

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659873	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Tarrant County Public Health Dept	Street Address, City, State 1101 South Main Street, Fort Worth, 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	<p>The Laboratory Director, Technical Supervisor-8 (TS-8), Testing Person-7 (TP-7), TS-7, TP-4, TP-2, TP-1, LIMS Admin, and TS-5 were at the entrance conference conducted 11/05/2018. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Laboratory Director, TS-8, TP-3, TP-2, TP-1, TP-8, and TS-5 on 11/07/2018. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Department of State Health Services, Health Facility Compliance Arlington Group.</p>
D5393	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of specimen collection procedures, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory's quality assurance plan failed to identify and correct that the laboratory's policies and procedures for collection of HIV Screening with reflex to to confirmation were inconsistent. The findings included: 1. Review of the laboratory's collection procedure for HIV Combo Ag/Ab EIA Screen under, "Specimen Collection Instructions" stated, "Minimum 3.0 mL whole blood in a red top tube; must be submitted within 3 days of collection and must be stored centrifuged at 2-8 degrees Celsius until submitted to the laboratory." The procedure had a picture of a gold top BD Vacuater collection tube and further</p>

stated, "Collection Medium: BD Vacutainer SST #367986 Gold top tube." 2. Review of the TCPH/NTRL HIV Testing Protocol, signed by the laboratory director on September 4, 2018 under, "C. Specimen Collection" it stated, "Collection Device: Only BD SST Vacutainer tubes are accepted. 5 mL gold top or 8.5 mL tiger top vacutainers are used for collection..." 3. Interview of testing person two (as listed on Form CMS 209) on 11/06/2018 at 09:00 hours in the laboratory confirmed the findings. She stated that the specimen utilized for testing was a "Gold top." Key: HIV - Human Immunodeficiency Virus EIA - enzyme immunoassay Ag - antigen Ab - antibody mL - milliliter BD - Becton Dickinson SST - serum separator tube TCPH - Tarrant County Public Health NTRL - North Texas Regional Laboratory CMS - Centers for Medicare and Medicaid Services

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:

Based on review of laboratory's policies and procedures, manufacturer's instructions for AmpliVue HSV 1+2 Assay, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimen storage and preservation for 6 of 6 specimens after a failed run (10/02/2018) and then re-tested on 10/04/2018 for Herpes Simplex Virus (HSV) testing. Findings: 1. Review of the laboratory's procedure and the AmpliVue HSV 1+2 Assay package insert both stated the following: "STORAGE, HANDLING AND STABILITY, HSV Specimens" (Bullet 2) "Swabs collected from lesions can be stored in the viral transport medium at 2C to 8C for up to 5 days before being tested. Swabs can also be stored at -70C or below for long term storage." 2. Review of the AmpliVue HSV 1+2 Quality Control log revealed that on 10/02/2018 the HSV-2 Positive Control Result, (lot #117553 expiration date 02/02/2019) failed. The result under the column for HSV-2 Positive Control Result was documented as "HSV-", meaning the expected result of "positive" failed and a "negative" result was obtained. In the comments section of the log "Repeat run" initiated by Testing Person-3 as listed on the CMS 209 form was documented; patient specimens were also to be repeated. Review of the AmpliVue HSV 1+2 Quality Control log revealed that on 10/04/2018 in the comments section it was documented "specimen repeated (10/2/18 run)." On 11/07/2018 at 9:20 am, Testing Person 1 as listed on the CMS 209 form stated that on 10/02/2018 (the date of the quality control failure) the QC and patient testing were not repeated for testing that same day. The original patient specimens were re-frozen and thawed for repeat testing 10/04/2018. The manufacturer did not state that original patient specimens (swabs) were allowed to go through freeze/thaw cycles. 3. A review of the AmpliVue HSV 1+2 Patient Accession Log revealed the following patient specimens that were frozen, thawed, refrozen and thawed for testing on 10/04/2018: Patient: 0142 Date specimen received 09/28/2018 Date reported: 10/04/2018 Patient: 0143 Date specimen received 10/01/2018 Date reported: 10/04/2018 Patient: 0144 Date specimen received 10/01/2018 Date reported: 10/04/2018 Patient: 0145 Date specimen received 10/01/2018 Date reported: 10/04/2018 Patient: 0146 Date specimen received 10/01/2018 Date reported: 10/04/2018 Patient: 0147 Date specimen received 10/01/2018 Date reported: 10/04/2018 4. On 11/07/2018 at 10:30 am, the Technical Supervisor-5 (TS-5) as listed

on the CMS 209 form stated that the manufacturer communicated via electronic mail, they had not conducted studies that included freeze/thaw cycles on patient specimens. TS-5 confirmed the laboratory had not conducted studies that included freeze/thaw cycles for HSV testing on the Amplivue.