

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0469942	(X3) Date Survey Completed 11/20/2018
Name of Provider or Supplier Pathology Consultation Services Inc	Street Address, City, State 501 Alameda, Suite B, Norman, 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 survey was performed on 11/20/18. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the cytotechnologist at the conclusion of the survey.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the cytotechnologist, the laboratory failed to ensure the manufacturer's environmental specifications were met for the instruments used in the laboratory. Findings include: HUMIDITY (1) At the beginning of the survey, the cytotechnologist stated to the surveyor the laboratory performed histology and cytology testing; (2) The surveyor reviewed the manufacturer's humidity specifications for the instruments used to process the samples received for testing: (a) Thin Prep 2000: Used to prepare patient Pap smears for screening. The manufacturer required a humidity of 20-90%; (b) Cellient Automated Cell Block System: Used for automated filtration and preparation of sample cell blocks. The manufacturer required a humidity of 20-80%; (c) Thin Prep Imaging System: The computerized analysis system used to read ThinPrep smears. The manufacturer required a humidity of 20-80%. (3) The surveyor then reviewed the humidity records from 9 months (February, August, November, and December 2017; and January, April, May, June, and September 2018). The surveyor identified on 8 of</p>

the 166 days of patient testing reviewed, the manufacturers' humidity requirement had not been met: (a) December 2017: 7 of 20 days of patient testing: (i) 0%: Days 11,12,13,14,15 (ii) 15%: Days 6,8 (b) January 2018: 1 of 22 days of patient testing: (i) 3%: Day 30 (4) The surveyor reviewed the findings with the cytotechnologist, who stated to the surveyor the laboratory failed to ensure the manufacturers' humidity requirement was met on the days listed above.

REFRIGERATOR TEMPERATURE

(1) The surveyor identified the Sears Coldspot Mini-fridge located in the laboratory. Inside the refrigerator were 2 boxes of Histogel. The manufacturer required a storage temperature of 2-8 degrees C (Centigrade); (2) The surveyor asked the cytotechnologist how the Histogel material was used. The cytotechnologist stated to the surveyor the material was used to make cell blocks when a small amount of sample was submitted for testing; (3) The surveyor then reviewed temperature records for the refrigerator from 9 months (February, August, November, and December 2017; and January, April, May, June, and September 2018). The surveyor identified on 15 of the 166 days of patient testing reviewed, the refrigerator was 1 degree C, which was lower than the manufacturer's storage temperature requirement, as follows: (a) December 2017: 5 of 20 days of patient testing: (i) 1 degree C: Days 6,12,13,14,20 (b) November 2017: 1 of 20 days of patient testing: (i) 1 degree C: Day 7 (c) January 2018: 8 of 22 days of patient testing: (i) 1 degree C: Days 2,3,8,9,10,17,18,19 (d) May 2018: 1 of 22 days of patient testing: (i) 1 degree C: Day 31 (4) The surveyor reviewed the findings with the cytotechnologist, who stated to the surveyor the laboratory failed to store testing materials, as required by the manufacturer.