

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0952507	(X3) Date Survey Completed 09/23/2019
Name of Provider or Supplier University Pediatrics	Street Address, City, State 615 East University Drive, Edinburg, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies, patient records, and confirmed in interview of facility personnel, revealed the laboratory failed to have a mechanism in place to ensure that if specimens are received in the laboratory with the same first and last name or date of birth, the laboratory can distinguish between the specimens. The findings were: 1. Surveyor observation of a patient sample in the laboratory to be tested on 09/23/2019 at 1634 hours revealed one sample labeled with</p>

only the patient's first and last name. 2. Review of laboratory policies revealed no policy for specimen labeling was available for review. 3. Interview with the TP #2 on 09-23-2019 at 1645 hours in the laboratory confirmed the findings. TP #2 (as listed on CMS-Form 209) stated "This is how I label specimens with first and last name, date of birth, my initials and time and date of collection. This is how I learned in medical assistant school". 4. Interview with TP #4 (as listed on CMS-Form 209) stated " I label specimens with first and last name, date of birth, my initials and collection date and time." Key: TP - Testing Personnel CMS- Centers for Medicare and Medicaid Services

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 observation and confirmed personnel interview, the laboratory failed to ensure expired supplies were not available for use. The findings were: 1. Surveyor observation made in the laboratory on 09/23/2019 at 13:10 hours revealed the following expired item: BD Universal Viral Transport for Viruses, Chlamydiae, Mycoplasma and Ureplasma (ref 220527) Lot # L171709200 expired 2019-03 Quantity: 7 tubes 2. Interview with Testing Personnel #1 (as listed on Form CMS-209) on 09/23/2019 at 13:10 hours in the laboratory confirmed the findings. After his review of the expired item, he agreed the transport tubes should have been removed. Key: CMS- Centers for Medicare and Medicaid Services TP- Testing personnel