TS) and (LD) on November 19, 2020 at 1:00 pm confirmed the above findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of

	the method. This STANDARD is not met as evidenced by: Based on staff interview, review of the Thermo-Scientific NanoDrop One performance verification procedures, lack of documentation, the laboratory director (LD) failed to ensure verification performance procedures were performed for the Thermo-Scientific NanoDrop One according to the manufacture instructions. Findings Include 1. On November 19, 2020 at approximately 11:00 am, during a review of the laboratory's Thermo- Scientific NanoDrop protocols titled - S081 - Instructions NanoDrop One- "Performance Verification Check" revealed the following statements "Recommend Schedule: Every 6 months. Section Performance Check Procedure. Line 16 A Results can be exported &printed at this time or at a later time from the Data Viewer" 2. During an interview at 11:52 am with the (TP), the surveyor asked for documentation for the NanoDrop performance verification checks. (TP) stated "We were logging it before, we didn't record and don't have those records." 3. During the exit interview with the (TS) and (LD) on November 19, 2020 at 1:00 pm confirmed the above findings.