Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0903558	02/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Clinical Labs Inc	800 Business Center Drive, Horsham, PA	

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
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 the review of written policies and procedures, review of laboratory records, and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of two of three required statistics for nongynecologic specimens in 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure to evaluate two required statistics for nongynecologic specimens in 2017 and 2018. a. The number of specimens processed by specimen type; b. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. The Survey Team requested and the laboratory failed to provide an annual statistical evaluation for two required statistics for nongynecologic specimens in 2017 and 2018. a. The number of specimens processed by specimen type; b. The number of patient cases reported by diagnosis, to include unsatisfactory. 3. The Laboratory Director and Cytology Supervisor confirmed these findings during an interview on 2/12/19 at 4:00 PM.

D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of written policies and procedures and the review of 1504 gynecologic cytology cases (1545 slides) from January and February 2019 it was determined that the laboratory failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The laboratory failed to follow the procedure titled CRITERIA FOR PAP ADEQUACY AND ENDOCERVICAL COMPONENT POLICY which stated: "Set a minimum limit of 5,000 well visualized /preserved squamous cells for LBP (liquid based preparation)." 2. The laboratory failed to identify and report six of fourteen gynecologic ThinPrep Pap Tests from January and February 2019 as being "Unsatisfactory for Evaluation." Cases include: -HC190022465 -HC190020776 -HC190021164 -HC190026117 -HC190024574 -HC190022970 3. These findings were reviewed and confirmed by the Survey Team Pathologist on 2/15/19 at 8:00 AM.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of 1289 routine negative gynecologic cases (1325 slides) from January 2019 and February 2019 and confirmation by the Survey Team Pathologist on February 15, 2019 at 8:00 AM it was determined that the Technical Supervisor failed to verify the accuracy of eleven gynecologic tests. 1. HC190026065 2/4/19 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High-Grade Squamous Intraepithelial Lesion 2. HC190017354 2/4/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High-Grade Squamous Intraepithelial Lesion 3. HC190026229 2/4/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 4. HC19000252 1/8/19 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 5. HC190014690 2/1/19 I-TPPT LABORATORY DIAGNOSIS: Unable to provide interpretation due to unsatisfactory specimen adequacy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 6. HC190022465 2/1/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for

	Interpretation Scant cellularity and obscuring blood 7. HC190020776 2/2/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Lubricant 8. HC190021164 2/6/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant cellularity 9. HC190026177 2/4 /19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant cellularity and obscuring inflammation 10. HC190024574 2/6/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant cellularity and obscuring inflammation 11. HC190022970 2/6/19 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant cellularity
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.