

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2237181	<b>(X3) Date Survey Completed</b> 06/07/2022
<b>Name of Provider or Supplier</b> Virtual Scientific	<b>Street Address, City, State</b> 2119 W Hurd Rd, Monroe, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Administrator, the laboratory failed to follow written policies to assess consultant competency for 7 (November 2021 to June 2022) of 7 months the laboratory has been in operation. Findings include: 1. A review of the laboratory's "Competency Assessment" policy revealed a section stating, "Competency assessment will be conducted on all personnel performing patient testing and/or reporting patient results, including but not limited to technical and clinical consultants, technical supervisors, general supervisors and other laboratory staff. Competency shall be based on position responsibilities." 2. The surveyor requested the competency assessment documentation for the Clinical Consultant and the Technical Supervisor on 6/7/22 at 11:22 am and it was not made available. 3. An interview on 6/7/22 at 12:40 pm with the Administrator confirmed the Clinical Consultant and Technical Supervisor competency assessment documentation was not available.</p>
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Administrator, the laboratory failed to follow its policy to perform corrective actions when verification of accuracy testing does not meet established requirements for 1 (January 2022 Event) of 1 event performed. Findings include: 1. A review of the laboratory's "Proficiency Testing" policy revealed a section stating, "If there are discrepancies 7.1. The Phoenix site will communicate it to the individual site 7.2. A proficiency testing investigation will be initiated by the Phoenix site and discussed with the individual site." 2. A review of the laboratory's verification of accuracy documentation revealed the January 2022 event was unacceptable. 3. An interview on 6/7/22 at 11:31 am with the Administrator revealed corrective action for the failed verification of accuracy event was not performed and documented.

**D5301**

TEST REQUEST  
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Administrator, the laboratory failed to have a test request for its cytogenetic testing for 4 (Patients 1-4) of 4 patient test records reviewed. Findings include: 1. A review of patient test records revealed the following patients had cytogenetic testing performed by the laboratory: a. Patient 1 received testing on 12/01/2021. b. Patient 2 received testing on 01/10/2022. c. Patient 3 received testing on 03/23/2022. d. Patient 4 received testing on 05/05/2022. 2. The surveyor requested test requests from an authorized person for the patients listed above at 12:34 pm and they were not made available. 3. An interview on 6/7/22 at 12:40 pm with the Administrator confirmed the test requests from an authorized person for the patients listed above were not available.