

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2065372	<b>(X3) Date Survey Completed</b> 05/02/2022
<b>Name of Provider or Supplier</b> Healthland Housecall Services	<b>Street Address, City, State</b> 100 E Big Beaver Road Suite 900, Troy, MI	
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>D5022</b>	<p><b>TOXICOLOGY</b> CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to verify the performance specifications for Oxycodone toxicology testing. Refer to D5421.</p>
<b>D5301</b>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to have a documented request for patient testing from an authorized person for 1 (patient 1) of 11 patient charts reviewed. Findings include: 1. A review of patient testing logs revealed 1 (patient 1) of 11 patient charts reviewed there was no order documented in the patients plan for the toxicology testing performed on 12/13 /21. 2. An interview on 5/02/2022 at 11:22 am, the TC confirmed there were no orders documented in the patients chart for the toxicology testing performed.</p>

<p><b>D5407</b></p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory director failed to approve, sign, and date 1 of 1 procedure reviewed in the "Healthland PC Lab Manual". Findings include: 1. A review of "Healthland PC Lab Manual" revealed for 1 of 1 procedure located in the front pocket of the manual titled "Healthland UDS Collection and Requisition Policy" was not approved and signed by the Laboratory Director. 2. An interview on 5/02/2022 at 9:44 am, the TC confirmed the policy was in use and not signed and dated by the Laboratory Director.</p>
<p><b>D5413</b></p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document refrigerator temperatures that store the urine specimens prior to testing for 2 (May 2020 to May 2022) of 2 years of testing. Findings include: 1. Review of the "Refrigerator Temperature" policy states "Refrigerator temperatures will be checked daily and initialed by the person recording the temperature." 2. A record review of the laboratory's temperature charts revealed a lack of documentation for the General Electric (GE) refrigerator for 2 of 2 years in use. 3. An interview on 5/02/2022 at 9:09 am, the TC confirmed the urine specimen refrigerator temperatures were not performed and documented. B. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to document temperature for 2 (January- February 2022) of 24 months reviewed. Findings include: 1. Review of the "Refrigerator Temperature" policy states "Refrigerator temperatures will be checked daily and initialed by the person recording the temperature." 2. A review of the laboratory's temperature charts revealed a lack of documentation of the room temperature for 2 (January- February 2022) of 24 months reviewed. 3. An interview on 5/02/2022 at 10:30 am, the TC confirmed the laboratory did not have documentation of the room temperature for January and February in 2022.</p>
<p><b>D5415</b></p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and</p>

when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview with the Technical Consultant (TC), the laboratory failed to label reagents used in toxicology testing with the concentration, preparation date, and expiration date for 1 of 2 reagent bottles observed on the Medica easy ra toxicology instrument. Findings include: 1. An observation by the surveyor on 05/02/2022 at 9:10 am revealed 1 of 2 reagent bottles on the easy ra toxicology instrument was not labeled with the concentration, preparation date, and expiration date. 2. An interview on 05/02/2022 at 9:10 am, the TC confirmed the deionized water + surfactant bottle on the easy ra instrument was not labeled with the concentration, preparation date, and expiration date.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to verify the performance specifications for Oxycodone toxicology testing for 2 (May 2020 to May 2022) of 2 years of testing. Findings include: 1. A review of the laboratory's test menu revealed the laboratory performs oxycodone testing. 2. A review of the laboratory's "Easy RA startup Verification Date & Inserts" revealed a lack of documentation of verification of performance specifications for oxycodone testing. 3. When requested on 5/02/2022 at 9:18 am by the surveyor, the verification of performance specification data for oxycodone testing was not made available. 4. An interview on 5/02/2022 at 9:18 am, the TC confirmed the verification of performance specification data was not available.

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure all test results were entered into the electronic medical record (EMR) system for 1 (Patient MG021142) of 11 patient charts reviewed. Findings include: 1. A review of 1 (Patient MG021142) of 11 patient records in the EMR revealed the "BZO" test had an error message "SE" (sample error). 2. The surveyor requested the test report for the repeated patient error and that result was made available to the surveyor but the result was not entered into the patient's chart in the EMR. 3. An interview on 5/02/2022 at 11:15 am, the TC confirmed the test report for patient MG021142 was incomplete in the EMR.