

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2156145	(X3) Date Survey Completed 02/04/2021
Name of Provider or Supplier Viome Inc	Street Address, City, State 81 Camino Entrada, Suite 100, Los Alamos, NM	
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
D0000	The following deficiencies were cited as the result of a recertification survey completed on 02/04/2021 for 42 CFR part 493 Laboratory Requirements.
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 and interview with the Technical Supervisor, the laboratory failed to ensure that chemical safety protocols were established and followed in regards to the storage of chemical reagents in the laboratory. Findings are: A. During observation on 02/04/2021 at 10:30 am, the surveyor noticed a 4 Liter, amber glass, Sigma Aldrich bottle of 2-Propanol (molecular grade ethanol widely used in laboratories) sitting on the bottom shelf in the Post Amplification Room. 1. The 2-Propanol bottle was labeled with an open date of 5/14/2018. There was no expiration date indicated by the manufacturer or the laboratory. B. During interview on 02/04/2021 at 10:30 am, the Technical Supervisor was asked if the laboratory had a place to keep all their chemical/flammable reagents such as a safety chemical cabinet that is fire resistant. She stated that they did not have one in the Post Amplification Room and that the 2-propanol was only being used for cleaning purposes.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems</p>

quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the review of the Quality Manual QM-100 (Section 13.3 Internal Assessments) which describes the Quality Management system of the laboratory, and interview with the Technical Supervisor, the laboratory failed to document the monthly evaluation and review of maintenance for the six Automated Hamilton Microlab STAR-Liquid Handler Robotic Systems used for dispensing patients samples into 96-well plates. Findings are: A. Review of the Quality Manual QM-100, Section 13.3.1, Titled "Internal Audits," revealed the laboratory had a written policy /method which gathered information, findings, any gaps, or nonconformities (incidents that do not follow written expectations) regarding equipment used in the laboratory on a monthly basis, but failed to document the monthly review/evaluation by the Laboratory Director or the Technical Supervisor. B. During interview on 2/4 /2021 at 11:10 am, the Technical Supervisor stated that the monthly maintenance, for all six automated Hamilton Microlab STAR-Liquid Handler Robotic Systems, is kept electronically and is reviewed monthly but that there is no documentation of the "sign-off" from the Laboratory Director.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on direct observation and interview with the Technical Supervisor, the Laboratory Director failed to ensure that chemical safety protocols were established and followed in the laboratory. Findings are: A. During observation on 02/04/2021 at 10:30 am, the surveyor noticed a 4 Liter, amber glass, Sigma Aldrich bottle of 2-Propanol sitting on the bottom shelf in the Post Amplification Room. B. During interview on 02/04/2021 at 10:30 am, the Technical Supervisor was asked if the laboratory had a place to keep all their chemical/flammable reagents such as a safety chemical cabinet that is fire resistant. She stated that they did not have one in the Post Amplification Room and that the 2-Propanol was only being used for cleaning purposes.