Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0894713	12/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rnj Services Inc	35-37 Progress St, Edison, NJ	

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 proficiency testing desk review survey was performed on December 4, 2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of CASPER report 155 and graded results from the College of

	American Pathologists (CAP), the laboratory failed to achieve 80% or more in two out of three events for Endocrinology for the analyte Human Chorionic Gonadotropin (hCG). Refer to D2107.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of CASPER report 155 and graded results from the College of American Pathologists (CAP), the laboratory failed to participate in Endocrinology PT events 1 and 2 of 2024 for Human Chorionic Gonadotropin (hCG) test. The findings include: 1) hCG PT results for event 1 samples HCG-01 through 05 obtained Code 47 "No credit assigned due to absence of response". 2) hCG PT results for event 2 samples HCG-06 through 10 obtained Code 47 "No credit assigned due to absence of response". 3) A review of CASPER report 155 and CAP graded results confirmed the failure to participate in the above mentioned PT events.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER 155 report and graded results from College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance (80% or greater) for two consecutive events in the subspecialty Endocrinology for the analyte Human Chorionic Gonadotropin (hCG). The findings include: 1) A Review of the CASPER 155 report revealed the following: a) The laboratory scored 0% in event 1-2024. b) The laboratory scored 0% in event 2-2024. 2. A review of CAP graded results confirmed the aforementioned failed PT events.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the CASPER 155 report and graded results from College of American Pathologists (CAP) the Laboratory Director (LD) failed to provide overall management and direction to laboratory personnel to ensure that the Proficiency Testing (PT) surveys are performed satisfactorily and in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. The findings include: 1. The LD failed to ensure PT surveys are performed satisfactorily and in compliance with CLIA regulations. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the CASPER 155 report and graded results from College of American Pathologist (CAP) the Laboratory Director (LD) failed to ensure successful participation in a Department of Health and Human Services (DHHS) approved Proficiency Testing (PT) program for two consecutive PT events for the analyte Human Chorionic Gonadotropin (hCG), resulting in initial unsuccessful performance. Refer to D2107.