

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0882642	(X3) Date Survey Completed 05/22/2018
Name of Provider or Supplier Pathology Professional Services, Pa	Street Address, City, State 1301 East River Avenue, El Paso, 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
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and interview with facility personnel, the laboratory failed to make written instructions available to the laboratory's clients for specimen collection, labeling, storage and preservation, conditions for transportation, processing, and acceptability and rejection. The findings included: 1. At 11:35 hours on 5/22/2018 in the office, the laboratory was asked to provide a client service manual or other written instructions that would be available to clients for specimen collection, labeling, storage and preservation, conditions for transportation, processing, and acceptability and rejection. 2. At 11:38 hours on 5/22/2018 in the office, when asked about the availability of written instructions, the laboratory manager stated the laboratory would train new clients on proper labeling and transportation and that if clients ever had questions, they were typically handled via telephone. When asked if the laboratory had any written instructions available to clients, the Laboratory Manager stated "Basically, no".</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
Based on surveyor observations, and interview of facility personnel, the laboratory failed to ensure that 2 of 2 reagents and solutions were labeled with the preparation and expiration dates, lot numbers and storage requirements for all histopathology reagents stored in the laboratory. Findings included: 1. Observations made during the tour of the facility conducted on May 22, 2018 found that the laboratory stored aliquots of xylene and Ethanol that were not labeled with the preparation expiration dates, lot numbers and storage requirements. The laboratory had a wash bottle labeled ETOH on the counter next to the frozen section stain line, and a square glass container labeled Xylene found in the histopathology processing room. 2. Interview of the histotechnician conducted on May 22, 2018 at 11:32 AM confirmed that the laboratory did not include the lot number expiration date preparation date and storage requirements on the ethanol and xylene aliquots stored in laboratory.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor observations and interview with facility personnel, the laboratory failed to ensure that 1 of 6 tissue marking dyes had not exceeded the manufacturer's expiration date and was available for testing on May 22, 2018. The findings included: 1. Based on surveyor observations at 11:44 hours on 5/22/2018 in the laboratory, the following 1 of 6 tissue marking dyes had exceeded the expiration date and was available for testing: Stat Lab Green tissue marking dye Lot: 045378 Ref: SL662GR-2 Expiration: 02/2018 Elapsed time of expiration: 82 days 2. In an interview at 11:44 hours on 5/22/2018 in the lab, the lead Histotech acknowledged the tissue marking dyes had not exceeded the manufacturer's expiration date and was available for testing.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with facility personnel, the Technical Supervisor failed to assess and document the competency of 1 of 1 cytotechnologist performing high complexity testing in the year 2017. The findings included: 1. Based on review of the 1 of 1 cytotechnologists personnel records, competency assessments were completed on the following dates: 1/26/2016 2/7/2018 Elapsed time between competency assessments: 2 years and 1 week 2. In an interview

at 11:12 hours on 5/22/2018 in the office, when asked if there was a competency assessment performed in the year 2017, the Laboratory Director stated there was not one performed in 2017.