Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2091356	12/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Akrivia Pathology	36 Townsend Drive, Florham Park, NJ	

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 surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure which included number of cytology cases examined, specimens processed by type and patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) from 1/23/17 to the date of the survey. The LD confirmed on 12/19/18 at 1:30 pm the laboratory did not have the above procedure.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

	This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual (PM), review of laboratory records, and interview with the Technical Supervisor (TS)/Laboratory Director (LD), the laboratory failed to establish written policies or procedures to ensure that the TS established a maximum workload limit for three of three TS who performed the primary screening of cytology specimens from 1/23/17 to the date of the survey. The TS/LD confirmed on 12/19/18 at 1:45 pm that there were no written procedures to establish individual workload limits and no workload limits established by the TS/LD.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual (PM), review of laboratory records, and interviews with the Laboratory Director (LD), the laboratory failed to a establish written procedure to ensure that the workload limit is reassessed at least every 6 months and adjusted when necessary from 1/23/17 to the date of the survey. The LD confirmed on 12/19/18 at 1:40 pm the above procedure was not established.
D5639	CYTOLOGY CFR(s): 493.1274(d)(2)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure which ensures the maximum number of slides read in an 8 hour period does not exceed 100 regardless of the location from 1/23/17 to the date of the survey. The LD confirmed on 12/19/18 at 1:15 pm the laboratory did not establish the above procedure.