Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2068721	**(X3) Date Survey Completed** 07/17/2024
Name of Provider or Supplier Nova Southeastern University - Inim Em Papper	**Street Address, City, State** 3321 College Ave 4th Fl Ste 490, Davie, FL	
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	An announced CLIA validation survey was conducted at Nova Southeastern University - Inim EM Papper Clinical Immunology Laboratory from 07/16/2024 to 07/17/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: -D5400 Analytic Systems. CFR 493.1250 -D6168 Testing Personnel. CFR 493.1487 -D6076 Laboratory Director. CFR 493.1445
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the Testing Personnel (TP) failed to sign attestation for Proficiency Testing (PT) for Hematology specialty off cycle event in 2023, and the TP and Laboratory Director (LD) failed to sign attestations for Infectious Disease Serology 1st event in 2024. Findings included: 1- Review of the PT off cycle event dated October 10, 2023, from College of American Pathologist (CAP) Hematology Automated Differential Survey FH9-C 2023 revealed that the TP failed to sign attestation for the off cycle event performed on 09/20/2023. 2- LD and TP failed to sign attestation on April 02, 2024 from College of American Pathologist (CAP) VR3-A Infectious Disease Serology proficiency testing event. 3- Interview on 7/16/2024 at 02:26 PM the Laboratory General Supervisor admitted there were no records of signatures.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of quality control (QC) records and interview, the laboratory failed to perform maintenance for Beckman Coulter Navios as specified by the manufacturer for three out of three years reviewed (2022, 2023 and 2024) (Refer to D5429), failed to run a positive and negative control each day testing on the Beckman Coulter Navios Flow Cytometer for two out of two years (2022 and 2023), and failed to run a negative control each testing day on the Beckman Coulter Navios Flow Cytometer for seven months (January to July 2024). Refer to D5475.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 record review and interview, the laboratory failed to perform maintenance for Beckman Coulter Navios as specified by the manufacturer for three out of three years reviewed (2022, 2023 and 2024). Findings included: 1- Filter replacement records for the Beckman Coulter Navios serial number AZ24273, were not provided for the years 2022, 2023 and 2024. 2- Review of the instrument manual PN A96247AD section 11 and laboratory procedure refer to Maintenance Log. Step 2. Filter cleaning a. Filter must be replaced every 6 months. 3- Interview on 07/16/2024 at 4:15 PM the Laboratory Office Manager stated that records would be sent via email 07/17/2024. Records for filter replaced every 6 months were not received 07/17/2024.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) records and interview, the laboratory failed to run a negative and positive control each day patient testing was performed on the Beckman Coulter Navios EX Flow Cytometer for 2 of 2 (2022 and 2023) years. Based on review of QC records and interview the laboratory failed to run a negative control each day patient testing was performed from 01/01/2024 to 07/15/2024 on the Beckman Coulter Navios EX Flow Cytometer. Findings included: 1-Review of the Navios Ex flow Cytometer records revealed that there was no positive and negative

	control run for 2022 and 2023. 2-Review of the QC records from 01/01/2024 to 07/15 /2024 revealed that no negative control were ran during this period. 3-Review of Immuno-Trols records for February, May, June and July revealed that the Immuno-Trols cells (positive controls) were used on 02/13/2024, 05/13/2024, 06/26/2024 and 07/02/2024. 4-Results review of Patient(P)#1 (tested on 06/06/2024) on the Navios revealed that no positive or negative controls were used on the testing day. 5-Results review of P#2 (tested on 07/12/2024) on the Navios revealed that no positive or negative controls were used on the testing day. 6-A total of 932 patients were tested using the Beckman Coulter Navios EX Flow Cytometers during 2022 and 2023 with no positive and negative controls. A total of 257 patients were tested on 2024 using positive controls from 01/01/2024 to 07/16/2024 once per month instead of each day of testing. 7-The laboratory evaluated the following antibodies: -CD 2 (T cell lymphocytic marker). - CD3 (T cell lymphocytic marker). - CD4 (T cell lymphocytic marker). -CD8 (T cells marker). - CD19 (B cell marker). - CD3/CD4, CD3/CD8. - CD3-/CD56+ (Natural Killer cells). 8-Based on interview on 07/16/2024 at 02:30 PM, the Laboratory Office Manager stated that they only ran a Immuno-Trols positive control once for the last seven months. The Laboratory Office Manager also confirmed that the laboratory tested P#1 and P#2 without running a positive and negative control and that the laboratory did not have an IQCP (Individualized Quality Control Plan) to run controls monthly instead of each day of testing.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that three out of four Testing Personnel (TP) performing tests in the specialty of Hematology and subspecialty of General Immunology met the requirements specified in Section 493.1425 for moderate complexity testing, they failed to have Florida State Licensure (Refer to D6064) and failed to verify the foreign Diploma for one out of four TP (Refer to D6065).
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that two out of three Testing Personnel performing tests in the specialty of Hematology and subspecialty of General Immunology met the requirements specified in Section 493.1425 for moderate complexity testing. Findings included: 1-Review of Centers for Medicare and Medicaid Services FORM 209, Laboratory Personnel (CLIA), revealed that the Laboratory Director was also the Clinical Consultant and Technical Supervisor. The laboratory listed three Testing Personnel (TP) performing high complexity testing (TP#1, TP#2 and TP#3), and one TP (TP#4) performing only

	moderate complexity testing. 2-Review of Testing Personnel records revealed that: -TP#2 had a PhD in Biology and Florida State Licensure for Microbiology but did not have Florida State Licensure for Hematology and Immunology. -TP#3 had a Bachelor of Science, but did not have Florida State Licensure. -TP#4 had a Bachelor of Science, but did not have Florida State Licensure. 3-Review of Daily Maintenance books for year 2023 and year 2024 revealed the following: TP#4, ran controls for XN-430 in June, May, April of 2024. TP#2 ran controls for XN-430 in December 2023 and signed Corrective Action for Hematology Proficiency Testing in October 2023. 4-Review of 2023 Attestations for Medical Laboratory Evaluation Proficiency Testing (PT) revealed the following: - First event: TP#2 signed for C-reactive protein (CRP) on 02/16/2023, Total serum Immunoglobulin (Ig) A, IgG and IgM. TP#3 signed Hematology and Erythrocyte Sedimentation Rate (ESR) on 02/15/2023. -Second event: TP#2 signed for CRP, IgG, IgM and IgA and Hematology on 05/31/2024 and TP#3 signed for ESR. -Third event 2023: TP#3 signed for ESR on 09/18/2022 and TP#2 signed for Hematology on 09/18/2023 and for CRP and total IgG, IgA and IgM on 09/22/2023. 5-During an interview on 07/16/2024 at 4:30 PM, the Laboratory Office Manager and Laboratory Director confirmed that the TP #2, TP#3 and TP#4 failed to have Florida State Licensure for the testing performed in the laboratory.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the education qualification (degree) for one Testing Personnel (TP) out of four. Findings included: 1-Review of FORM CMS 209 revealed that the laboratory had four TP (TP#1, TP#2, TP#3 and TP#4). 2-Review of Testing Personnel records revealed that TP#4 had a foreign diploma, and the laboratory only had a translation and failed to have the equivalence of the diploma. 3-During an interview on 07/16/2025 at 4:35 PM, the Laboratory Office Manager and Laboratory Director confirmed that the laboratory failed to verified the equivalence for the foreign diploma for TP#4.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Director and the Laboratory Office Manager, the Laboratory Director failed to ensure the laboratory was using positive and negative quality control each day of Patient testing on the Beckman Coulter Navios Flow Cytometer testing during 2022, 2023 and 2024 (Refer to D6093) and failed to ensure the laboratory had licensed Testing Personnel (Refer to D6101).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 record review and interview, the Laboratory Director failed to ensure that positive and negative quality control for General Immunology testing were performed each day of testing in 2022, 2023 and 2024. Refer to D5475.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director failed to ensure that the Testing Personnel met the education and experience requirement needed to perform high complexity testing because they failed to have Florida State Licensure to perform testing in the subspecialty of General Immunology. Refer to D6168 and D6170.
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 record review and interview, the laboratory failed to ensure that two out of three Testing Personnel performing tests in the subspecialty of General Immunology met the requirements specified in Section 493.1495 for high complexity testing. Findings included: 1-Review of Centers for Medicare and Medicaid Services FORM 209, Laboratory Personnel (CLIA), revealed that the Laboratory Director was also the Clinical Consultant and Technical Supervisor. The laboratory listed three Testing Personnel (TP) performing high complexity testing (TP#1, TP#2 and TP#3). TP#1

	was also the Laboratory General Supervisor (GS). 2-Review of Testing Personnel folders revealed that the TP#1/GS started in the laboratory on May 2024 and is in training. The previous GS left the laboratory in January 2023. 3-Review of academic records for TP#2 revealed that she had a PhD in Biological Sciences and a Florida State Licensure for Microbiology. TP#3 had a Bachelor of Science and no Florida State Licensure. 4-Review of records for Quality Controls for the Navios on 02/13 /2024, 05/13/2024, 06/2024 and 07/02/2024 revealed that the initials of the Testing personnel that performed the controls was TP#3. 5-During an interview on 07/16/2024 at 4:00 pm, the Laboratory Office Manager confirmed that TP#2 ran controls for Cell flow on the days listed above and the test for Cell flow for patient (P)#3. TP#3 ran the test for Cytokines for P#3 tested on 06/06/2024. 6-During an interview at 5:15 PM on 07/16/2024 the Laboratory Director confirmed that TP#2 and TP#3 were performing the tests, she explained that inspector from COLA the accrediting organization told them that the unlicensed personnel could perform tests under the supervision of a Licensed Technologist.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that two out of three Testing Personnel performing high complexity tests in the subspecialty of General Immunology had Florida State Licensure. Findings included: 1-Review of Centers for Medicare and Medicaid Services FORM 209, Laboratory Personnel (CLIA), revealed that the Laboratory Director was also the Clinical Consultant and Technical Supervisor. The laboratory listed three Testing Personnel (TP) performing high complexity testing (TP#1, TP#2 and TP#3). TP#1 was also the Laboratory General Supervisor (GS). 2-Review of Testing Personnel folders revealed that the TP#1/GS started in the laboratory on May 2024 and is in training. The previous GS left the laboratory in January 2023. 3-Review of academic records for TP#2 revealed that she had a PhD in Biological Sciences and a Florida State Licensure for Microbiology. TP#3 had a Bachelor of Science and no Florida State Licensure. 4-Review of records for Quality Controls for the Navios on 02/13/2024, 05/13/2024, 06 /2024 and 07/02/2024 revealed that the initials of the Testing Personnel that performed the controls was TP#3. 5-During an interview on 07/16/2024 at 4:00 pm, the Laboratory Office Manager confirmed that TP#2 ran controls for Cell flow on the days listed above and the test for Cell flow for patient (P)#3. TP#3 ran the test for Cytokines for P#3 tested on 06/06/2024. 6-During an interview at 5:15 PM on 07/16 /2024 the Laboratory Director confirmed that TP#2 and TP#3 were performing the tests, she explained that inspector from COLA the accrediting organization told them that the unlicensed personnel could perform tests under the supervision of a Licensed Technologist. 49641