Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659922	06/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Assocs Of North Texas Pa	1209 Brook Avenue, Wichita Falls, TX	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Observations, review of the manufacturer's instructions for use and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions for storing patient specimens after testing using the Aptima Assays for Trichomonas, HPV and Combo 2. The findings included: 1. Observations made during the inspection found 10 test tube racks filled with previously tested specimens in the refrigerator. 2. Review of the Aptima manufacturer's instructions Trichomonas, HPV and Combo 2 Assays found under the heading Specimen Collection and Storage: " Specimen storage after testing: 1. Specimens that have been assayed must be stored upright in a rack. 2. The specimen transport tubes should be covered with a new, clean plastic film or foil barrier." 3. Interview of testing personnel conducted on June 13, 2019 at 10:59 AM confirmed that the laboratory stored patient specimens previously tested for the Aptima Assays for Trichomonas, HPV and Combo 2 in the refrigerator for 30 days without covering with a new barrier.
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: Review of the CMS Form-209 Laboratory Personnel Report, policies and procedures, cytotechnologists workload records from 2017 and 2018, and interview of facility personnel found that the laboratory failed to reassess individual workload limits at least every 6 months for all testing personnel involved in cytology testing. The findings included: 1. Review of the CMS Form-209 Laboratory Personnel Report found the Laboratory Listed 2 Cytotechnologists as performing Anatomic Pathology procedures. 2. Review of policies and procedures revealed that the laboratory had established procedures for reassessing workload limits at least every 6 months. 3. Review of 2017 and 2018 six-month workload records for cytologist one (as listed on Form CMS-209) revealed that her workload had been evaluated as follows: January 3, 2017 July 6, 2017 February 21, 2018 There was no second (6-month) evaluation of workload for 2018 available for review. 4. Review of 2017 six-month workload records for cytologist two (as listed on Form CMS-209) revealed that his workload had been evaluated as follows: January 3, 2017 There was no second (6-month) evaluation of workload for 2017 available for review. 5. Interview of general supervisor two (as listed on Form CMS-209) conducted on June 13, 2019 at 11:15 hours confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services