Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1083614	09/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Eoh Acquisition Group Llc	300 Central Avenue, East Orange, NJ	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all TP who performed Toxicology, Chemistry and Hematology tests participated in the College of American Pathologists (CAP) PT events in the calendar years 2022, 2023 and 1st and 2nd events of 2024. The finding includes: 1. A review conducted on 9/5/24 of all PT events revealed that one out of twelve TP performed PT all events in 2022, 2023 and 1st and 2nd events of 2024. 2. TP #1 listed on CMS form 209 confirmed on 9/5/24 at 12:30 pm that PT events were not rotated between TP.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct

	problems identified in the analytic systems from 11/8/21 to 9/5/24 The finding include: 1. Record review on 9/5/24 revealed that the laboratory lacked a Quality Assurance (QA) procedure to monitor the accuracy of patient results being transmitted from the Gem Premier 5000 analyzer to the Electronic Medical Records (EMR). 2. TP #1 listed on the CMS-209 form confirmed on 9/5/24 at 11:40 am that the laboratory failed to have the above mentioned procedure.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Gem Premier 5000 analyzer were adequate from 11/8/21 to 9/5/24. The finding includes: 1. The LD did not ensure that the Laboratory Information System (LIS) was verified for the Gem Premier 5000 analyzer prior to patient testing. 2. TP #1 listed on CMS-209 form confirmed on 9/5 /24 at 1:20 pm that PS records were not adequate.