| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 22D0681917 | 05/20/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dothouse Health | 1353 Dorchester Ave, Dorchester, MA | |

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 |
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| **D0000** | A validation survey was completed 05/20/2026. Standard level deficiencies were cited. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the manufacturer's package insert, the laboratory's procedure, and an interview with the Laboratory Director, the laboratory failed to ensure the laboratory's written policies were consistent with the manufacturer's storage requirements for 1 of 3 tests reviewed. Findings Include: a. A review of the manufacturer's package insert "Alinity c Direct LDL Reagent Kit", revised February 2022, revealed: "Specimen Storage ...Temperature 2-8C ...Maximum Storage Time 5 days ...Temperature -80C ...Maximum Storage Time 3 months. b. A review of the laboratory's procedure "DH ALIN 0119 DH Alinity LDL, effective 10/01/2025, revealed on page 2: "B. Specimen Storage ...1. Serum stored at 2 - 8C is stable for 5 days in the primary tube. 2. Aliquot serum is stable for 7 days at 20 - 25C. 3. If specimen cannot be tested within the maximum storage time, the specimen should be stored frozen at -80C. The specimen is stable for 3 months at this temperature." Aliquoted serum stability is not provided in the manufacturer's instructions. c. During an interview on 05/20/2026 at 2:26 PM, the Laboratory Director confirmed the findings. |
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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on direct observation and an interview with Technical Consultant (TC) #2, the laboratory failed to ensure that supplies were stored according to the manufacturer's instructions for 2 of 2 areas where supplies were stored. Findings Include: a. On 05/20/2026 at 10:16 AM, a observation of the storage room revealed the following items (sampling) stored in the room: 1. 10 cases; BD Vacutainer lavender top; lot number 5225504, expiration date 12/31/2026; Store at 4C [degrees Celsius]-25C. 2. 11 cases; BD Vacutainer SST [serum separator tube]; lot number 5324057; expiration date 11/30/2026; Store at 4C-25C. b. On 05/20/2026 at 11:12 AM, a observation of the patient draw room, revealed the following items (sampling) stored in the room: 1. 2 cases; BD Vacutainer lavender top; lot number 5351560; expiration date 04/30/2027; Store at 4C-25C. 2. 30 tubes; BD Vacutainer SST; lot number 6019779; expiration date 01/31/2027; Store at 4C-25C. c. During an interview on 05/20/2026 at 10:16 AM and 11:12 AM, TC #2, as listed on the CMS-209, confirmed that the temperature of the storage room and patient draw room was not monitored. II. Based on a review of the manufacturers' package inserts, the laboratory's temperature records and an interview with Technical Consultant (TC) #2, the laboratory failed to define room temperature according to the manufacturer's instructions for 5 of 7 quality control materials. a. A review of the manufacturer's package inserts revealed: 1. "Liquichek Unassayed Chemistry Control Levels 1 and 2 ...Procedure ...If the product has been stored frozen, allow it to stand at room temperature (18 to 25C) for approximately 1 hour or until completely thawed ... Thawed Opened: If the product has been stored refrigerated allow it to reach room temperature (18 to 25C) before use." 2. "InteliQ Immunoassay Plus Control Levels 1, 2, and 3 ...To the Thaw the Product: Allow the frozen product to thaw at room temperature (18 to 25C) for approximately 60 minutes or until completely thawed prior to use." b. A review of the laboratory's temperature records revealed that room temperature was defined as 15 to 30C. c. During an interview on 05/20/2026 at 11:32 AM, TC #2 confirmed the laboratory's room temperature range. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's quality control (QC) records, patient test reports, and an interview with Technical Consultant (TC) #2, the laboratory failed to evaluate 44 of 44 patients' test results back to the last acceptable QC when total protein QC exceeded the laboratory's acceptable limits and test system adjustments were made. Findings Include: a. A review of the laboratory's total protein QC from the Alinity analyzer and patient records revealed QC exceeded the laboratory's acceptable limits (Range 6.5-6.9) on: 1. 05/04/2026 at 8:10 AM; Result=7.0; the reagent was replaced with a new lot/new shipment. The last acceptable QC was performed on 05/02/2026 at 9:09 AM. The laboratory performed 22 patient test results on 05/02/2026. 2. 05/05 /2026 at 8:35 AM; Result=7.0; the test was calibrated and QC was repeated. The last acceptable QC was performed on 05/04/2026 at 10:18 AM. The laboratory performed 22 patient test results on 05/04/2026. b. The laboratory was asked to provide evidence of evaluations of the 44 patients' test results above. No documentation was provided. c. During an interview on 05/20/2026 at 9:20 AM, TC #2, as listed on the CMS-209, confirmed that all patients' test results were not evaluated. |