

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D1048272	<b>(X3) Date Survey Completed</b> 05/03/2022
<b>Name of Provider or Supplier</b> North-West Pathology C S P	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5032</b>	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review cytology procedure manual, pathologist cytology monthly workload report and cytotechnologist monthly workload (years 2021 and 2022), interview with the laboratory histotechnologist and laboratory staff who transcribe results, it was determined that the laboratory failed to be in compliance with the analytic system requirements of cytology non gynecologic slides examination from January 1, 2021 to March 30, 2022. Refer to D 5637 (May 3, 2022 at 10:45 am, the laboratory did not reassess the workload limits each 6 months for the cytology non gynecologic slides examination from January 1, 2021 to March 30, 2022. Refer to D 5639 (May 3, 2022 at 10:55 am, the laboratory failed to establish and follow written procedures to ensure that the maximum number of slide examined by an individual each 24-hour period does not exceed the workload limits).</p>
<b>D5637</b>	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: 1. Based on review of cytology procedure manual and interview with the</p>

histotechnologist, it was found that the laboratory did not have written procedures to monitor and evaluate the workload limits. The findings include: a. On May 3, 2022 at 10:55 AM, reviewed the the cytology procedures manual showed that the laboratory did not have a protocol to establish a maximum workload limit for nongynecologic specimens nor a protocol to reassess the individuals workload limit at least every 6 months and adjusted when necessary. b. The histotechnologist confirmed on May 3, 2022 at 11:10 am, that the cytology procedures manual did not include any reference about how to evaluate the workload limit. 2. Based on review of Pathologist cytology monthly work load report, monthly report by cytotechnologist, lack of Workload limits protocol and interview with the histotechnologist, it was determined that the laboratory did not reassess the workload limits each 6 months from January 12, 2021 to March 30, 2022. The findings include: a. On May 3, 2022 at 10:45 AM, review of Pathologist cytology monthly work load report and monthly report by cytotechnologist workload showed that the laboratory performed non-gynecologic slide screened from January 12, 2021 to March 30, 2022. b. On May 3, 2022 at 11:00 AM, the laboratory did not have records to showed that it reassess the Pathologist and the cytotechnologist workload limit at least every 6 months and adjusted when necessary from January 12, 2021 to March 30, 2022. c. On May 3, 2022 at 11:10, the histotechnologist confirmed that the laboratory did not have a protocol to establish the workload limit nor a protocol to reassess the workload limit for non-gyn cytology screen specimens. d. The laboratory processed the 1,254 nongynecologic cytology cases from January 12, 2021 to March 30, 2022.

**D5639**

**CYTOLOGY**  
CFR(s): 493.1274(d)(2)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:  
Based on review cytology procedure manual, pathologist cytology monthly workload report (years 2021 and 2022), interview with the laboratory histotechnologist and laboratory staff who transcribe results, it was determined that the laboratory failed to establish and follow written procedures to ensure that the maximum number of slide examined by an individual each 24-hour period does not exceed the workload limits from January 1, 2021 to March 30, 2022. The findings includes: 1. The laboratory performed nongynecologic cytology slide examination. 2. On May 3, 2022 at 10:50 AM, the pathologist cytology monthly workload report showed the following inconsistencies between the total slides screened and the total of hours spent evaluating the slides from January 12, 2021 to March 30, 2022: a. Review of the documentation showed that on the following days the total slides screened, exceeded the 12.5 slide per hours: Year Month Days 2021 January 12, 14, 18, 28. 2021 February 1,8,9,16, 19 2021 March 9,10,16,18,22,23 2021 April 8, 12, 15, 16, 25 2021 May 14, 17, 26 2021 June 16, 17, 24 2021 July 9, 12, 13, 14, 19 2021 August 9,10,11,16,18,19,20 2021 September 1, 7 2021 October 5, 11, 15, 27, 29 2021 November 2 2021 December 1, 3, 21, 30 2022 January 11, 19, 20, 28 2022 February 21, 22, 24 2022 March 1, 8 Total 69 days b. Review of the documentation showed that

on the following days the personnel in charge of slide evaluation exceeded the eight hours (8) period of time: Date Total Hours spent evaluating slides 1/25/2021 27.5 2/16/2021 12.75 2/25/2021 8.75 3/15/2021 9.00 3/17/2021 8.5 3/31/2021 9.5 4/14/2021 8.5 4/21/2021 15.0 5/06/2021 8.5 5/10/2021 11 6/07/2021 13.75 6/10/2021 10 6/14/2021 9.5 6/29/2021 10.5 8/05/2021 10.75 8/25/2021 10.75 9/20/2021 8.25 10/04/2021 11.0 10/08/2021 18.5 10/13/2021 15.75 10/18/2021 10.25 10/28/2021 8.75 11/10/2021 13.25 11/11/2021 15. 01/07/2022 9.75 01/24/2022 21.5 02/02/2022 10.25 02/09/2022 8.25 02/10/2022 10.25 02/23/2022 10.0 03/02/2022 8.5 03/07/2022 10.5 03/17/2022 11.25 03/21/2022 9.0 03/28/2022 8.25 03/30/2022 16.00 Total 48 days. 3. On May 3, 2022 at 11:00 AM, the laboratory histotechnologist stated that the laboratory staff, who perform the pathologist cytologist monthly workload reports is the personnel who transcript the laboratory results. 4. During the interview on May 3, 2022 at 11:05 AM, with the personnel in charge of the monthly workload reports stated the following: a. That the laboratory did not have a written protocol. b. That the cytology manual did include a table to calculate the workload limit based on individual screening of 100 cytoslides in eight (8) hours. The table showed the maximum number of slide examined by hours from one (1) to eight (8) hours. c. She stated that in order to calculated the workload every month, she adds the total workload limit she adds the total number of fine needle aspiration (FNA) cases, the total number of nongyn cases to the total slides screened by specimens. This represents the total of slides examined. d. Then, she used the workload limit table to calculated the total hours spent in the slides evaluation. e. She also stated that the total slides screened by specimens, by day, may include smears that were screened in different days. 5. The laboratory processed the 1254 nongynecologic cytology cases from January 12, 2021 to March 30, 2022.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review cytology procedure manual, pathologist cytology monthly workload report and cytotechnologist monthly workload (years 2021 and 2022), interview with the laboratory histotechnologist and laboratory staff who transcribe results, it was determined that the laboratory director failed to establish and follow written procedures to ensure that the maximum number of slide examined by an individual each 24-hour period does not exceed the workload limits from January 1, 2021 to March 30, 2022. Refer to D 6093 (May 3, 2022, 10:55 am, the laboratory director failed to establish workload limits written procedures).

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 cytology procedure manual, pathologist cytology monthly workload report and cytotechnologist monthly workload (years 2021 and 2022), interview with the laboratory histotechnologist and laboratory staff who transcribe results, it was determined that the laboratory director failed to establish and follow written procedures to ensure that the maximum number of slide examined by an individual each 24-hour period does not exceed the workload limits from January 1, 2021 to March 30, 2022. Refer to D 5032 (May 3, 2022 at 10:45 am and 10:55 am, the laboratory failed to compliance with the analytic system requirements of cytology non gynecologic slides examination from January 1, 2021 to March 30, 2022).