Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D2005937	**(X3) Date Survey Completed** 02/28/2024
Name of Provider or Supplier Wadsworth Center - David Axelrod Institute	**Street Address, City, State** New York State Department Of Health, Albany, NY	
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 & Medicaid Services (CMS) CLIA federal surveyors conducted an announced CLIA recertification survey at Wadsworth Center - David Axelrod Institute from February 26, 2024 to February 28, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiency were found during the announced routine CLIA recertification survey completed on February 28, 2024 at 4:00 pm.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of laboratory's written policy and procedures, lack of received specimen documentation, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to document the transportation of Cerebrospinal Fluid (CSF) specimen acceptability for the detection of Neisseria meningitidis for two of two specimens received in 2023 and 2024. Findings include: 1. On 02/27/2024, a review of "SOP MB 20 Detection of Neisseria meningitidis DNA by Real-time PCR" under "B. Specimen criteria" section, "1. Acceptable Specimens" stated, "A. CSF- at least 0.5 mL is preferred but any amount can be processed. Transport cold (4C).". 2. On 02/27/2024, a review of the laboratory's "Bacteriology Laboratory Bench Worksheet" for two CSF specimens revealed no documentation the specimens were transported cold (4C). a. Patient# 66172-01-00 specimen collected on 11/8/2023, received on 11/14/2023, and reported on 11/15/2023. b. Patient# 11334-01-00 specimen collected on

	02/20/2024, received on 02/23/2024, and reported on 02/23/2024. 3. Interview on 2/29 /2024 at 10:20 am with TS #2 confirmed the findings.
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: A. Based on the review of laboratory humidity records and interviews with laboratory staff, the laboratory failed to monitor and document humidity conditions of the Parasitology, Mycology, Virology, and Newborn Screening laboratories from 2022 to 2024. Finding Include: 1. The Cepheid Gene Xpert Quick Reference Instructions recommend the environmental operating conditions of 20-80% relative humidity. 2. The Thermo Fisher Scientific 3500 Genetic Analyzers user guide stated, Environmental requirements, operating conditions of 20% to 80% relative humidity, noncondensing. 3. The Roche Diagnostics E-plex onboard procedure under Environmental Conditions states, Relative Humidity: 15 - 85% (non-condensing). 4. The Olympus BX51/BX52 system microscope instructions, 8. operating environment states, Maximum relative humidity 80%. 5. The Abbott Alinity manufacture manual stated environmental conditions of 20% to 65% for Humidity. 6. The Abbott Architect onboard manual for performance characteristics and specifications requires a humidity between 10%-85%. 7. The Bio-Rad Variant specifications manual for operating environment requires a humidity between 10% to 90%, non-condensing. 8. The Applied Biosystems Real-Time PCR System operations manual for environmental requirements requires a humidity between 20% and 80% relative humidity, noncondensing. 9. The Perkins-Elmer/Revvity GSP system on board operations manual requires a humidity between 10% and 65% 10. From the days of the survey, February 26, 2024, to February 28, 2024, the laboratory could not provide documentation of humidity conditions monitored in the Parasitology, Mycology, Virology, and Newborn Screening laboratories from 2022 to 2024. 11. Laboratory staff confirmed humidity was not monitored or documented in the Parasitology, Mycology, Virology, and Newborn DNA Screening on February 28, 2024, around 3: 00 pm. B. Based on the review of laboratory temperature records and interviews with laboratory staff, the laboratory failed to document daily laboratory rooms, refrigerators, and freezers temperatures in the,Virology and Newborn Screening (NBS) laboratories from 2022 to 2023. Finding Include: 1. From the days of the survey, February 26, 2024, to February 28, 2024, a review of the monthly laboratory rooms, refrigerators, and freezers temperatures in the Virology and NBS DNA laboratories from 2022 to 2024 revealed, the laboratory personnel did not document temperatures during the following sampling of days in 2022 and 2023: - Viral Disease Laboratory Temperature - Room 4027: 04 of 31 days in March 2023. - Viral Disease Laboratory Temperature - Room 4025: 06 of 31 days in January 2023. 05 of 29 days in February 2023. 05 of 31 days in March 2023. 03 of 31 days in June 2023. 03 of 31 days in August 2023. 01 of 30 days in September 2023. 14 of 31 days in October 2023. 04 of 30 days in November 2023. 13 of 31 days in December 2023. -NBS/

	DNA Laboratory Temperature - Room 5009: 01 of 31 days in May 2022. 01 of 31 days in June 2022. -NBS/ DNA Laboratory Temperature - Room 5071: 01 of 31 days in May 2022. 01 of 31 days in June 2022. -NBS/ DNA Laboratory Temperature - Room 5069: 02 of 31 days in June 2022. -NBS/ DNA Laboratory Walk in Freezer- Room 5070: 01 of 31 days in April 2022. 01 of 31 days in May 2022. 01 of 31 days in June 2022. -NBS/ DNA Laboratory Walk in Refrigerator - Room 5070: 01 of 31 days in April 2022. 01 of 31 days in May 2022. 01 of 31 days in June 2022. 2. Laboratory staff confirmed the above findings on February 28, 2024, around 3:00 pm. C. Based on the laboratory's written policy and procedure, record review of refrigerator temperatures, and interview with Technical Supervisor #12 (TS #12), the laboratory failed to ensure laboratory materials for Succinylacetone (SUAC) and X-Linked Adrenoleukodystrophy (X-ALD) screening were stored as required for three of three months, Finding include: 1. On 02/28/2024, a review of the written laboratory policy and procedure for the Newborn Screening laboratory titled, "Screening for SUAC and X-ALD using Tandem Mass Spectrometry" under "3.18" stated the following for the Stock LPC IS solution, "The expiration date for this solution is up to 10 months when refrigerated at 4-8C". 2. Record review on 02/28/2024 of refrigerator records (Building room 5086) for September 2023, October 2023, and January 2024 revealed the laboratory failed to store Stock LPC IS solution (extraction solution) as required for three of three months as follows: a. September 2023 - 19 out of 20 temperature records were documented as less than 4C (days 1,6,7,8,11,12,13,14,15,18,19,20,21,22, 25,26,27,28,29). b. October 2023 - 16 out of 16 temperature records were documented as less than 4C (days 2,3,4,5,6,10,11,12,13,16,17,18,19,20,23,24). c. January 2024 - 21 out of 21 temperature records were documented as less than 4C (days 2,3,4,5,8,9,10,11,12,16,17,18,19,22,23,24,25,26,29,30,31). 3. Interview with TS #12 on 02/28/2024 at 10:26 am confirmed the findings above.
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 a review of testing personnel education qualification, and interview with the Quality Assurance (QA) Officer and Assistant QA Officer, the laboratory director failed to ensure that 1 out of 127 testing personnel performing high complexity testing had foreign education credentials that were evaluated for United States education equivalency and were qualified to perform testing. Refer to: D6171.
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 have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60

semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (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; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of testing personnel educational qualifications, and interview with the Quality Assurance (QA) Officer and Assistant QA Officer, the laboratory director failed to ensure that 1 out of 127 testing personnel performing high complexity testing had foreign education credentials that were evaluated for United States (US) education equivalency and were qualified to perform testing. Findings Include: 1. TP# 102 provided the Institute of Foreign Credential Services, Inc. General analysis evaluation report states, "US equivalency of a Doctor of Philosophy in Biosecurity".

	2. On the day of the survey, a review of TP education records revealed, that 1 out of 127 testing personnel performing high complexity testing was not qualified as TP#102 equivalency evaluation did not include a breakdown of credits earned. 3. The QA officer was given until March 7, 2024, close of business (COB) to provide additional documentation to qualifying TP#102 to perform high complexity testing. 4. On March 6, 2024 at 9:57 am the QA offer emailed a copy of a document that was not evaluated by a US education equivalency program. 5. The assistant QA officer and QA officer confirmed the findings above on February 28, 2024, at 10:00 am and did not provide documentation to qualify TP#102 to perform high complexity testing by March 7, 2024 COB.