Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D2040806	**(X3) Date Survey Completed** 07/25/2018
Name of Provider or Supplier Aegis Sciences Corporation	**Street Address, City, State** 365 Great Circle Rd, Nashville, TN	

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
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 5 of 5 patient test records, pre-survey review of the Centers for Medicare System (CMS) 2567 form and interview with the Quality manager determined the final patient records failed to contain the name and address of the laboratory from 2017-18. The findings include: 1. Review of 5 of 5 patient test records dated 2/15/17, 11/29/17, 5/23/18, 6/13/18, 7/11 /18 revealed missing the name and address of the laboratory in 2017 and 2018. 2. Pre-survey review of the CMS-2567 form revealed a past deficiency in which the laboratory failed to list the name and address of the laboratory in 2014 on patient test records. 3. An interview with the Quality manager at approximately 3:00 p.m. July 25, 2018 confirmed the final patient records did not contain the name and address of the laboratory from 2017 and 2018. ==========
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable

	levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on a review of the Quality Assurance (QA) policy, pre-survey review of the 2014 Plan of Correction (PoC) and an interview with the Quality Manger, the Technical Supervisor failed to maintain quality assessment audits to ensure the name and address on patient test records. Findings include: 1. A lack of periodic QA audits of the patient test records determined the laboratory was missing the name and address during 2017 and 2018. 2. Pre-survey review of the 2014 PoC revealed the QA department was to include verification of testing facility name and address during the QA audits during 2017 and 2018. 3. An interview with the Quality manager on July 25, 2018, at 3:40 PM confirmed the Technical Supervisor failed to maintain quality assessment audits for patient test records in 2017 and 2018.