Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1034991	07/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Brigid Freyne Md Inc	39755 Murrieta Hot Springs Rd Ste F110, Murrieta, CA	

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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Rheumatoid Factor (RA) in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed total Rheumatoid Factor (RA), which is listed in the subpart I of 42 CFR part 493. b. The laboratory enrolled Diagnostic Immunology PT program with College of American Pathologists (CAP) for total RA testing. c. The laboratory failed to participate the 2018 CAP second PT event and resulted in no scores for that PT event, which was unsatisfactory RA performance for the testing event. d. The laboratory performed RA in approximately 30 patient sample each month.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) result reports by College of American Pathologists (CAP), and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to verify and ensure the accuracy of RF IgM, qual (RF); Anti-tTG IgG, qual (tTG); and Parathyroid Hormone (PTH) , CAP assigned a proficiency testing score that did not reflect laboratory test performance. The findings included: a. The laboratory performed RF and PTH testing which are not listed in the subpart I of 42 CFR part 493. b. In order to verify and ensure the accuracy of the testing, the laboratory elected to enroll with CAP PT programs to verify, at least twice annually, and ensure the accuracy of RF, rTG and PTH testing systems. c. The laboratory obtained Exception Reason Codes of [26] = Educational challenge, for RF in S-C 2018 Diagnostic Immunology for samples RF-11 thru RF-15, and for rTG in CES-A 2019 for samples CES-01 thru CES-03. d. The laboratory obtained Exception Reason Codes of [20] = No appropriate target/response cannot be graded, for PTH in Y-A 2019 Ligand-Special for samples ING-01 thru ING-03. e. The laboratory failed to address and document actions taken to verify and ensure the accuracy of RF, rTG, and PTH testing systems when the PT provider assigned a proficiency testing score that did not reflect laboratory test performance.
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: Based on review of the laboratory's temperature charts and interview with the laboratory testing personnel, it was determined that the laboratory has defined acceptable temperature ranges for proper storage of reagents, specimens, but failed to monitor its daily temperature and failed to document corrective actions when the temperature exceed outside of the acceptable temperature range. The findings included: a. The laboratory used a temperature monitor system which continue monitor the temperature conditions 24/7, and transmit and document the temperature graphically. No exact dates or times on the charts were identified. b. The laboratory established its acceptable temperature range for the refrigerated storage device between 2 to 8 Celsius degree (oC). c. One of the graphic records, "Lab Ref A", a refrigerated storage device, the temperature charts from January 24, 2019 thru July 03, 2019 indicated the majority of the temperatures (exceeded 8 oC to 15 oC) outside of the acceptable temperature range, starting approximately from mid March 2019 thru late June 2019. d. There were no remedial actions taken by the laboratory.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature charts and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to document all corrective actions taken for the equipment Lab Ref A (refrigerator) that performed outside of established operating parameters or performance specifications. The findings included: a. A temperature chart, Lab Ref A" showed majority of temperature conditions for Lab Ref A outside of the acceptable temperature between mid March 2019 and late June 2019 (see D-5413)
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) result reports and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings included: a. There are no evidence shown that the laboratory's PT reports received and reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (see D-5215)
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, and the temperature charts, and interview with the laboratory testing personnel (PT), it was

	determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Rheumatoid factors, ANA profiles and other testing systems pertaining to Rheumotiod specialty. The findings included: a. The laboratory elected to participate in CAP PT programs and failed to verify and ensure the accuracy of testing systems the laboratory performed, namely, RF, rTG, and PTH (see D-5215) b. A "Lab Ref A" storage device had shown significant deviations from the laboratory established performance specifications from mid March 2019 and late June 2019. c. The laboratory failed to take remedial actions and document (see D-5413 and D-5781)
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature charts and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented when significant deviations from the laboratory established performance specifications were identified. The findings included: a. A "Lab Ref A" storage device had shown significant deviations of temperatures (between 8 oC to 15 oC) from the laboratory established performance specifications (acceptable between 2 oC to 8 oC) starting mid March 2019 to late June 2019 and on the date of survey. b. The laboratory failed to take remedial actions and document (see D-5413 and D-5781)