

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2147408	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Advanced Pathology	Street Address, City, State 4208 Sw Lee Blvd, Lawton, OK	
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	The initial certification survey was performed 07/17/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory supervisor, and histotechnician at the conclusion of the survey.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, histotechnician, and the laboratory director, the laboratory failed to perform maintenance procedures as defined by the manufacturer, with at least the frequency required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor, the laboratory performed non-gynecologic cytology testing on samples submitted for processing, staining, microscopic examination and interpretation for diagnosis. Examples of samples types received for testing included the following: (a) Body fluids-pleural, ascites, synovial, urine (b) Fine needle aspirates (c) Brushings/washings-bronchial, esophageal, pelvic, abdominal (d) Sparsley cellular fluids-Cerebral spinal fluid, bladder washings (2) The laboratory director stated to the surveyor low volume samples and fluids with low numbers of cellular components, were concentrated by centrifugation using the CytoTek Centrifuge. The surveyor reviewed the manufacturer's instructions for the cytocentrifuge. The manufacturer required the following maintenance procedures: (a) Daily Maintenance: (i) "Wipe the external instrument surfaces with a clean cloth moistened with neutral detergent. Pat dry any excessively moist areas;" (ii) "Wipe the motor bowl vigorously with a cloth wet with</p>

disinfecting solution. Then, clean the rotor bowl by wiping with a clean cloth moistened with neutral detergent. Disconnect the drain hose at the rear of the instrument, and place a drain pan under the drain port of the instrument. Thoroughly rinse the rotor bowl with clear water. Completely dry the rotor bowl with clean, lint-free cloths;" (iii) "CAUTION: Do not use excessive quantities of fluid when cleaning the rotor bowl, as V-rings are not intended to provide a leak-proof seal." (b) Periodic Maintenance: (i) "At least once weekly, clean the rotor. It can be soaked in a chlorhexidene hydrochloride solution (5%) or a sodium hypochlorite solution (5% or less), then soaked in a neutral detergent solution. Complete the cleansing by rinsing with clear water, then drying thoroughly;" (ii) "CAUTION: If infectious specimens have been processed, the rotor must be autoclaved at a temperature of 250 degrees F (121 degrees C)." (ii) "Examine lid for seal cracks or signs of deterioration. Replace the seal if cracks or fatigue is evident. See Section 6 for service information." (c) 3-month Maintenance: (i) "Remove the V-ring and grease (with the Super Lube grease) the skirt (the bottom edge of the V-ring);" (ii) "Lift the lip of the lid seal packing, wipe with a cloth wet with disinfection solution as required to remove dirt. To prevent lodging of dirt in the gaps after cleaning, apply grease (SuperLube) to the edge of the guard bowl." (3) The surveyor then reviewed maintenance records from 01/01/18 through 05/31/19. There was no documentation the manufacturer's required maintenance procedures listed above had been performed on the CytoTek centrifuge; (4) The surveyor reviewed the manufacturer's maintenance requirements with the laboratory supervisor and the histotechnician and asked if the daily, weekly, and 3-month maintenance procedures had been performed as required. The laboratory supervisor and the histotechnician stated to the surveyor the manufacturer's maintenance procedures listed above had not been performed.