

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2142358	(X3) Date Survey Completed 12/18/2018
Name of Provider or Supplier Lake Charles Memorial	Street Address, City, State 1000 Walters Street, 2nd Floor, Lake Charles, LA	
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	An Initial Survey was performed on December 17, 2018 through December 18, 2018 at Southwest Louisiana Hospital Association, DBA Lake Charles Memorial, CLIA ID # 19D2142358. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure test requisitions included sex of the patient. Findings: 1. Review of the laboratory's test requisitions revealed the laboratory did not include sex of the patient. 2. In interview on December 18, 2018 at 12:35 pm, Personnel 3 stated the laboratory's requisitions do not include sex of the patients. Personnel 2 stated the laboratory does not require the ordering facilities to provide the patient's sex. Personnel 2 and Personnel 3 further stated they were unaware that documentation of sex of the patient</p>

was a requirement. 3. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 664,748 Toxicology tests annually.

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 observation, record review, and interview with personnel, the laboratory failed to establish and verify performance specification for reference (normal) values for the Waters instrument utilized for Toxicology testing. Findings: 1.. Observation by surveyor during laboratory tour on December 17, 2018 revealed the laboratory utilizes one (1) Waters Acquity LC-MS/MS instrument for Urine Drug Confirmation testing of the following drugs: Citalopram, Fluoxetine, Venlafaxine, O-Desmethylvenlafaxine, Paroxetine, Sertraline, Amitriptyline, Nortriptyline, Doxepin, Imipramine, Desipramine, MDPV, Mephedrone, Methylone, Benzocetgonine, MDA, MDMA, 6-Acetylmorphine, Mitragynine, Phencyclidine, Carisoprodol, Meprobamate, Cyclobenzaprine, Buprenorphine, Norbuprenorphine, Dextromethorphan, Dextroorphan, Fentanyl, Norfentanyl, Meperidine, Normeperidine, Methadone, EDDP, Codeine, Morphine, Hydrocodone, Norhydrocodone, Hydromorphone, Oxycodone, Tapentadol, N-Desmethyltapentadol, Tramadol, O-Desmethyl Tramadol, Naloxone, Naltrexone, Amphetamine, Methamphetamine Phentermine, Alprazolam, OH-Alprazolam, 7-Aminoclonazepam, Diazepam, Nordiazepam, Temazepam, Cotinine, Gabapentin, Ketamine, Norketamine, Methylphenidate, Ritalinic Acid, Pregabalin, Zaleplon, Zolpidem, Zolpidem phenyl-4-COOH. 2. Review of the laboratory's "LC-MS/MS Waters 5 Method Validation Plan and Data Summary" revealed under the "Preface" section "These requirement state that, before reporting patients test results, the laboratory must establish specifications for the following performance characteristics, as applicable: Accuracy, Precision, Analytical sensitivity, Analytical specificity to include interfering substances, Reportable range of test results to include limit of detection, Reference intervals, and any other performance characteristics required." 3. Further review of the laboratory's "LC-MS/MS Waters 5 Method Validation Plan and Data Summary" revealed the laboratory did not include Reference interval studies. 4. In interview on December 18, 2018 at 1:40 pm, Personnel 3 stated the laboratory did not include reference interval studies in their validation. Personnel 3 stated the Laboratory Director determined the cut-off values which are competitive with other Toxicology laboratories. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 664,748 Toxicology tests annually.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

	<p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory established reference values for Toxicology testing. Refer to D5423.</p>
D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5305.</p>
D6112	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to ensure laboratory personnel performed test methods as required. Refer to D5305.</p>
D6115	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisors failed to ensure the laboratory established reference (normal) values for Toxicology testing. Refer to D5423.</p>