Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2028332	02/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ships Medical, Llc	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 19D2028332, on February 25, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, and personnel records; as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Findings: 1. Review of the laboratory's "Competency Assessment Policy" revealed the laboratory did not include competency assessment of the Technical Supervisor. 2. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Technical Supervisor. 3. In interview on February 25, 2026 at 1: 59 p.m., the Technical Supervisor confirmed the laboratory did not have a policy for competency assessment of the Technical Supervisor. II. Based on review of the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, and personnel records; and interview with personnel, the laboratory failed to ensure personnel competency assessments for one (1) of one (1) personnel serving as Clinical Consultant, General Supervisor, and Technical Supervisor were performed and complete. Findings: 1. Review of the laboratory's "Competency Assessment Policy" revealed "Documented competency assessment shall be required for individuals fulfilling the following staff responsibilities outlined in Subpart M of the CLIA regulations: Clinical Consultant (CC), Technical Consultant (TC), General Supervisor (GS), Testing Personnel (TP). CCs, GSs and TCs, who do not perform testing on

	patient specimens will have an initial competency performed within 3 months from hire." 2. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Clinical Consultant, Technical Supervisor, and General Supervisor. 3. Review of the laboratory's personnel records revealed the laboratory utilized a form for the competency assessment for the General Supervisor that included columns for description of responsibilities, date assessed, and the Laboratory Director's initials. The form also included a signature line at the bottom of the page for the Laboratory Director. 4. Further review of the laboratory's personnel records revealed a form for competency assessment of the Clinical Consultant which included a checkoff list of responsibilities, a line for determination of satisfactory or unsatisfactory performance, and a signature line at the bottom of the page for the Laboratory Director. 5. Review of personnel records for Personnel 2 revealed the laboratory did not have documentation of the Laboratory Director performing competency assessments for the roles of Technical Supervisor, General Supervisor, and Clinical Consultant. 6. In interview on February 25, 2026 at 1:59 p.m., the Technical Supervisor stated he was hired in April 2025. He further stated the competency assessment for his roles of General Supervisor and Clinical Consultant were sent to the Laboratory Director to sign with an electronic signature. He confirmed the Laboratory Director did not sign the competency forms for his roles as General Supervisor and Clinical Consultant and did not perform a competency assessment for his role as Technical Supervisor.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) (b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of patient records and interview with personnel, the laboratory failed to document the time specimens were received into the laboratory for thirteen (13) of thirteen (13) patients reviewed. Findings: 1. Review of a random selection of final patient test reports revealed the following patient specimens were collected and delivered to the laboratory on three different dates but all were documented as received in the laboratory at 2 p.m.: Accession 0100005183 - Received 2:00 PM on 02 /03/2026; test date 02/06/2026 Accession 0100005257 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005259 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005263 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005261 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005260 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005264 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005265 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005262 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005266 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005258 - Received 2:00 PM on 02/10 /2026; test date 02/20/2026 Accession 0100005316 - Received 2:00 PM on 02/16 /2026; test date 02/20/2026 Accession 0100005317 - Received 2:00 PM on 02/16 /2026; test date 02/20/2026 2. In interview on February 25, 2026 at 12:24 p.m., Testing Personnel 1 stated specimens are collected at outside clinics and delivered to the laboratory but she is not always present when specimens are delivered. She further stated the delivery person will leave the specimens in the laboratory refrigerator with a manifest of the patient specimens. 3. Review of the patient specimen manifests from 02/03/2026, 02/10/2026, and 02/16/2026 revealed the following columns: "Time Patient Label POC Results Initials/Date/Time - Sent to Confirmation Lab Initials/Date

	/Time - Sent to Ships Lab Comments (Ships Lab Use Only)" 4. Further review of the manifests identified above revealed the column "Initials/Date/Time - Sent to Confirmation Lab" only included initials and did not include a date and time. The column "Initials/Date/Time - Sent to Ships Lab" was left blank for each specimen listed. 5. In interview on February 25, 2026 at 3:20 p.m., Testing Personnel 1 stated the received date and time for each specimen is documented in the patient's chart by the person collecting and delivering the specimens to the laboratory. She further stated does not document the received she was unsure if the documented received time of 2 p.m. for the specimens identified above was the time the collector delivered the specimens to the laboratory.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation; review of the laboratory's policy and procedure manual, calibration verification records, and test menu; as well as interview with personnel, the laboratory failed to perform calibration verification procedures on the Olympus AU400e analyzer utilized for urine drug screen (UDS) testing at least once every six (6) months in 2024 and 2025. Findings: 1. Observation by surveyor during the laboratory tour on February 25, 2026 at 12 p.m. revealed the laboratory utilized the Olympus AU400e analyzer for testing of the following analytes on urine specimens: 6-acetylmorphine, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, EDDP (methadone), Marijuana (THC), Methamphetamine, Opiates, and Oxycodone. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for performing calibration verification at least every six (6) months. 3. Review of the laboratory's calibration records revealed the laboratory did not have documentation of performance of calibration verification at least every six (6) months in 2024 and 2025. 4. In interview on February 25, 2026 at 2: 26 p.m., the Technical Supervisor stated the laboratory ceased testing in March 2025 and later moved locations. Testing Personnel 1 stated the instrument was validated in October 2025 and patient testing began again in January 2026. The Technical Supervisor confirmed the laboratory did not have a policy for performance of

	calibration verification and did not have documentation of calibration verification performance as identified above. 5. Review of the laboratory's test menu revealed the laboratory performs 22,000 urine drug screens annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D5313.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5439.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Refer to D5209 I. 2. The laboratory failed to ensure personnel competency assessments for one (1) of one

	(1) personnel serving as Clinical Consultant, General Supervisor, and Technical Supervisor were performed and complete. Refer to D5209 II.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) 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 policies and personnel records and interview with personnel, the Laboratory Director failed to provide a written job description for the Technical Supervisor. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not have a job description for the role and responsibilities of the Technical Supervisor. 2. In interview on February 25, 2026 at 1: 59 p.m., the Technical Supervisor confirmed the laboratory did not have a job description for Technical Supervisor.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 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. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to document the time specimens were received into the laboratory for thirteen (13) of thirteen (13) patients reviewed. Refer to D5313. 2. The laboratory failed to perform calibration verification procedures on the Olympus AU400e analyzer utilized for urine drug screen (UDS) testing at least once every six (6) months in 2024 and 2025. Refer to D5439.