Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	04/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pocahontas Memorial Hospital	150 Duncan Road, Buckeye, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration/calibration verification records and interview with the Laboratory Manager(LM)/General Supervisor #1 (GS1), the laboratory failed to perform and document calibration verification every 6 months for Alanine Aminotransferase, Albumin, Alcohol-Ethanol, Alkaline Phosphotase, Ammonia, Amylase, Aspartate Aminotransferase, Bilirubin Direct, Brain Natriuretic Peptide, Blood Urea Nitrogen, C-Reactive Protein, Calcium, Chloride, Cholesterol,

	Creatine Kinase MB, Creatine Kinase Total, Creatinine, Digoxin, Dilantin, Ferritin, Folic Acid, Glucose, Hemoglobin A1C, High Density Lipoprotein, Iron, Lactate, Lactate Dehydrogenase, Lipase, Magnesium, Micro-albumin, Neonatal Bilirubin, Phosphorus, Potassium, Total Protein, Salicylate, Sodium, Tegretol, Total Thyroxine, Total Billirubin, Triglycerides, FreeTriiodothyronine, Free Thyroxine, Troponin, Gentamycin, Vancomycin, Thyroid Stimulating Hormone, T3, Uric Acid, and Vitamin D performed on the Vitros 5600. Record review was from June 2016 to April 2018. The findings include:. 1. Review of the Vitros 5600 calibration/calibration verification records from June 2016 to April 2018 identified no calibration verification for Alanine Aminotransferase, Albumin, Alcohol-Ethanol, Alkaline Phosphotase, Ammonia, Amylase, Aspartate Aminotransferase, Bilirubin Direct, Brain Natriuretic Peptide, Blood Urea Nitrogen, C-Reactive Protein, Calcium, Chloride, Cholesterol, Creatine Kinase MB, Creatine Kinase Total, Creatinine, Digoxin, Dilantin, Ferritin, Folic Acid, Glucose, Hemoglobin A1C, High Density Lipoprotein, Iron, Lactate, Lactate Dehydrogenase, Lipase, Magnesium, Micro-albumin, Neonatal Bilirubin, Phosphorus, Potassium, Total Protein, Salicylate, Sodium, Tegretol, Total Thyroxine, Total Billirubin, Triglycerides, FreeTriiodothyronine, Free Thyroxine, Troponin, Gentamycin, Vancomycin, Thyroid Stimulating Hormone, T3, Uric Acid, and Vitamin D performed on the Vitros 5600. from June 2016 to April 2018. 2. On 4/25/18 at approximately 8:30AM, the LM/GS1 confirmed the findings. The LM/GS1 stated calibration verification was performed when the Vitros 5600 was installed in April 2016 but not since then.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, "Procedure-by patient listing for HCG", and interview with the General Supervisor #2, for the Sure-Vue Qualitative Serum HCG test, the laboratory failed to perform and document a positive and negative control for 177 of 179 days of patient testing. Record review was June 2016 to April 2018. The findings include: 1. Review of quality control records for the Sure-Vue Qualitative Serum HCG test identified documentation of quality control for 6/13/16, 8/1/16, 9/12/16, 10/12/16, 10/24/16, 2/13/17, 4/19/17, 5/17/17, 6/24/17, 7/17 /17, 10/17/17, 10/24/17 and 1/18/18. 2. Review of the laboratory's "Pregnancy Test - Qualitative Log Sheet" identified patient testing was performed on the following days: 6/5/16, 6/13/16, 6/21/16, 6/28/16, 6/29/18, 6/30/16, 7/7/16, 7/15/17, 7/19/16, 7/21/16, 7/26/16, 7/30/16, 8/3/16, 8/6/16, 8/15/16, 8/17/16, 8/18/16, 8/21/16, 8/22/16, 8/22/16, 8/24/16, 8/25/16, 8/30/16, 8/31/16, 9/2/16, 9/3/16, 9/6/16, 6/7/16, 9/20/16, 9/23/16, 9 /24/16, 9/29/16, 10/4/16, 10/6/16, 10/9/16, 10/11/16, 10/14/16, 10/19/16, 10/21/16, 10 /25/16, 10/29/16, 11/2/16, 11/10/16, 11/14/16, 11/16/16, 11/17/16, 11/18/16, 11/21 /16, 11/22/16, 11/23/16, 11/28/16, 11/30/16, 12/1/16, 12/2/16, 12/6/16, 12/13/16, 12 /15/16, 12/16/16, 12/18/16, 12/21/16, 12/22/16, 12/25/16, 12/27/16, 12/30/16, 12/31 /16, 1/5/17, 1/6/17, 1/8/17, 1/11/17, 1/15/17, 1/16/17. 1/17/16, 1/20/16, 1/22/17, 1/23 /17, 1/24/17, 1/28/17, 1/31/17, 2/2/17, 2/3/17, 2/5/17, 2/7/17, 2/18/17, 2/19/17, 2/20 /17, 2/23/17, 2/24/17, 2/26/17, 3/1/17, 3/2/17, 3/6/17, 3/7/17, 3/14/17, 3/16/17, 3/20

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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 manual, media log sheets and interview with the General Supervisor #2 (GS2), the laboratory failed to check each lot number and shipment of Signal Blood Culture System Bottles for sterility and ability to support growth from June 2016 to April 2018. The findings include: 1. Review of the laboratory's policy and procedure manual identified no quality control plan for the Signal Blood Culture System Bottles. 2. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked each lot number and shipment of Signal Blood Culture System Bottles for sterility and ability to support growth from June 2016 to current. 3. On 4/24 /18 at approximately 12:45 PM, GS2 stated that they were keeping the certificates and not checking for sterility or the ability to support growth for the Signal Blood Culture System Bottles. B. Based on review of the laboratory's policy and procedure manual, media log sheets and interview with the General Supervisor #2 (GS2), the laboratory failed to check each lot number and shipment of Chocolate agar for sterility for 14 of 14 lots/shipments from June 2016 to April 2018. The findings include: 1. Review of the laboratory's policy and procedure manual identified no quality control plan for the Chocolate agar. 2. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked each lot number and shipment of Chocolate agar for sterility for 14 of 14 lots/shipments from June 2016 to current. 3. On 4/24/18 at approximately 12:45 PM, GS2 stated that they were keeping the certificates and only checking for ability to support growth for the Chocolate agar. C. Based on review of the laboratory's policy and procedure manual, media log sheets and interview with the General Supervisor #2 (GS2), the laboratory failed to check each lot number and shipment of Triple Soy Agar (TSA) for sterility for 15 of 15 lots /shipments from June 2016 to April 2018. The findings include: 1. Review of the laboratory's policy and procedure manual identified no quality control plan for the TSA. 2. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked each lot number and shipment of

	TSA for sterility for 15 of 15 lots/shipments from June 2016 to current. 3. On 4/24/18 at approximately 12:45 PM, GS2 stated that they were keeping the certificates and only checking for ability to support growth for the TSA. D. Based on review of the laboratory's policy and procedure manual, media log sheets and interview with the General Supervisor #2 (GS2), the laboratory failed to check each lot number and shipment of Sheep Blood/MacConkey Bi-plate Agar for sterility for 16 of 16 lots /shipments from June 2016 to April 2018. The findings include: 1. Review of the laboratory's policy and procedure manual identified no quality control plan for the Sheep Blood/MacConkey Agar. 2. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked each lot number and shipment of Sheep Blood/MacConkey Agar for sterility for 16 of 16 lots /shipments from June 2016 to current. 3. On 4/24/18 at approximately 12:45 PM, GS2 stated that they were keeping the certificates and only checking for ability to support growth for the Sheep Blood/MacConkey Agar. E. Based on review of the laboratory's policy and procedure manual, media log sheets and interview with the General Supervisor #2 (GS2), the laboratory failed to check each lot number and shipment of MacConkey Agar for sterility for 15 of 15 lots/shipments from June 2016 to April 2018. The findings include: 1. Review of the laboratory's policy and procedure manual identified no quality control plan for the MacConkey agar. 2. Review of the laboratory's quality control records identified a lack of documentation demonstrating the laboratory checked each lot number and shipment of MacConkey for sterility for 15 of 15 lots/shipments from June 2016 to current. 3. On 4/24/18 at approximately 12: 45 PM, GS2 stated that they were keeping the certificates and only checking for ability to support growth for the MacConkey Agar.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's media quality control records, patient records and interview with General Supervisor #2 (GS2), the laboratory failed to perform quality control for 12 of 12 days of patient testing for identification and susceptibility performed on the Dade Behring AutoScan-4. Record review was from March 2018 to April 2018. The findings include: 1. Review of the laboratory's quality control records for the Dade Behring AutoScan-4 identified a positive and negative control organism was performed on the following days: 3/3/18, 3/17/18, 3/23/18, 4/6/18, 4/13/18 and 4 /20/18. 2. Review of the laboratory's patient records for the AutoScan-4 identified patients were analyzed on 3/17/18, 3/19/18, 3/21/18, 3/24/18, 3/25/18, 3/28/18, 4/1 /18, 4/4/18, 4/5/18, 4/8/18, 4/18/18, and 4/19/18. 2. On 4/24/18 at approximately 1:15 PM, GS2 confirmed the findings. GS2 stated they are performing quality control on Dade Behring AutoScan-4 for each of their panels when a new lot/shipment is received and every Friday.

D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: A. Based on direct observation of the laboratory's Thermo Scientific Ultra Freezer where Fresh Frozen Plasma is stored, Thermo Scientific Ultra Freezer temperature log sheets and interview with the General Supervisor #1 (GS1), the laboratory failed to monitor the Thermo Scientific Ultra Freezer on a continuous basis for 694 of 694 days between 6/1/16 and 4/24/18. The findings include: 1. Direct observation of the laboratory's Thermo Scientific Ultra Freezer identified a lack of a continuous monitor of the freezer's temperature. 2. Review of the laboratory's Thermo Scientific Ultra Freezer log sheet identified the laboratory was recording the temperature of the freezer every hour since 5/27/16. 3. On 4/24/18 at approximately 11:05 AM, GS1 confirmed the findings. B. Based on review of the laboratory's Blood Bank alarm check records and interview with the General Supervisor #1 (GS1), the laboratory failed to perform and document the alarm check for the Thermo Scientific Ultra Freezer from 6/2016 to 4/2018. The findings include: 1. Review of the laboratory's Blood Bank alarm check records identified a lack of alarm checks for the Thermo Scientific Ultra Freezer from 6/2016 to 4/2018. 2. At approximately 11:05 AM, GS1 stated the freezer had an alarm but it was not regularly tested.