

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2068079	(X3) Date Survey Completed 11/10/2025
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the general supervisor, the laboratory failed to follow its urine specimen labeling policy for one of one specimen collection observed. Findings include: 1. The surveyor observed the urine specimen collection area on 11/10/25 at 9:10 am and saw one urine specimen labeled with the first initial, last name, and date of birth handwritten on the urine collection cup. 2. A review of the laboratory's "Urine Collection" policy revealed a section stating, "Specimens are labeled to assure appropriate identification throughout the pre-analytic (pre-testing) and analytical phases of testing. Containers containing patient specimens for testing are labeled as follows: Patient name and laboratory identification number (e.g. DOB, or other unique patient identifier such as medical record or chart number) Sex and age, where appropriate Source/type of specimen (e.g. anatomical site, urine) Time and date of collection." 3. An interview on 11/10/25 at 9:10 am with the general supervisor confirmed the specimen was labeled only with the first initial, last name, and date of birth handwritten on the urine collection cup.</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not</p>

limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the general supervisor, the technical supervisor failed to perform direct observations of routine patient test performance for two (4/30/25 and 11/7/25) of two competency assessments performed for testing personnel #1. Findings include: 1. A review of competency assessments for testing personnel #1 revealed the initial competency assessment for urine toxicology testing was performed on 4/30/25 and the six-month competency assessment was performed on 11/7/25. Both assessments included electronic signatures for the technical supervisor. 2. An interview on 11/10/25 at 12:05 pm with the general supervisor confirmed the technical supervisor had not performed direct observations of patient test performance as part of the competency assessments for testing personnel #1.