Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2256153	01/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Capsulomics, Inc Dba Previse	1450 S Rolling Road Suite 3 013, Halethorpe, MD	

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	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on review of the polymerase chain reaction (PCR) testing worksheets and interview with the general supervisor (GS), the laboratory failed to ensure that a specimen stability study was performed to establish that a treated specimen could be frozen, thawed, retested and provide accurate test results after the initial PCR testing was performed and failed. Findings: 1. During the review of the PCR worksheets, the GS stated that sometimes the PCR testing for one of the four genes will fail and they will defrost the frozen specimen and retest that particular gene the next day. 2. The GS was asked if a stability study had been performed for freezing, thawing, and retesting the PCR specimen to verify that the test results would still be accurate. According to the GS, the laboratory had not performed a stability study for freezing, thawing, testing the treated specimen for PCR testing. 3. During the exit interview on 01/09/2025 at 3:30 PM, the GS confirmed that a stability study had not been performed to establish that a specimen could be frozen, thawed, retested and the effects would not impact patient results that were reported and interpreted.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the general supervisor (GS), the laboratory's procedure manual failed to ensure that the written policies and procedures included interpretation instructions for results tested in duplicate or triplicate. Findings: 1. The GS stated that the quality control (QC) samples were tested in duplicate and the patients were tested in triplicate on the Qubit fluorometer analyzer. 2. During the exit interview on 01/09/25 at 3:30 PM, the GS confirmed that the policies and procedures failed to include defined limits of acceptability of the specimens tested in duplicate and triplicate and corrective actions to be taken if the results fall outside the defined parameters.
D6149	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(1) The director or technical supervisor may delegate to the general supervisor the responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) result worksheet for the second event of 2024, PT procedure, and interview with the general supervisor (GS), the GS failed to ensure that the testing personnel were documenting the corrective actions when PT results were unacceptable. Findings: 1. The PT worksheet for the second event of 2024 showed that the RUNX3 (NMV) gene for sample number 24-2063 had a result of 54%. The result was printed in red on the worksheet. The GS confirmed that the red result was flagged as unacceptable. 2. Section "2.3 Corrective Action" of the PT procedure states "Any "unacceptable" values/grades must be recorded on QLY-FOR-012-F1 Nonconformance report and discussed with general supervisor and technical staff." 3. During the survey on 01/09/2025 at 3:30 PM, the GS confirmed that there was no documentation showing that a Nonconformance report had been completed and investigated for the failure and discussed with the technical staff.