Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466383	04/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jacksonville Medical Care	1300 Braden Street, Jacksonville, AR	

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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of the policy and procedure "Sysmex CA-530", Levey-Jennings Report for prothrombin time, laboratory requisition listing and interview it was determined that the laboratory reported patient results when quality control results exceeded the range of acceptability on one of twenty-three days reviewed in March of 2017. Findings follow: A. Review of the policy and procedure for the "Sysmex CA-530" revealed that "a run is rejected when a single control measurement exceeds the mean plus or minus 2SD" (standard deviation). B. Review of the Levey-Jennings Report for prothrombin for March, 2017 revealed that on March 10, 2017 at 07:14 AM, the abnormal prothrombin time control (lot # 548460) with an acceptable range of 39.3 to 43.1 was reported as 38.5 which was outside of the plus or minus 2 SD range. C. Review of the "requisition listing" report for March 10, 2017 revealed that prothrombin time results were reported on patient 607223 on 3/10/17and patient 607228 on 3/10/17 at 11:18 AM . D. In an interview on 4/19/18 at approximately 11: 00 AM the laboratory director identified as number one on the CMS 209 report confirmed that quality control results for prothrombin times on March 10, 2017 were below acceptable limits and results were reported on the patients 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 review of the "Sysmex CA-530" policy and procedure, Levey-Jennings Report for November 2017, Requisition Listing for November 30, 2018 and interview it was determined that the laboratory failed to evaluate patient results to the last instance of successful quality control after an occurence of an instance of quality control failure in one of fourteen instances of quality control failure for prothrombin time assays in November 2017. Findings follow: A. Review of the policy and procedure for the "Sysmex CA-530" revealed that "a run is rejected when a single control measurement exceeds the mean plus or minus 2SD" (Standard Deviation). B. Review of the Levey-Jennings Report for prothrombin for November, 2017 revealed that both levels of quality control for prothrombin time assays were successful on November 30, 2017 at 8:36 AM C. Review of the Levey-Jennings Report for prothrombin for November, 2017 revealed that on November 30, 2017 at 4:20 PM, the abnormal prothrombin time control (lot # 548479) with an acceptable range of 38.6 to 42.4 was reported as 35.40 with a comment appended "rerun"; on November 30, 2017 at 4:20 PM, the abnormal prothrombin time control (lot # 548479) with an acceptable range of 38.6 to 42.4 was resulted as 36.1 with a comment appended "rerun, rerun with fresh control"; on November 30, 2017 at 4:20 PM, the abnormal prothrombin time control (lot # 548479) with an acceptable range of 38.6 to 42.4 was resulted as 35.6 with a comment appended "rerun, rerun with fresh control, rerun with new reagent"; on November 30, 2017 at 4:20 PM, the abnormal prothrombin time control (lot # 548479) with an acceptable range of 38.6 to 42.4 was resulted as 43.3 with a comment appended "rerun, rerun with fresh control, rerun with new reagent, rinse probe" . No successful instance of abnormal quality control for prothrombin times were documented since 8:36 AM on November 30, 2017. D. Review of the requisition listing report for November 30, 2017 revealed that prothrombin times were reported on patient 633387 at 9:50 AM and patient 633476 at 8:32 AM. E. Upon request, the laboratory could not provide documentation of prothrombin time evaluations for the patients identified above. F. In an interview on 4/19/18 at approximately 11:00 AM the laboratory director identified as number one on the CMS 209 report confirmed that quality control results for prothrombin times on November, 2017 identified above exceeded acceptable limits and results were reported on the patients identified above and evaluation did not take place after the failure of quality control.