

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2277321	(X3) Date Survey Completed 02/13/2024
Name of Provider or Supplier Acies Tx, Llc	Street Address, City, State 309 Water St, Suite 112, Boerne, 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
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 review of the laboratory's policies, review of patient test records from December 2023 to January 2024, and staff interview, the laboratory failed: A) to ensure 1 of 9 patient samples were tested within the required time, and B) have a mechanism in place to ensure samples were maintained at the required temperature during transport. The findings include: A) 1. A review of the laboratory's policy titled "Laboratory Operations Manual for DNA/RNA Based Pathogen Testing" (approved by the laboratory director on 09/15/2023) under the section titled "Stability of Samples and Storage" determined: "Specimens are to be held at room temperature at 20-25C and processed within 3 days." 2. A review of the laboratory's policy titled "Client Manual - Pre-analytical" (approved by the laboratory director on 09/15/2023) determined: "Specimens should be refrigerated at 4-8C or stored at room temperature at 20-25C and processed within 72 hours." 3. A review of patient test records from December 2023 to January 2024 identified 1 of 9 patient samples tested more than 72 hours after collection. The patient was: Report ID: ACLTX-004 Collection date: 1/13/2024 Received date: 1/17/2024 Resulted date: 1/18/2024 4. Testing personnel number 2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 2/13/2024 at 1330 hours in the conference room. B) 1. A review of the laboratory's policy titled "Laboratory Operations Manual for DNA/RNA Based Pathogen Testing" (approved by the laboratory director on 09/15/2023) under the</p>

section titled "Stability of Samples and Storage" determined: "Specimens are to be held at room temperature at 20-25C and processed within 3 days." 2. A review of the laboratory's policy titled "Client Manual - Pre-analytical" (approved by the laboratory director on 09/15/2023) determined: "Specimens should be refrigerated at 4-8C or stored at room temperature at 20-25C and processed within 72 hours." 3. The laboratory was asked to provide documentation of how it ensured samples were maintained at the required temperature during transport. No method was in place. 4. A review of patient test records from November 2023 to January 2024 identified 9 patient samples were sent to the facility. They were: Report ID: ACLTX-001 ACLTX-002 ACLTX-003 ACLTX-004 ACLTX-005 ACLTX-003030 ACLTX-003027 ACLTX-003029 ACLTX-003011 5. Testing personnel number 2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 2/13/2024 at 1000 hours in the conference room.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, and staff interview, the laboratory failed to have documentation of performing monthly wipe tests for 2 of 2 months. The findings include: 1. The laboratory's policy titled "Laboratory Operations Manual for DNA/RNA Based Pathology Testing" (approved by the laboratory director on 09/15/2023) under the section titled "Wipe Test" stated: "Once every month, take a patient sample swab and swab the area where sample preparation is performed... Record the test and any corrective actions on the Maintenance Log, and keep the raw data for two years." 2. The laboratory was asked to provide documentation of the wipe test being performed in December 2023 and January 2024. No documentation was provided. 3. The compliance officer stated the facility did not perform the wipe test as stated in policy since testing had started in December 2023. This interview was conducted on 02/13/2024 at 1430 hours in the conference room.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, review of patient test records from December 2023 to February 2024, and staff interview, the laboratory failed to have documentation of performing establishment studies for 44 of 44 laboratory-developed test (LDT) performed on the QuantStudio 12K Flex. The findings include: 1. A review of the laboratory's test menu determined the laboratory performed the following 44 laboratory-developed tests on wound swabs: *Acinetobacter baumannii*, *Bacteroides fragilis*, *Candida species albicans/glabrata/tropicalis*, *Candida species dubliniensis/parpsilosis*, *Fingoldia magna*, *Clostridium perfringens*, *Enterobacteriaceae bacterium*, *Citrobacter braakii*, *Enterococcus faecalis*, *Eschericia coli*, *Klebsiella pneumoniae*, *Peptostreptococcus prevotti*, *Propionibacterium acnes/Cutibacterium acnes*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Streptococcus viridans group ACC*, *CMY/LAT*, *CMY/MOX*, *CTX-M*, *CTM-M expanded*, *DHA*, *IMP Group1*, *IMP Group2*, *MecA*, *NIM*, *OXA*, *SHV*, *Sul 1*, *Sul 2*, *Tet B*, *VanA/VanB*, *dfrA1*, *erm(A)*, *erm(B)*, *mefA*, *mphC*, *qnrA (qnrA1, A2 and A9)*, *qnrS (S1, S10, S11, S12, S13, S14, S4, S7, S8, S9)* 2. The laboratory was asked to provide documentation of performing the required establishment studies. No documentation was provided. 3. The laboratory reported performing testing on 9 patient samples from December 2023, January 2024 and February 2024. Testing personnel number 2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 02/13 /2024 at 1030 hours in the conference room.