Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2025193	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Associated Pathologists, Llc Dba Pathgroup	3700 South Main Street, Blacksburg, VA	

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
D0000	An announced CLIA Recertification survey was conducted at Associated Pathologists on May 1, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 record review, lack of documentation, policy and procedures (P&P), and interview with the laboratory director, the laboratory failed to follow the established policy of reassessing the workload limits every six (6) months for eighteen (18) of the twenty-four (24) months reviewed. Findings include: 1. Record review of the reassessments of the workload limits revealed lack of documentation from July 31, 2017 and up to the date of survey on May 1, 2019. The inspector requested to review the reassessment documentation of the workload limits. The documentation was not available for review. 2. Review of the P&P "Assessing Maximum Workload Limits" (signed by the lab director on 5/24/2018) revealed the following statement: "Workload maximum limits for each individual primary screener must be reassessed at least every six months." 3. An interview with the laboratory director at approximately 12: 40 PM confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, policy and procedures (P&P), and interview with the laboratory director, the laboratory failed to follow the established policy of performing and documenting the review of the monthly Quality Assurance Reports for twenty-four (24) of the twenty-four (24) months reviewed. Record review included calendar years 2017 and 2018. Findings include: 1. Record review of the available "Pathologist QA/QC Cumulative QA Summary" reports revealed a lack of documentation for the calendar years 2017 and 2018. The inspector requested to review the reports. The reports were pulled from the Pathsys Laboratory Information System (LIS) at the date of survey on May 1, 2019. 2. Review of the P&P "Quality Assurance Program in Surgical and Cytopathology" (signed by the lab director on 5/24 /2018) revealed the following statement: "M. Monthy departmental QA reports will be written by the director of Pathology or designee. These will be signed by the Director of Pathology and distributed to all pathologists for comments. These will be reported to the appropriate hospital committee and available QA and credentialing purpose within the department and hospital." 3. An interview with the laboratory director at approximately 12:40 PM confirmed the findings.