Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2028332	03/24/2022
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 on March 24, 2022 at Ships Medical L.L.C., CLIA ID # 19D2028332. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 by surveyor, review of manufacturer's package inserts, review of patient test reports 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 March 24, 2022 at 11:12 am revealed the laboratory utilizes the Olympus AU400e Chemistry analyzer for Urine Drug Screen (UDS) testing to include the following tests: 6-acetylmorphine (6-AM), Amphetamine (AMP), Barbituate (BAR), Benzodiazapine (BENZ), Buprenorphine (BUP), Cocaine (COC), 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Opiates (OPI), Oxycodone (OXY), Phencyclidine (PCP), Tetrahydrocannabinol (THC), 3,4-Methylenedioxymethamphetamine (MDMA/XTC) 2. Review of the Olympus AU400e Chemistry analyzer package inserts for the above identified tests revealed "The Immunalysis Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be

	used in order to obtain a confirmed analytical result. GC-MS or Liquid Chromatography-tandem mass spectrometry (LC-MS/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 laboratory's patient test reports revealed the laboratory did not include the disclaimer for intended use on patient reports to state the entire confirmatory process. 4. In interview on March 24, 2022 at 11:47 am, Personnel 2 stated she was unaware the disclaimer for intended use was not included on patient reports. 5. Review of the Task 1&3 form provided to surveyor revealed the laboratory performs 74,880 UDS tests annually.
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 review of laboratory records and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.