Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0888671	03/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cmg Pathology Laboratory	San Juan Health Centre De Diego 150, Santurce, 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
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 Pap smears requisition records (March 2019) review and laboratory director (cytology supervisor) interview on March 19, 2019 at 10:45 AM, it was determined that the laboratory failed to ensure that 10 out 13 Pap smears requisitions had the require information. The findings include: 1. Thirteen (13) Pap smears test requisitions from March 7, 2019 to March 14, 2019 were reviewed on March 19, 2019 at 10:45 AM. 2. The following Pap smears test requisitions did not include information about the last menstrual period: C 19-0064, C 19-0065, TP 19-0504, TP 19-505, TP 19-0475, TP 19-0530, C 19-0066, C 19-0067, TP 19-0534 and TP 19-0522. 2. The laboratory director (cytology supervisor) confirmed on March 19, 2019 at 10:45 AM, that those Pap smears test requisitions did include the information about the patient last menstrual period.

D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on histopathology (special stains) quality control records review from May 26, 2017 to March 12, 2019 and laboratory director interview on March 19, 2019 at 10:34 AM, it was determined that the laboratory did not document the lot numbers nor expiration date of the staining reagents used for the special stains since May 26, 2017. The findings include: 1. The special stains (Periodic Acid Schiff (PAS), Acid Fast Stain (AFB), Quick Stain, Grocott Methenamine Silver (GMS) quality control log sheet from May 26, 2017 to March 12, 2019 were reviewed on May 26, 2017 at 10:34 AM. 2. None of the quality control logs included any information regarding lot number used nor the reagents expiration dates. 3. The laboratory director stated that the following stains were performed: Periodic Acid Schiff (PAS), Acid Fast Stain (AFB), Quick Stain, Grocott Methenamine Silver (GMS) from May 26, 2017 to March 12, 2019. 4. The laboratory director stated during interview that the information about lot number used and expiration dates were not documented. 5. The laboratory performed 153 special stains from May 26, 2017 to March 12, 2019. .
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 histopathology quality control log records review and laboratory director interview on March 19, 2019 at 10:45 am, it was determined that the laboratory director did not ensure that the information about lot number and expiration dates of the staining reagents were included in the quality control records logs. The finding includes: 1. Review of histopathology quality control records review from May 26, 2017 to March 12, 2019 did not include any information about the staining reagents lot numbers nor their expiration dates. Refer to D5609.