Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0646416	05/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Immunology Lab Rosalind Franklin Univ	3333 Green Bay Rd, - Rfu, North Chicago, IL	

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 recertification survey was conducted on 05/27/2026. The laboratory was found to be out of compliance with the CLIA regulations (42 CFR Part 493) for the following condition-level deficiencies: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to twice annually verify the accuracy of ten of ten tests/procedures performed utilizing in-house proficiency blind testing in the subspecialties of nontransplant histocompatibility, general immunology, routine chemistry, and endocrinology reviewed in 2024 and 2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Manual", which stated, under "15. Proficiency Testing", "The laboratory does in-house proficiency blind testing for: "1. Natural Killer [NK] Cell Assay "2. [T-Helper] Th1:TH2 Cytokine ratio "3. Leukocyte Antibody Detection "4. Reproductive Immunology Phenotype "5. T-Reg[ulatory] "6. TH17 "7. Molecular Tests: Thrombophilia Panel ([Cardiovascular Disease] CVD Strip) .... "[8]. Total Iron Binding Capacity (TIBC) "[9]. Phospholipid [PL] Antibodies ... "[10]. [Erythrocyte Transketolase Activity Coefficient] ETKAC (Vitamin B1)". 2. Review of laboratory policies and procedures revealed the procedure titled "Quality Manual", which stated, under "15.1. Procedure for Analysis of Proficiency Testing Samples", "For in-house proficiency, blind samples are used. Five specimens are picked for Molecular tests. Five specimens are picked for NK Assay, Cytokine ratio, Leukocyte Antibody Detection, Reproductive Immunology

	Phenotype and T-Reg. Three specimens are picked for TH17. For TIBC, five patients are picked and run on the Vitros Chemistry analyzer. These samples are frozen until they are tested with the [College of American Pathologists] CAP Chemistry survey. For PL ..., Five PL specimens are aliqoted and frozen. The blind specimens are tested with the current workload. 3. Review of laboratory in-house proficiency blind testing revealed the laboratory failed to verify the accuracy of the above-mentioned ten tests /panels for four of four in-house proficiency blind testing events reviewed in 2024 and 2025. 4. Interview with the laboratory representative on 05/27/2026, at 3:25 pm, confirmed the laboratory failed to twice annually verify the accuracy of ten of ten tests /procedures performed utilizing in-house proficiency blind testing in the subspecialties of nontransplant histocompatibility, general immunology, routine chemistry, and endocrinology reviewed in 2024 and 2025.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to have a system in place that biannually evaluates and defines the relationship between QuantiFERON (QFT) test results on two of two automated Enzyme Linked Immunosorbent Assay (ELISA) instruments from the installation of the second ELISA instrument in October, 2024 through the date of survey, 05/27 /2026. Findings include: 1. Upon a tour of the laboratory on 05/27/2026, at 11:23 am, surveyors observed two automated ELISA instruments performing QFT testing. Instrument: Serial Number: 1) Dynex DS2 1BSA3973 2) ThunderBolt 2409-406 2. Review of laboratory policies and procedures revealed the policy titled "Quality Manual", which stated, under "11.3. Multisystem Validation", "Every 6 months a multisystem validation will be performed." 3. Review of laboratory records revealed the laboratory lacked documentation for instrument-to-instrument comparison /multisystem validation of QFT test results on two of two automated ELISA instruments. 4. Interview with the laboratory representative on 05/27/2026, at 11:29 am, confirmed the laboratory failed to have a system in place that biannually evaluates and defines the relationship between QFT test results on two of two automated ELISA instruments from the installation of the second ELISA instrument in October, 2024 through the date of survey, 05/27/2026.
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 review of the CMS-209 (Laboratory Personnel Report) Form, laboratory

	personnel educational records, and interview with the laboratory representative; the laboratory failed to ensure one of ten testing personnel met the educational requirements for high complexity testing (see 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 (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 review of the CMS-209 (Laboratory Personnel Report) Form, laboratory personnel educational records, and interview with the laboratory representative; the laboratory failed to ensure one of ten testing personnel met the educational requirements for high complexity testing. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed ten TP performing high complexity laboratory-developed tests. 2. Review of personnel educational records revealed one of ten TP (TP #8) failed to have documentation of the required minimum of six biology credit hours from an accredited institution to meet the educational requirements to qualify as a high complexity TP. 3. Interview with the laboratory representative on 05/27/2026, at 1:23 pm, confirmed the laboratory failed to ensure

	one of ten testing personnel met the educational requirements for high complexity testing.