

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2028332	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Ships Medical, Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed at Ships Medical, LLC, CLIA ID 19D208332 on November 28, 2023. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and proficiency testing records as well as interview with personnel, the laboratory failed to retain proficiency testing records for at least two (2) years for one (1) of four (4) events reviewed. Findings: 1. Review of the laboratory's "Laboratory Record Retention" policy revealed "Ships Medical Laboratory, records will be kept for: Proficiency testing 2 years." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2022 and 2023 revealed the laboratory did not retain the raw data to support proficiency testing results for the following event: - 2022 Chemistry - Miscellaneous-1st Event 3. In interview November 28, 2023 at 11:38 a. m., Testing Personnel 1 confirmed the laboratory did not retain the raw data for the proficiency testing event identified above.</p>
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL 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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings:
 1. In interview on November 28, 2023 at 11:30 a.m., Testing Personnel 1 stated the laboratory receives samples from outside clinics. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have detailed instructions for providers that included the following: (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. 3. In interview on November 28, 2023 at 11:30 am, Office Personnel 1 confirmed the laboratory did not provide written instructions to outside providers who submit samples.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on observation, review of the laboratory's temperature records and policy and procedure manual, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on November 28, 2023 at 10:20 a.m. revealed the laboratory stored Medlab Wash Solution (manufacturer's storage requirements 2 - 25 degrees Celsius) in the laboratory. 2. Review of the laboratory's temperature logs revealed the laboratory defined the acceptable room temperature limits as 18 - 30 degrees Celsius. 3. In interview on November 28, 2023 at 12:30 p.m., Testing Personnel 1 confirmed the laboratory's acceptable room temperature range exceeded the manufacturer's temperature limits.

D5435

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(2)

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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	<p>This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual, and interview with laboratory personnel, the laboratory failed to establish function check protocols for the Drucker Centrifuge to ensure equipment performance. Findings: 1. Observation by surveyor during laboratory tour on November 28, 2023 at 10:20 a.m. revealed the laboratory utilized one Drucker Diagnostics centrifuge for centrifugation of turbid urine specimens. 2. Review of the laboratory's policy "Centrifuge Maintenance" revealed the laboratory did not include function checks for the centrifuge. 3. In interview on November 28, 2023 at 1:45 p.m., Testing Personnel stated the laboratory did not have the operator's manual for the Drucker centrifuge. He confirmed the laboratory did not perform function checks for the centrifuge.</p>
<p>D5793</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Refer to D5413. 1. The laboratory failed to establish function check protocols for the Drucker Centrifuge to ensure equipment performance. Refer to D5435.</p>
<p>D6087</p>	<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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for supplies stored in the laboratory. Refer to D5413.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing records were maintained. Refer to D3037.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory 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.</p>
<p>D6095</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</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 establishment of maintenance procedures as required. Refer to D5435.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to ensure a competency assessment was performed annually for testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the Laboratory Director also serves as the Technical Supervisor. 2. Review of personnel records revealed Testing Personnel 1 had a semi-annual evaluation performed in November 2021 but did not have documentation of an</p>

annual competency assessment in May 2022. 3. In interview on November 28, 2023 at 11:05 p.m., Testing Personnel confirmed an annual competency assessment was not performed as identified above.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form and personnel records as well as interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of General Supervisor. Findings: 1. Review of the laboratory's CMS 209 form revealed Testing Personnel 1 also serves as the General Supervisor. 2. Review of personnel records for Testing Personnel 1 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to him. 3. In interview on November 28, 2023 at 10:57 a.m., Testing Personnel 1 confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to him.