Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0958702	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Moretti & Racco Medical Associates, Pc	1870 Richmond Road, Staten Island, NY	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the proficiency test verification records and an interview with the laboratory director, the laboratory failed to perform verification of accuracy for the interpretation of FISH images and Cytology slide interpretations. Findings Include: On January 15, 2019, at approximately 12:45 PM the laboratory director confirmed that the laboratory failed to perform twice annual verification for FISH images and Cytology slide interpretation from March 2017 through the date of this survey. Approximately 600 patient specimens were tested and reported for FISH and Cytology slide testing during this time.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial

	lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on a review of cytology procedures and confirmed by the laboratory director in an interview on January 15, 2019, at approximately 12:30 pm, the laboratory failed to established policies and procedures for a program to evaluate and compare the laboratory statistics annually to detect errors in the performance of cytological examinations and reporting results. The procedure must include: 1. Cytology cases examined; 2. Specimens processed by specimen type; 3. Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation).
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on a review of urine cytology procedures and confirmed by the laboratory director in an interview on January 15, 2019, at approximately 12:30 pm, the laboratory failed to establish written policies and procedures for workload limits for the individual examining slides in less than an 8-hour workday.
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 a review of procedures and an interview with the laboratory director, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5217, D5629 and D5641.