

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2028332	<b>(X3) Date Survey Completed</b>  01/29/2020
<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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (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.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Ships Medical, LLC, CLIA ID 19D208332 on January 29, 2020. Based on observation, record review, and interview with personnel, the laboratory failed to follow manufacturer sample storage requirements for urine drug screening (UDS). Findings: 1. In interview on January 29, 2020 at 2:35 pm, the Testing Personnel stated the laboratory was awaiting reagents and samples stored in the refrigerator were awaiting testing. 2. Observation by surveyor on January 29, 2020 and review of the laboratory's pending worklist revealed patient urine samples stored in the laboratory's refrigerator with the following collection dates: January 14, 2020 January 15, 2020 January 17, 2020 January 20, 2020 January 21, 2020 3. In interview on January 29, 2020 at 2:54 pm, the Testing Personnel stated samples are stable for thirty days in the refrigerator. 4. In telephone interview on January 29, 2020, the Technical Consultant stated samples are stable for thirty days. 5. Review of the manufacturer package inserts revealed the following specimen storage requirements: a) Thermo Scientific DRI Barbiturate Assay: "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8 degrees C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees C." b) Thermo Scientific DRI Ecstasy Assay:"Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory</p>

may be placed into a secure refrigeration unit at 2 to 8 degrees C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees C for 21 weeks." c) Thermo Scientific Amphetamines Assay: Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8 degrees C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees C." 6. Further review of the laboratory's pending list revealed the following fifty eight (58) patient samples exceeded the manufacture storage requirements: January 14, 2020: Patient 0100002468, Patient 0100002456, Patient 0100002463, and Patient 0100002461 (total 15 patients) January 15, 2020: Patient 0100002488, Patient 0100002498, Patient 0100002561, and Patient 0100002491 (total 13 patients) January 17, 2020: Patient 0100002543 and Patient 0100002490 January 20, 2020: Patient 0100002534, Patient 0100002547, Patient 0100002539, and Patient 0100002543 (total 11 patients) January 21, 2020: Patient 0100002562, Patient 0100002555, Patient 0100002570, and Patient 0100002574 (total 17 patients)

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
A Revisit survey was performed at Ships Medical, LLC, CLIA ID 19D208332 on January 29, 2020. Based on record review and interview with personnel, the laboratory failed to ensure patient samples for urine drug screening (UDS) were analyzed per manufacturer requirements. Findings: 1. In interview on January 29, 2020 at 2:54 pm, the Testing Personnel stated samples are stable for thirty days in the refrigerator. 2. In telephone interview on January 29, 2020, the Technical Consultant stated samples are stable for thirty days. 3. Review of the manufacturer package inserts revealed the following specimen storage requirements: a) Thermo Scientific DRI Barbiturate Assay: "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8 degrees C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees C." b) Thermo Scientific DRI Ecstasy Assay: "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8 degrees C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees C for 21 weeks." c) Thermo Scientific Amphetamines Assay: Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8 degrees C for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees C." 4. Review of patient final reports from December 2019 and January 2020 revealed the following patients exceeded manufacturer storage requirements for testing: Patient 0100002233: Collection date: December 18, 2019; Test date: December 26, 2019 Patient 0100002232: Collection date: December 18, 2019; Test date: December 26, 2019 Patient 0100002354: Collection date: January 7, 2020; Test date: January 17, 2020

Patient 0100002353: Collection date: January 7, 2020; Test date: January 17, 2020  
Patient 0100002352: Collection date: January 7, 2020; Test date: January 17, 2020  
Patient 0100002514: Collection date: January 7, 2020; Test date: January 17, 2020  
Patient 0100002358: Collection date: January 7, 2020; Test date: January 17, 2020  
Patient 0100002357: Collection date: January 7, 2020; Test date: January 17, 2020  
Patient 0100002356: Collection date: January 7, 2020; Test date: January 17, 2020 5.  
In interview on January 29, 2020 at 2:54 pm, the Testing Personnel confirmed the identified patient samples were stored in the refrigerator prior to testing.