Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1034991	11/15/2021
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature monitoring records, observation of the refrigerator condition, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory failed to select a test system (a temperature monitoring device) and failed to perform following the manufacture's instruction or in a manner that provided test results (temperature control) within the laboratory's stated performance specifications, and failed to ensure the reliability of the storage temperature conditions to maintain the quality of the reagents and the patient samples in the refrigerator. The findings included: a. The laboratory has established the acceptable temperature range for storing the laboratory reagents and/or the patient samples in a refrigerator between 2 to 8 degree Celsius. b. The laboratory elected to use Lacos system, an Internet thumb drive recording, continuous monitoring the temperature of the refrigerator which stores the reagents and/or the patient samples. c. Review of the laboratory's continuous monitoring temperature records from Jan 01, 2021 thru Nov.7, 2021, . d. The temperature conditions was recorded and indicated by each week column and continuous drawing graphic. e. Between Feb 7 and Feb 13, the temperatures in the refrigerator were recorded outside of 8 oC. f. Between May 15 and May 22 the temperature records exceeded 8 oC and reached to 18 oC. g. Between June 12 and June 26 the temperature records exceeded 8 oC and reached beyond 12 oC. i. Between July 18 and July 26 the temperature records exceeded 8 oC and stayed above 10 oC for a week. j. Many more records indicated the

	temperature inside the refrigerator were out of the acceptable temperature and no corrective actions were taken.
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 monitoring records, observation of the refrigerator conditions, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when the temperature conditions did not meet the laboratory's established performance specifications including the equipment (the temperature monitoring system) that perform outside of established operating parameters or performance specifications; The findings included: a. The laboratory has established the acceptable temperature range for storing the laboratory reagents and/or the patient samples in a refrigerator between 2 to 8 degree Celsius. b. The laboratory elected to use Lacos system, an Internet thumb drive recording, continuous monitoring the temperature of the refrigerator which stores the reagents and/or the patient samples. c. Review of the laboratory's continuous monitoring temperature records from Jan 01, 2021 thru Nov.7, 2021 and more, d. The laboratory failed to document all corrective actions taken. e. The laboratory testing personnel and the laboratory director affirmed (11/19/2021 @ 12:30 pm) that they were aware of the out-of-control temperature conditions of the refrigerator, see D-5411
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature monitoring records, observation of the refrigerator condition, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory failed to establish the quality assessment including a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. The findings included: a. The laboratory has established the

	acceptable temperature range for storing the laboratory reagents and/or the patient samples in a refrigerator between 2 to 8 degree Celsius. b. The laboratory elected to use Lacos system, an Internet thumb drive recording, continuous monitoring the temperature of the refrigerator which stores the reagents and/or the patient samples. c. Review of the laboratory's continuous monitoring temperature records from Jan 01, 2021 thru Nov.7, 2021, . d. The temperature conditions were noted outside of the acceptable temperature ranges (2 to 8 oC) frequently. e. The laboratory failed to establish a quality assessment including a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate, see D-5411 and D-5781
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of the laboratory's temperature monitoring records, observation of the refrigerator condition, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory has established the acceptable temperature range for storing the laboratory reagents and/or the patient samples in a refrigerator between 2 to 8 degree Celsius. b. The laboratory elected to use Lacos system, an Internet thumb drive recording, continuous monitoring the temperature of the refrigerator which stores the reagents and/or the patient samples. c. Review of the laboratory's continuous monitoring temperature records from Jan 01, 2021 thru Nov.7, 2021. d. The laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur, see D-5411
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 temperature monitoring records, observation of the refrigerator condition, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory has established the acceptable temperature range for storing the laboratory reagents and/or the patient samples in a refrigerator between 2 to 8 degree Celsius. b. Review of the laboratory's continuous

	monitoring temperature records from Jan 01, 2021 thru Nov.7, 2021. c. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system, see D-5793.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature monitoring records, observation of the refrigerator condition, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. The findings included: a. The laboratory has established the acceptable temperature range for storing the laboratory reagents and/or the patient samples in a refrigerator between 2 to 8 degree Celsius. b. Review of the laboratory's continuous monitoring temperature records from Jan 01, 2021 thru Nov.7, 2021. c. The laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics were identified, see D-5781