

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2028332	<b>(X3) Date Survey Completed</b>  08/01/2019
<b>Name of Provider or Supplier</b>  Ships Medical, Llc	<b>Street Address, City, State</b>  501 West St Mary Blvd, Ste 110, Lafayette, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification Survey was performed at SHIPS Medical, LLC- CLIA # 19D2028332 on August 2, 2019. SHIPS Medical, LLC was found not in compliance with the following <b>CONDITION LEVEL DEFICIENCIES</b> : 42 CFR 493.1403 <b>CONDITION</b> : Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1415 <b>CONDITION</b> : Laboratories Performing Moderate Complexity Testing; Clinical Consultant
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This <b>STANDARD</b> is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Findings: 1. Review of personnel records for the Clinical Consultant revealed a competency assessment was not performed for their duties. 2. In interview on August 1, 2019, the Technical Consultant confirmed the Laboratory Director did not perform a competency assessment for the Clinical Consultant.</p>
<b>D5317</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> 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>

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to ensure written specimen labeling and transport instructions for providers to maintain the integrity of samples were current. Findings: 1. In interview on August 1, 2019 at 10:09 am, the Technical Consultant and Testing Personnel stated the laboratory provides outside clinics the "Urine Specimen Collection" procedure. 2. In interview on August 1, 2019, the Technical Consultant stated urine samples from outside clinics in Opelousas and New Iberia are delivered by an employee at room temperature on varying days of the week. 3. Review of the laboratory's "Urine Specimen Collection" procedure under "Specimens Storage and Transport" section revealed the following instructions: a) "Place two ice packs in an insulated shipping container." b) "Each Friday place the specimen bags on top of ice packs and seal the insulated shipping container. Ensure the specimens are transported to the laboratory in a secured insulated shipping container to eliminate the possibility of spillage or damage during shipment and to prevent undetected tampering." c) "Lonestar Courier will collect the specimens every Friday by 4:00 pm" 4. Further review of the laboratory's "Urine Specimen Collection" procedure revealed the laboratory did not include written instructions for specimen labeling. 5. In interview on August 1, 2019 at 10:30 am, the Technical Consultant confirmed the laboratory's written urine transport instructions need to be updated to reflect the laboratory's current practice.

**D5403**

PROCEDURE MANUAL  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures manual revealed the laboratory did not include the following procedure: a) Quality Control to include: The establishing of means and ranges for quality control material, to include but not limited to: How to establish ranges for quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. Also to include what quality control is required and the acceptability criteria for each. 2. In interview on August 1, 2019 at 11:55 am, the

Technical Consultant confirmed the laboratory's quality control policy did not include the identified information.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to perform centrifuge maintenance per laboratory policy. Findings: 1. Review of the laboratory's "Centrifuge Maintenance " policy under " Preventative Maintenance" section revealed the following tasks: "Document all maintenance on log Form 5.1" a) " Weekly: Clean surfaces with a mild cleaning fluid and cloth" b) "Monthly: Clean and disinfect centrifuge and rotor" 2. Review of the laboratory's 2019 maintenance records revealed the laboratory did not have documentation of performance of centrifuge maintenance. 3. In interview on August 1, 2019 at 10:28 am, the Technical Consultant stated the laboratory began patient testing in March 2019. 4. In interview on August 1, 2019 at 12:33 pm, the Testing Personnel stated she does not document the centrifuge maintenance. The Testing Personnel further stated she has not performed the centrifuge monthly maintenance.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Urine Drug Screen testing. Findings: 1. Observation by surveyor during laboratory tour on August 1, 2019 revealed the laboratory utilized the Indiko Plus with Thermo Scientific MGC Select DAU (analytes: Ecstasy and Heroin) and MAS DOA Total (analytes: Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine,

Cannibinoid, Cocaine, EDDP, Opiates, Oxycodone, PCP, Propoxyphene) Controls for Urine Drug Screen Testing. 2. In interview on August 1, 2019 at 10:04 am, the Technical Consultant stated the laboratory utilizes the manufacturer's quality control ranges. The Technical Consultant further stated the laboratory had not implemented establishing its own ranges yet. The Technical Consultant stated he was in the process of collecting enough QC data. 3. Review of the MAS DOA Total package insert under the "Control Range" section revealed "Expected values may vary slightly with different reagent and/or methodologies used. Values provided are for this lot of control only and should be used to assist the laboratory in establishing its own target values." 4. Review of QC records revealed the laboratory utilized Thermo Scientific MAS DOA Total Control Lot numbers DAT1922, DAT19123, DAT1924 and DAT1925 without establishment of QC means and ranges. 5. Review of the laboratory's test volume revealed the laboratory performs 132,000 Urine Drug Screen tests (to include the following analytes: Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cannibinoid, Cocaine, EDDP, Opiates, Oxycodone, PCP, Propoxyphene) annually.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's quality control (QC) procedure revealed the laboratory did not have a written procedure specific to the laboratory's Toxicology testing. Refer to D5403. 2. Review of the laboratory's "Internal Assessment Form" performed by the Laboratory Director and dated "7/17/19" revealed the following: "Methods of Assessment: Log books were retrieved and reviewed by the laboratory director. Identified issues were recorded and conveyed to the Technical Consultant. Laboratory logs were reviewed for all entries through the end of June 2019." "Daily QC process: Develop clearer rules for QC acceptance and /or alternative measures when results are outside the established range." 3. Review of quality control records for July 2019 revealed the laboratory accepted a "failed" QC result for Benzodiazepine level 5 on July 15, 2019 without establishing acceptability criteria. The Technical Consultant reviewed the identified QC on July 31, 2019. 4. In interview on August 1, 201 at 11:59 am, the Technical Consultant stated the QC acceptability criteria was not included in the laboratory's policy. The Technical Consultant further stated he had not been at the laboratory since the Laboratory Director's Internal Assessment was performed to address. 5. Review of the laboratory's records revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to perform centrifuge maintenance per laboratory policy. Refer to D5433. b) the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Urine Drug Screen testing. Refer to D5469.

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to ensure patient test results were reported. Findings: 1. Review of random selection of patient test records on August 1, 2019 revealed a "Backlog" list. Further review of the "Backlog" list revealed pending tests for the following three (3) patients: Patient 0100000965 Collected June 19, 2019; pending Urine Drug Screen test Patient 01000001021 Collected July 3, 2019; pending Urine Drug Screen test Patient 01000001031 Collected July 9, 2019; pending Urine Drug Screen test 2. In interview on August 1, 2019 at 11:39 am, the Testing Personnel stated she was unaware the identified patients were pending. The Testing Personnel stated the patients were not on the "Backlog" list prior to August 1, 2019. 3. In interview on August 1, 2019, the Technical Consultant stated the laboratory did not take any actions prior to August 1, 2019 for the identified patients.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on August 1, 2019 revealed the laboratory utilizes the Indiko Plus for UDS testing. 2. Review of the Thermo Scientific CEDIA and DRI assay package inserts under "Intended Use" section revealed "This assay provides only a preliminary analytical test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result particularly when preliminary positive results are used." 3. Review of the UDS final report for Patient 0100001187 revealed the following comment: "These assays provide only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed

	<p>result." 4. In interview on August 1, 2019, the Technical Consultant confirmed the laboratory did not report UDS as stated in the manufacturer's package inserts.</p>
<p><b>D5807</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure reference results were included on patient final test reports for Urine Drug Screens. Findings: 1. Review of final test reports for Patient 0100000172 and Patient 01000001187 revealed the laboratory reported a qualitative with measurement value. The patient final test reports did not include the reference result. 2. In interview on August 1, 2019 at 11:39 am, the Technical Consultant stated he was unaware the reference result was not included on the patient final reports. The Technical Consultant confirmed the identified patients final test reports did not include reference results. 3. Review of the laboratory's test volume revealed the laboratory performs 156,000 Urine Drug Screen tests annually.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure final reports for Urine Drug Screens included required pertinent information. Refer to D6026. 5. The Laboratory Director failed to ensure the Clinical Consultant met educational requirements. Refer to D6029. 6. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

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 personnel were performing test methods as required. Findings: 1. The laboratory failed to ensure written specimen labeling and transport instructions for providers to maintain the integrity of samples were current. Refer to D5317. 2. The laboratory failed to perform centrifuge maintenance per laboratory policy. Refer to D5433. 3. The laboratory failed to ensure patient test results were reported. Refer to D5801.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5469.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.

**D6026**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for Urine Drug Screens included required pertinent information. Findings: 1. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Refer to D5805. 2. The laboratory failed to ensure reference results were included on patient final test reports for Urine Drug Screens. Refer to D5807.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure the Clinical Consultant met educational requirements. Refer to D6057.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:  
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure written specimen labeling and transport instructions for providers to maintain the integrity of samples were current. Refer to D5317. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 3. The laboratory failed to perform centrifuge maintenance per laboratory policy. Refer to D5433. 4. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793. 5. The laboratory failed to ensure patient test results were reported. Refer to D5801. 6. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Refer to D5805. 7. The laboratory failed to ensure reference results were included on patient final test reports for Urine Drug Screens. Refer to D5807.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D5469.

**D6056**

**CLINICAL CONSULTANT**  
CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance

with 493.1419 of this part.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to provide documentation that the Clinical Consultant met education requirements for moderate complexity testing. Refer to D6057.

**D6057**

**CLINICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to ensure the Clinical Consultant met education requirements. Findings: 1. Review of personnel records for the Clinical Consultant revealed the laboratory did not have documentation of his education. 2. In interview on August 1, 2019 at 10:21 am, the Technical Consultant stated the laboratory did not have a copy of the Clinical Consultant's medical degree.