

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2119113	(X3) Date Survey Completed 08/11/2023
Name of Provider or Supplier Genzeva, Llc	Street Address, City, State 9430 Key West Hwy Suite 130, Rockville, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) Next-generation sequencing (NGS)-Germline proficiency testing (PT) records and interview with the general supervisor (GS), the laboratory failed to ensure that the laboratory staff signed the attestation worksheet showing that PT samples were tested in the same manner as the patients. Findings: 1. The CAP NGS PT records from 2023 and 2022 (3 events) were reviewed. Three of three of the PT attestation worksheets showed that the name of the laboratory director (LD) and testing personnel (TP) were typed on the worksheets. The worksheets failed to include the signature of the laboratory director and TP per the CAP PT instructions. 2. During the survey on 08/11/2023 at 12:30 PM, the GS and LD confirmed that the PT attestation worksheets failed to have the signature of LD and TP involved in the performance and interpretation of the PT results.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

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 policy and procedure manuals, laboratory records, and interview with the general supervisor (GS), the laboratory's policy and procedure manuals failed to include written instructions for the identification (ID) numbers (#) assigned to the "Run Name" for each patient run. Findings: 1. The patient run worksheets for July 12, 2023 were reviewed. The "Run Name" for patient testing showed a hand-written ID# of "7.12.23-MAGMAX-1" on the "Automated DNA[deoxyribonucleic acid] Extraction QA[quality assurance] Checklist." The "Run Name" for patient testing showed a hand-written ID# of "7.12.23-WESLP-1 (07.24.23 WESCPSEQ-1" on the "Genzeva Exome QA Checklist." 2. According to the GS the old software would automatically generate the patient run ID#. Since the software was updated on 07/13/2023, the ID# was no longer added to the worksheets. The testing personnel continued to manually label the runs in the same manner. The GS stated that the instructions for labeling the runs had not been updated in the procedure manual. 3. During the survey on 08/11/23 at 12:30 PM, the GS confirmed that the policy and procedure manual failed to include written instructions for providing each patient run with the appropriate "Run Name" ID#.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the final patient test report, and interview with the general

supervisor (GS) and laboratory director (LD), the final test report did not include all the address of the laboratory performing the testing. Findings: 1. The laboratory provided five final patient test reports for review. Five of the five reports failed to include the address of the laboratory that performed the next-generation sequencing testing. 2. During the survey on 08/11/2023 at 12:30 PM, the GS and LD confirmed that the final patient report failed to include the address of the laboratory that performed the next-generation sequencing testing.