Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0925953	11/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Barnabas Health Medical Group	804 West Park Avenue, Ocean, 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
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 surveyor review of the Procedure Manual (PM), Manufacturers Package Insert (MPI) and interview with the Testing Personnel (TP) the laboratory failed to have an accurate quality control (QC) procedure for Hardy Selective Strep Agar (SSA) media performed from 8/17/21 to the date of survey. The findings include: 1. The PM stated " one plate inoculated using quality control organism Kwikswab Streptococcus Agalactiae, (AKA Strep Negative) Inoculating Swab." 2. Streptococcus

	agalacitae is not an organism listed on the MPI to be used as a negative control for SSA media. 3. TP #11 as listed on the CMS 209 form confirmed on 11/14/23 at 11:35 am that the PM did not have an accurate QC procedure for SSA media.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, the Procedure Manual and interview with Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Selective Strep Agar (SSA) media for its ability to inhibit specific organisms from 8/17/21 to the date of the survey. The findings include: 1. The laboratory failed to use at least one organism to confirm the inhibitory characteristic of SSA media. 2. The TP #11 as listed on the CMS-209 form confirmed on 11/14/23 at 11:30 am the laboratory did not perform the above mentioned QC on SSA media.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Interlaboratory Qualtiy Assurance Program (IQAP) for the Beckman Coulter AC*T Diff2 analyzer and interview with Testing Personnel (TP) the laboratory failed to perform and document corrective action for IQAP reports from 8/17/21 to the date of survey. The findings include: 1. The IQAP report states "when a note to review SDI data is generated one must asses the clinical significance between the participant and the pool mean. 2. Report Identification (ID) 5203367 stated "Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 087800 Gr%/Gr." 3. . Report Identification (ID) 5233071 stated "Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 089300 MPV and 079300 MPV." 4. There was no documented evidence for corrective action for the above mentioned IQAP reports. 5. TP #11 as listed on the CMS 209 form confirmed on 11/14/23 at 11:00 am the laboratory failed to perform corrective action.