Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236863	01/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Braxton County Memorial Hospital	100 Hoylman Drive, Gassaway, WV	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Instrumentation Laboratories ACL 1000 reagent and quality control (QC) records, and interview with Technical Supervisor #1(TS1), the laboratory failed to periodically verify the International Normalized Ratio (INR) calculation for 2 of 2 lot changes of HemosIL PT-Fibrinogen Reagent. Record review was for 2016 and 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a lack of a policy outlining the procedure for periodically verifying the INR calculation. 2. Review of the Instrumentation Laboratories ACL 1000 reagent and quality control (QC) records identified no documentation of the laboratory periodically verifying the INR calculation when the laboratory changed the lot of HemosIL PT-Fibrinogen Reagent on 8/15/16 and 7/3/17. 3. On 1/9/18 at approximately 3:00 PM, TS1 confirmed that the laboratory has never periodically verified the INR calculation.
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:
A. Based on review of the laboratory's policy and procedure manuals and interview with Technical Supervisor #1(TS1), the laboratory failed to check each lot number and shipment of Bac T/Alert BPA Bottles for sterility and ability to support growth from January 2016 to current. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Media Quality Control", which stated "1. Record the lot number, expiration date, received date and initial of tech unpacking on the Microbiology Media Record for each medium type; 2. Remove package label from one package of each lot received and attach to Microbiology Media Record for each medium type; 3. Notify the microbiology tech of receipt of chocolate (or any nonexempt as defined by CLSI) media so growth properties can proceed ASAP. Procedure for microbiology tech: For chocolate agar (or any nonexempt medias as defined by CLSI) verify acceptable growth properties as follows: Growth properties-Inoculate one plate with the control organisms listed on the Chocolate Agar Media Growth Support Record...." 2. Review of the laboratory's policy and procedure manual identified no quality control plan for the Bac T/Alert BPA bottles. 3. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked each lot number and shipment of BacT/Alert BPA (platelet) Bottles for sterility and ability to support growth from January 2016 to current. 4. On 1/9/18 at approximately 2:00 PM, TS1 stated that they were keeping the certificates and not checking for sterility or the ability to support growth and they did not have an IQCP plan that included the BacT/Alert BPA bottles.
B. Based on review of the laboratory's policy and procedure manuals and interview with Technical Supervisor #1(TS1), the laboratory failed to check each lot number and shipment of BBL Fluid Thioglycolate Medium for sterility and ability to support growth for 1 of 1 shipments in 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Media Quality Control", which stated "1. Record the lot number, expiration date, received date and initial of tech unpacking on the Microbiology Media Record for each medium type; 2. Remove package label from one package of each lot received and attach to Microbiology Media Record for each medium type; 3. Notify the microbiology tech of receipt of chocolate (or any nonexempt as defined by CLSI) media so growth properties can proceed ASAP. Procedure for microbiology tech: For chocolate agar (or any nonexempt medias as defined by CLSI) verify acceptable growth properties as follows: Growth properties-Inoculate one plate with the control organisms listed on the Chocolate Agar Media Growth Support Record...." 2. Review of the laboratory's policy and procedure manual identified no quality control plan for the Thioglycolate broth. 3. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 3/7/17 shipment of BBL Fluid Thioglycolate Medium for sterility and ability to support growth. 4. On 1/9/18 at approximately 2:00 PM, TS1 stated that they were keeping the certificates and not checking for sterility or the ability to support growth and they did not have an IQCP plan that included the BBL Fluid Thioglycolate Medium.
C. Based on review of the laboratory's policy and procedure manuals and interview with Technical Supervisor #1 (TS1), the laboratory failed to check each lot number and shipment of MacConkey II Agar for sterility and ability to support growth for 20 of 20 shipments in 2016 and 19 of 19 shipments in 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Media Quality Control", which stated "1. Record the lot number, expiration date, received date and initial of tech unpacking on

the Microbiology Media Record for each medium type; 2. Remove package label from one package of each lot received and attach to Microbiology Media Record for each medium type; 3. Notify the microbiology tech of receipt of chocolate (or any nonexempt as defined by CLSI) media so growth properties can proceed ASAP. Procedure for microbiology tech: For chocolate agar (or any nonexempt medias as defined by CLSI) verify acceptable growth properties as follows: Growth properties-Inoculate one plate with the control organisms listed on the Chocolate Agar Media Growth Support Record...." 2. Review of the laboratory's policy and procedure manual identified no quality control plan for the MacConkey II Agar. 3. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 1/8/16, 1/26/16, 2/9/16, 2/24/16, 3/23/16, 4/8/16, 4/22/16 (2 lot numbers in shipment), 5/17/16, 6/7/16(2 lot numbers in shipment), 6/21/16, 7/8 /16, 7/22/16, 8/12/16, 8/30/16, 9/16/16, 9/27/16, 10/21/16, 11/8/16, 12/6/16, and 12/23 /16 shipments of MacConkey II Agar for sterility and ability to support growth. 4. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 1/13/17, 2/3/17, 2/21/17, 3/10/17, 4/4/17, 4 /21/17, 5/2/17, 5/16/17, 6/2/17, 6/27/17, 6/30/17, 7/11/17, 8/1/17, 9/22/17, 10/10/17, 10/31/17, 11/14/17, 11/28/17, and 12/26/17 shipments of MacConkey II Agar for sterility and ability to support growth. 5. On 1/9/18 at approximately 2:00 PM, TS1 stated that they were not checking for sterility or the ability to support growth and they did not have an IQCP plan that included the MacConkey II Agar. D. Based on review of the laboratory's policy and procedure manuals and interview with Technical Supervisor #1(TS1), the laboratory failed to check each lot number and shipment of PEA media for sterility and ability to support growth for 15 of 15 shipments in 2016 and 9 of 9 shipments in 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Media Quality Control", which stated "1. Record the lot number, expiration date, received date and initial of tech unpacking on the Microbiology Media Record for each medium type; 2. Remove package label from one package of each lot received and attach to Microbiology Media Record for each medium type; 3. Notify the microbiology tech of receipt of chocolate (or any nonexempt as defined by CLSI) media so growth properties can proceed ASAP. Procedure for microbiology tech: For chocolate agar (or any nonexempt medias as defined by CLSI) verify acceptable growth properties as follows: Growth properties-Inoculate one plate with the control organisms listed on the Chocolate Agar Media Growth Support Record...." 2. Review of the laboratory's policy and procedure manual identified no quality control plan for the PEA media. 3. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 1/8/16, 2/9/16, 3/9/16, 3/25/16, 4/15/16, 4/22 /16, 5/17/16, 6/7/16, 6/21/16, 7/22/16, 8/16/16, 8/19/16, 10/21/16, 11/29/16, and 12/30 /16 shipments of PEA media for sterility and ability to support growth. 4. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 1/24/17, 3/24/17, 4/28/17, 6/2/17(2 lot numbers in shipment), 7/7/17, 8/1/17, 8/29/17, 10/3/17, 10/31/17, and 11/28/17 shipments of PEA media for sterility and ability to support growth. 5. On 1/9/18 at approximately 2:00 PM, TS1 stated that they were not checking for sterility or the ability to support growth and they did not have an IQCP plan that included the PEA media. E. Based on review of the laboratory's policy and procedure manuals and interview with Technical Supervisor #1(TS1), the laboratory failed to check each lot number and shipment of TSA II 5% Sheep Blood Agar media for sterility and ability to support growth for 30 of 30 shipments in 2016 and 28 of 28 shipments in 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Media Quality Control", which stated "1. Record the lot number, expiration date, received date and initial of tech unpacking on the Microbiology Media Record

	for each medium type; 2. Remove package label from one package of each lot received and attach to Microbiology Media Record for each medium type; 3. Notify the microbiology tech of receipt of chocolate (or any nonexempt as defined by CLSI) media so growth properties can proceed ASAP. Procedure for microbiology tech: For chocolate agar (or any nonexempt medias as defined by CLSI) verify acceptable growth properties as follows: Growth properties-Inoculate one plate with the control organisms listed on the Chocolate Agar Media Growth Support Record...." 2. Review of the laboratory's policy and procedure manual identified no quality control plan for the TSA II 5% Sheep Blood Agar. 3. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 1 /8/16, 1/26/16, 1/29/16, 2/9/16, 2/22/16, 3/15/16(2 lot numbers in shipment), 3/25/16, 4/8/16, 4/15/16, 4/22/16, 4/29/16, 5/10/16(3 lot numbers in shipment), 5/27/16, 6/21 /16, 7/1/16(2 lot numbers in shipment), 7/12/16(2 lot numbers in shipment),7/22/16(2 lot numbers in shipment), 8/5/16, 8/12/16, 8/30/16(2 lot numbers in shipment), 9/9/16, 9/20/16(2 lot numbers in shipment), 9/27/16, 10/4/16, 10/7/16(2 lot numbers in shipment), 11/8/16, 11/29/16(2 lot numbers in shipment), 12/9/16, 12/13/16, and 12/23 /16(3 lot numbers in shipment)shipments of TSA II 5% Sheep Blood Agar for sterility and ability to support growth. 4. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked the 1/6/17, 1 /13/17, 1/24/17, 2/3/17, 2/21/17, 3/3/17, 3/14/17, 3/24/17, 4/4/17, 4/21/17, 5/4/17, 5/12 /17, 5/23/17, 6/2/17(2 lot numbers in shipment), 6/20/17(2 lot numbers in shipment), 7 /7/17, 8/1/17, 8/22/17, 9/15/17, 9/22/17, 10/3/17, 10/10/17(3 lot numbers in shipment), 10/31/17, 11/10/17, 11/21/17, 11/28/17, 12/13/17 and 12/26/17 shipments of TSA II 5% Sheep Blood Agar for sterility and ability to support growth. 5. On 1/9 /18 at approximately 2:00 PM, TS1 stated that they were not checking for sterility or the ability to support growth and they did not have an IQCP plan that included the TSA II 5% Sheep Blood Agar.