

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2162472	(X3) Date Survey Completed 10/17/2024
Name of Provider or Supplier Saginaw Valley Medical Center	Street Address, City, State 3170 Hallmark Court, Saginaw, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to establish procedures to ensure laboratory personnel safety from chemical and biohazardous materials to two (October 2022 to October 2024) of two years reviewed. Findings include: 1. The surveyor observed the laboratory and saw a yellow Gatorade bottle on the chair near the Medica EasyRA qualitative urine toxicology analyzer on 10/17/24 at 9:25 am. 2. An interview on 10/17/24 at 9:31 am with the Testing Personnel revealed they sometimes drink in the laboratory. 3. A review of the laboratory's policies and procedures revealed a lack of established safety procedures. 4. An interview on 10/17/24 at 1:17 pm with the Technical Consultant confirmed the laboratory failed to establish safety procedures.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p>

This STANDARD is not met as evidenced by:
. Based on observation, record review, and interview with the Testing Personnel, the laboratory failed to follow established specimen labeling policies for 24 of 24 patient urine specimens observed. Findings include: 1. The surveyor observed 24 patient urine specimens on the laboratory counter on 10/17/24 at 9:25 am with patient labels on the caps of the urine containers. 2. A review of the laboratory's "Urine Collection" policy revealed a section stating, "The container must have a label that will adhere under refrigeration. The label must include the patient's identification and the date and time of specimen collection and the labels must be placed on the container, not on the lid." 3. An interview on 10/17/24 at 9:31 am with the Testing Personnel confirmed specimens are labeled on the lid only.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant, the laboratory failed to perform control procedures at least each date of patient testing for one (5/30/23) of seven patient testing dates reviewed. Findings include: 1. A review of the laboratory's "Quality Control" procedure revealed a lack of information about how often controls are performed. 2. A review of seven patient test records revealed Patient #6, with urine qualitative toxicology testing performed on 5/30/23, had a positive benzodiazepine result. 3. A review of control records for 5/30/23 revealed a lack of documentation of benzodiazepine control results. 4. An interview on 10/17/24 at 10:58 am with the Technical Consultant confirmed controls for benzodiazepine were not performed on 5/20/23 and 24 patients received benzodiazepine testing that date.