Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0662985	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Delaware Public Health Laboratory	30 Sunnyside Road, Smyrna, DE	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of manual test requisition form (updated 01/15/2019), LIMS test report #504789 and interview with technical supervisors, the laboratory failed to ensure that collection time was included in the test requisition. The findings included: a. Manual test requisition form , updated 01/15/2019, did not include a data field for collection time. b. Manual test requisition form, updated 01/15/2019, included test requested for bacterial, urine, and stool cultures. c. HCV Quantitative test required separation of serum or plasma from the cells within 6 hours of draw.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on reviewing the laboratory's procedure manual (SOP), lack of documentation and confirmation by the testing personnel, the laboratory failed to document that the timer used on the RPR rotator was within the limits established in the SOP of 8 minutes plus or minus 15 seconds. The laboratory also failed to document that two testing personnel read the results of the RPR tests as required in the laboratory SOP.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on reviewing the laboratory's policy for proficiency testing (PT) and lack of documentation, the laboratory director failed to delegate in writing the responsibility to sign PT attestation statements as is required in its PT policy.