Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1048272	06/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
North-West Pathology C S P	Carr Pr 2 Km 47 Bo Cotto Norte, Manati, PR	

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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: 1. Based on Quality Assessment (QA) written procedures review , annual statistical laboratory review (October 2016 to May 2018) and laboratory director interview on June 1, 2018 at 1:30 P.M., it was determined that the laboratory failed to follow written procedures when evaluate Fine needle aspiration (FNA) and Non- Gyn cases. The findings include: a. The laboratory director stated on June 1, 2018 that under the QA program the laboratory must review and document, every month, the FNA cases and Non-Gynecologic cytology cases by diagnosis. b. Review of the QA program showed that the laboratory did not to review not document the FNA cases and Non-Gynecologic cytology cases by diagnosis every month since October 2016. c. The laboratory director confirmed on June 1, 2018, that the laboratory failed to review and document the evaluation of the FNA cases and Non-Gynecologic cytology cases by diagnosis every month since October 2016. 2. Based on Quality Assessment (QA) written procedures, quality assessment records review (October 2016 to May 2018) and laboratory director interview on June 1, 2018 at 12:30 P. M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: a. The laboratory QA written procedures establishes that the laboratory must document and review the 100 % of the cases with malignancy each month. b. Review of the quality assessment records showed that the last review to the cases with malignancy was performed in October 2016. c. The laboratory director confirmed on June 1, 2018 at 1:00 P.M. that the laboratory failed to document the evaluation of the cases with

	malignancy monthly. 3. Based on review of quality assessment (QA) written procedures, quality assessment records review (October 2016 to May 2018) and laboratory director interview on June 1, 2018 at 12:30 P.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate inconsistencies between clinical diagnostics and Pathologist review. The findings include: a. The QA written procedures stated that the laboratory monitor and evaluate inconsistencies between clinical diagnostics and Pathologist review every month . b. The quality assessment records showed that the laboratory did not evaluate nor document any test inconsistencies between clinical diagnostics and Pathologist review since December 2016. c. The laboratory director confirmed on June 1, 2018 at 12: 45 A.M. that information regarding test inconsistencies were not evaluated as established in the QA written procedures since year 2016.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment (QA) written procedures, quality assessment records review (October 2016 to May 2018) and laboratory director interview on June 1, 2018 at 12:30 P. M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems. The findings include: a. The QA written procedures establishes that the laboratory must evaluate , document and review every month the accuracy in the diagnostics and turn around time of frozen sections and sentinel node. b. Review of the quality assessment records showed that the last review to the performance of frozen sections and sentinel node was performed in December 2016. c. The laboratory director confirmed on June 1, 2018 at 1:00 P.M. that the laboratory failed to document the evaluation of the performance of frozen sections and sentinel node since January 2017. .
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 Quality Assessment (QA) records review and laboratory director interview on June 1, 2018 at 1:30 PM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for analytic and postanalytic systems. 2. The laboratory director confirmed on June 1, 2018 at 1:30 P.M., that the laboratory failed to evaluate the established Quality Assessment Program since year 2016. Refer to D5791 and D5891.