Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0663739	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bay Health Medical Center-Kent Lab	640 S State Street, Dover, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 Standard Operating Procedures (SOPs) and interview with the laboratory administrative director it was determined that there was not a procedure for Human Papilloma Virus (HPV) by In-Situ Hybridization (ISH). Findings include: 1. At approximately 9:40 am on 9/12/2018, the surveyors requested the standard operating procedures for In-Situ Hybridization testing of Epstein-Barr Virus (EBV), Human Papilloma Virus (HPV), and Kappa and Lambda. At approximately 11:30 am, the administrative director provided a procedure entitled Automated Immunohistochemistry and Chromogenic Testing with a medical director approval

	date of 3/14/2018. 2.The procedure did not include HPV testing. 3.During interview at approximately 2:15 pm the administrative director confirmed that HPV testing was not included in the procedure provided and that there was no procedure specifically for HPV testing.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on review of Human Papilloma Virus (HPV) Test Reports and interview with laboratory testing personnel and laboratory administrative director it was determined that reports had not been updated for samples referred to another laboratory for testing. Findings include: 1. During interview at approximately 10:05 am on 9/12 /2018, testing person #2 stated that documentation of HPV controls was not maintained at Bayhealth laboratory because controls were run at the reference laboratory. 2.At approximately 12:00 pm on 9/12/2018, the surveyors reviewed 3 Human Papillomavirus (HPV) patient testing records in the laboratory's Epic information system. Three of 3 patient test reports stated that, "Known positive and negative (where appropriate) controls are confirmed with each analysis. The performance characteristics of the immunohistochemistry slide prepared for each antibody have been determined by Bayhealth Laboratory" and that, "Special stain controls stain appropriately." 3.Test records for the 3 HPV tests showed that processing and interpretation of the specimens was performed at Integrated Oncology. 4. The laboratory administrative director confirmed during interview at approximately 2:30 pm on 9/12/2018 that HPV test reports did not contain accurate information about the testing controls.