Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0649765	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oral Pathology Consultants	650 West Baltimore Street 7 North, Baltimore, MD	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory (lab) director, the lab did not establish written policies to ensure problems identified during the pre testing phase and accessioning of patient specimens are corrected to ensure positive patient identification and did not provide documentation of corrective actions taken. Findings: 1. The reference lab performing the technical component, submitted a mislabeled slide for microscopic examination (histology) testing to the lab. The problem was documented in the 2018 quality assurance record. The middle two numbers in the four digit identification were transposed. The description of the labs corrective action was incomplete as the date, time and name of the individual contacted in the reference lab to correct the error was not documented; and 2. During interview with the lab director on the day of survey, the lab director stated that the histology lab did not contact offices submitting patient specimens in unlabeled containers, even though this would allow the office to check their records and if needed declare to the lab that the patient in question did not have a biopsy performed. The lab should document the date, time, purpose of the call, along with who called and who was spoken to.
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 interview with the laboratory (lab) director, the lab did not have a written policy and records showing the number of cytology cases examined each year, including a description of the specimen types and patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation. This was confirmed during interview with the lab director on the day of survey.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory (lab) director, the laboratory final report did not include the name and address of the laboratory location where the technical component (tissue grossing) was performed. Findings: 1. Recently a reference lab began performing the technical component of the histology/cytology testing; and 2. The lab final reports did not include the name and address of the laboratory location where the technical component was performed and this was confirmed during interview with the director on the day of survey.