Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2183615	05/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Aeon Technologies, Llc	1 Technology Drive #1600, Frostburg, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to document a self-evaluation of PT scores that were ungraded by the College of American Pathologists (CAP) PT program to verify accuracy. Findings: 1. The laboratory was enrolled with CAP in three annual events (A, B, and C) for hematology auto differentials (FH3) and two annual events (A and B) for clinical microscopy (CM). 2. The CAP PT program used reason codes when a PT sample was not graded. 3. Reason code [27] was for "Lack of participant or referee consensus" and was used for "Urine Sediment ID" for sample CMP-05 in the CM-A 2023 PT event. 4. Reason code [26] was for "Educational challenge" and was used for "Blood Cell ID Ungraded" for samples BCP-06 through BCP-10 in the FH3-A 2023 PT event. 5. There was no documentation indicating that the ungraded PT results were compared with the results listed in the CAP participant summary to verify accuracy. 6. During the survey on 05/18/2023 at 4:30 PM, the LD confirmed that there was no documentation of the laboratory's self-evaluation of ungraded CAP PT results for the 2023 CM-A and FH3-A PT events.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system

	must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance verification records and email communication with the laboratory director (LD), the laboratory failed to provide documentation demonstrating comparable performance specifications to the manufacturer for the Sysmex CA-600 coagulation analyzer. Findings: 1. The laboratory used the Sysmex CA-600 coagulation analyzer to test for prothrombin time (PT), activated partial thromboplastin time (aPTT), fibrinogen, and D-dimer. 2. Performance verification records contained instrument printouts, but did not include documentation that the laboratory's results were comparable to the manufacturer's performance specifications for accuracy, precision, reportable range, and reference intervals for PT, aPTT, fibrinogen, and D-dimer. 3. In an email received on 05/19/2023 at 3:11 PM, the LD confirmed that the original signed validation/verification documentation for the Sysmex CA-600 coagulation instrument could not be found.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review, interview with the technical supervisor (TS), and email communication with the laboratory director (LD), the laboratory failed to perform a comparison of test results from two instruments used for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing at least twice a year. Findings: 1. The laboratory performed SARS-CoV-2 RT-PCR testing using a QuantStudio 7 Flex and a QuantStudio 12K Flex instrument. 2. During the survey on 05/18/2023 at 3:45 PM, the TS stated that a test results comparison from each instrument was last performed when the laboratory acquired the QuantStudio 7 Flex instrument. 3. In an email received on 05/19/2023 at 3:11 PM, the LD confirmed that the last instrument comparison was performed on 06/23/2022.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) results and interview with the laboratory director (LD), the LD failed to ensure that an investigation into failed PT results was performed and any applicable corrective actions were implemented for unacceptable PT results. Findings: 1. The laboratory performed three annual PT events (A, B, and C) for hematology auto differentials (FH3). 2. The laboratory received a score of 20% for red blood cell distribution width (RDW) in the FH3-A 2023 PT event. 3. There was no documentation of an investigation into the root cause, corrective actions taken, or whether patient results were potentially affected for the unacceptable RDW results. 4. During the survey on 05/18/2023 at 4:30 PM, the LD confirmed that there was no documentation of an investigation or corrective actions taken for unacceptable RDW results from the FH3-A 2023 PT event.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel competency evaluations and interview with the technical supervisor (TS), the TS failed to ensure that new testing personnel (TP) received a competency evaluation semiannually during the first year the TP tested patient specimens. Findings: 1. The laboratory listed three TP on the Laboratory Personnel Report (form CMS-209). 2. Records for TP #3 showed initial training was completed on 10/11/2022 and 10/20/2022. 3. There were no records for a 6-month competency evaluation for TP #3. 4. During the survey on 05/18/2023 at 4:30 PM, the TS confirmed that TP #3 was overdue for a 6-month competency evaluation.