

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0914253	<b>(X3) Date Survey Completed</b>  08/03/2018
<b>Name of Provider or Supplier</b>  Centro Citopatologico Del Caribe	<b>Street Address, City, State</b>  500 Ave Munoz Rivera Cond El Centro Local 21, San Juan, 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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on American Society for Clinical Pathology (ASCP) cytology gynecologic (Gyn) proficiency testing records(year 2016) review, lack of Gyn proficiency testing records (years 2017 and 2018), cytotechnologist workload reassessment documentation records (years 2017 and 2018) records review and interview with the cytotechnologist #1 on August 3, 2018 at 8:50 AM, it was determined that the laboratory failed to enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS for Gyn cytology smear examination during the years 2017 and from January 2018 to August 3, 2018. The findings include:</p> <ol style="list-style-type: none"> <li>1. The laboratory did not have evidence for the enrollment of the Gyn proficiency testing for the years 2017 and 2018 for the 4 cytotechnologist, laboratory director and technical supervisor. The last ASCP Gyn Proficiency testing records showed that the</li> <li>2. The cytotechnologist workload reassessment documentation records showed the following: a. 4 out of 4 cytotechnologist examined Gyn cytology cases during the following months of the year 2017: January, February, March, May, June, July, August, September, November and December. b. 1 out of 4 cytotechnologist examined Gyn cytology cases during the following months of the year 2018: January,</li> </ol>

February, March, May, June and July. c. 1 out of 4 cytotechnologist examined Gyn cytology cases during the following days in May 2018: 25, 28, 30 and 31. 3. The cytotechnologist #1 confirmed on August 3, 2018 at 8:50 AM, that the laboratory did not participate for the Gyn proficiency testing during the year 2017 and from January 2018 to August 3, 2018.

**D5305**

**TEST REQUEST**  
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on Papanicolaou (PAP) smears requisition records (December 2017) review and cytotechnologist # 1 on August 3, 2018 at 10:12 AM, it was determined that the laboratory failed to ensure that 6 out 20 PAP smear requisitions include the require information. The findings include: 1. The PAP smears requisition records (December 2017) showed that 6 out of 20 PAP smear requisitions did not include the require information: a. The 2 out of 20 PAP smear requisitions did not include the last menstrual period: requisitions # 1834 and # 0901. b. The 4 out of 20 PAP smear requisitions did not include clinical historic: requisitions # 2211, # 093, #1834 and # 0901. 2. The cytotechnologist # 1 confirmed on August 3, 2018 at 10:12 AM, that those PAP smear requisitions did not include the require information.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on Hood cabinet preventive maintenance records and cytotechnologist # 1 interview on August 3,2018 at 11:30 AM, it was determined that the laboratory failed to perform the annual Hood cabinet maintenance procedures since March 28, 2018. The findings include: 1. The Hood Cabinet preventive maintenance records showed that the annual preventive maintenance of the Hood Carbonate was due on March 27, 2018: ISO-14644, Integrity and Velocity tests. 2. The cytotechnologist # 1 confirmed on August 3,2018 at 11:30 AM, that the annual Hood cabinet maintenance was due on March 27, 2018.

**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 American Society for Clinical Pathology (ASCP) cytology gynecologic (Gyn) proficiency testing records(year 2016) review, lack of Gyn proficiency testing records (years 2017 and 2018), cytotechnologist workload reassessment documentation records (years 2017 and 2018) records review and interview with the cytotechnologist #1 on August 3, 2018 at 8:50 AM, it was determined that the laboratory director failed to ensure that the laboratory is enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS for Gyn cytology smear examination during the years 2017 and from January 2018 to August 3, 2018. Refer to D 2000.

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on Hood cabinet preventive maintenance records and cytotechnologist # 1 interview on August 3,2018 at 11:30 AM, it was determined that the technical supervisor failed to ensure compliance with the analytic system requirements. Refer to D 5429 (The laboratory failed to perform the annual Hood cabinet maintenance procedures since March 28, 2018).