

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2068079	(X3) Date Survey Completed 12/09/2020
Name of Provider or Supplier Vitruvian Health	Street Address, City, State 431 Swartz Ct, Ste 200, Ionia, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #1, the laboratory failed to ensure patient urine aliquots were labeled for 1 of 6 patient samples observed. Findings include: 1. An observation at 10:16 am on 12/9/20 revealed Testing Personnel #1 at 10:16 am on 12/9/20 preparing patient urine toxicology specimens to be tested and 1 aliquot did not have identifying information when loaded into the analyzer. 2. An interview with Testing Personnel #1 on 12/9/20 at 10:16 am confirmed the urine toxicology specimen aliquot did not have identifying information.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant, the laboratory failed to ensure quality control successfully passed for 1 (12/23/19) of 8 patient testing days reviewed. Findings include: 1. A review of the laboratory's quality control records revealed the negative control level for cocaine tested positive on 12/23/19. 2. A review of patient testing logs revealed 32 patients had toxicology testing performed on 12/13/19 when the cocaine control was out of range. 3. An interview on 12/9/20 at 11:50 am with the Technical Consultant confirmed the quality control testing for cocaine had not passed on 12/23/19.