Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0709453	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pa Dept Of Health Bureau Of Labs	110 Pickering Way, Exton, PA	

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 reviewing the laboratory procedure manual for microbiology and confirmation by the technical supervisor on March 21, 2019 at approximately 11:30 AM, the laboratory failed to include pertinent literature references for the use of 8 of 11 microbiology media procedures. The following microbiology media procedures lacked pertinent literature references: 1. 7H9 Broth 2. Chocolate agar plates and slants 3. Columbia agar plates 4. Hektoen Enteric agar plates 5. MacConkey plates 6. Mueller Hinton plates 7. Campylobacter plates 8. Thayer-Martin plates 08723 1. Based on review of procedure manuals, interview with the technical supervisor in

	Microbiology and laboratory director on March 21, 2019 at around 11 am, the laboratory failed to include steps to follow when the Vitek 2 Compact test systems provided a confidence level of low discrimination in the biotype result for the identification of organism. The findings included: a. The Vitek 2 Compact instrument provided percentage confidence level of biotype identification of an organism. b. The procedure manual, Bact TSOP-079-Vl indicated Excellent as having a 99% confidence level of identification, and Very Good as having 95% confidence level of identification. c. The procedure manual did not include steps to follow when the confidence level showed low discrimination. 2. Based on review of procedure manuals, interview with the technical supervisor of Microbiology and laboratory director, the laboratory failed to provide steps to follow when the the use of Difco Antisera to type different Serogroups of Salmonella showed "questionable results." The finding included: a. Procedure Manual,Bact-TSOP-058-V1 describes the procedures to serotype the groups of Salmonella organism, when using Difco antisera. b. The procedure manual did not describe the steps to follow, when using the CDC antisera reagents for initial "questionable results."