

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2149519	(X3) Date Survey Completed 08/20/2020
Name of Provider or Supplier Prime Mobile Care Inc	Street Address, City, State 24445 Northwestern Hwy Suite 212, Southfield, MI	
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
D5301	<p>TEST REQUEST 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 Testing Personnel #1 (TP1), the laboratory failed to have test requests for patient testing for 10 (patients 1-10) of 10 patients reviewed. Findings include: 1. A review of 10 patient toxicology test reports revealed a lack of a documented test request for the following patients: a. Patient 1 b. Patient 2 c. Patient 3 d. Patient 4 e. Patient 5 f. Patient 6 g. Patient 7 h. Patient 8 i. Patient 9 j. Patient 10 2. The surveyor requested the test requests for the patients listed above on 8/20/2020 at 10:36 am and the documents were not made available. 3. An interview on 8/20/2020 at 11:55 am with TP1 confirmed test requests for the patients listed above were not available.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable analytic system requirements and correct</p>

	<p>identified problems. Findings include: 1. The laboratory failed to have a procedure manual. Refer to D5401. 2. the laboratory failed to establish performance specifications for methodone testing before reporting patients. Refer to D5421.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with Testing Personnel #1 (TP1), the laboratory failed to have a procedure manual for 2 (2018 to 2020) of 2 years. Findings include: 1. The surveyor requested the laboratory's procedure manual on 8/20/2020 at 10:07 am and it was not made available. 2. An interview on 8/20/2020 at 11:55 am with TP1 confirmed the laboratory did not have a procedure manual.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to establish performance specifications for methodone testing before reporting patients for 1 (8/14/2020) of 1 days patients received testing. Findings include: 1. A record review of the laboratory's patient toxicology test results revealed 13 patients were tested for methodone on 8/14/2020 2. A review of the laboratory's records revealed a lack of verification of performance specifications for methodone testing. 3. An interview on 8/20/2020 at 11:55 am with TP1 confirmed the laboratory did not verify performance specifications for the methodone test system before reporting patients.</p>
<p>D6032</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures</p>

each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory director failed to specify the responsibilities and duties of each laboratory employee for 2 (2018 to 2020) of 2 years. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of the responsibilities of laboratory employees. 2. An interview on 8/20/2020 at 11:51 am with TP1 confirmed the laboratory did not specify the responsibilities and duties of each laboratory employee.