

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2070630	<b>(X3) Date Survey Completed</b> 10/17/2019
<b>Name of Provider or Supplier</b> Mercy Bella Vista	<b>Street Address, City, State</b> 1 Mercy Way, Bella Vista, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through review of the data used to determine the Normal Patient Mean value (MNPT) for prothrombin time assays, review of the package insert for STA Neoplastine Plus reagent , and interview it was determined that the laboratory failed to determine the normal patient mean value for the laboratory's patient population used in the calculation of INR values in accordance with manufacturer's instruction. Findings follow: A: Review of the package insert for STA neoplastine revealed that in determining the MNPT donors should be healthy and have no pathological condition, donors should not be taking any medication affecting coagulation, donors should span the adult age range, pediatric range should be established separately, and donors should be equally divided between males and females. B: Review of the documentation presented to establish the MNPT with the change to a new lot number of reagent, STA Neoplastine lot # 253049, revealed that the donors were identified as "Norm-1 .... Norm 20". C. In an interview on 10/17/19 at approximately 08:45 AM , the general supervisor, identified as number 3 on the CMS 209 form, stated that when establishing the MNPT that extra tubes are drawn on patients with no history of medication or pathologies that can affect coagulation and there are no records kept that can be used to evaluate the donors age, sex, medication history or possible pathologies..</p>
<b>D5469</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p>

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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Through review of manufacturer package insert, quality control results for erythrocyte sedimentation rate (ESR) assays for November 2018, March 2019 and July 2019, and interview, it was determined that the laboratory failed to establish its own control limits and to verify the criteria for acceptability of quality control results for the ESR assay for three of three months reviewed. Findings follow: A) The package insert for HemaTechnologies SedRite Plus ESR control material revealed that the individual laboratory should "establish its own mean and acceptable range" and the control means established by the laboratory should fall within the expected range specified for the control. B) Review of quality control results for ESR assay for November 2018, March 2019 and July 2019 revealed that the mean and acceptable range in three of the three months reviewed exactly matched the mean and expected range as listed on the HemaTechnologies SedRite Plus ESR control material package insert. C) In an interview on 10/17/19 at approximately 08:45 AM the laboratory staff member, identified as number 3 on the CMS 209 form stated that "we use the manufacturer's mean and ranges for the ESR controls". Through review of manufacturer package insert, quality control results for coagulation (prothrombin time (PT), and partial thromboplastin time (PTT) assays for November 2018, March 2019 and July 2019, and interview, it was determined that the laboratory failed to establish its own control limits and to verify the criteria for acceptability of quality control results for the coagulation assays for three of three months reviewed. Findings follow: A) The package insert for STA-Plus (N) and (ABN) coagulation controls stated "control ranges given are intended as only guidelines and it is recommended that each laboratory establish its own target and ranges". B) Review of quality control results for coagulation assays for November 2018, March 2019 and July 2019 revealed that the mean and acceptable range in 3 of the 3 months reviewed exactly matched the mean and expected range as listed on the STA- Plus package insert. C) In an interview on 10/17/19 at approximately 09:30 AM the laboratory staff member, identified as number 3 on the CMS 209 form stated that the laboratory used the manufacturer's mean and ranges for the coagulation controls.

**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:

Through review of the policy and procedure Document ID: BV3 Blood Bank "Component Storage and Transportation", blood bank refrigerator and fresh frozen plasma freezer temperature recording charts, lack of documentation and interview it was determined that the laboratory could not document proper storage temperature requirements were maintained on one of one occasions when the storage temperature for blood and blood components could not be confirmed on the temperature recording charts. Findings follow: A) Review of the policy and procedure Document ID: BV3 Blood Bank "Component Storage and Transportation" revealed " action to be taken if all refrigerators are out due to power failure: use the CBC Blood/Component Emergency Storage Record to monitor and record the blood temperature hourly". B) Review of the temperature recording charts for the blood storage refrigerator and the fresh frozen plasma storage freezer revealed that temperature records were not recorded on 5/29/19 12:00 PM until 5/29/19 08:00 PM with a hand-written notation stating "power off". C) Upon request, the laboratory was unable to provide documentation of hourly temperature recordings on the CBC Blood/Component Emergency Storage Record for 5/29/19 at 12:00 PM until 5/29/19 at 08:00 PM. D) In an interview on 10/17/19 at approximately 03:45 PM the laboratory staff members, identified as numbers one and two on the CMS 209 form , confirmed that the laboratory could not document proper storage temperatures for the blood storage refrigerator and the fresh frozen plasma freezer for the eight hour period identified above.

**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:

Through a review of quality control documentation for November 2018, March 2019, and July 2019, lack of documentation and interview with laboratory staff, it was determined the laboratory failed to document all corrective actions taken when results of control material failed to meet established criteria for acceptability on one of one occasions for partial thromboplastic time (PTT) assays. Survey findings follow: A) On 7/15/19 the Level 2 PTT control, with an acceptable range of 52.0 to 76.0, was resulted as 84.4 (3.4 SDI) at 03:02 PM ,as 84.4 (3.4 SDI) at 03:29 PM before an acceptable result of 71.8 at 03:54 PM. B) Upon request the laboratory was unable to provide documentation of corrective action taken to bring control results for PTT, identified above, into acceptable range C) In an interview at approximately 10:00 AM on 10/17/19, laboratory employee #3 (as listed on the form CMS-209) confirmed that the quality control results identified above were not acceptable and there were no documented corrective actions taken to bring the controls into acceptable range.