

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0468584	<b>(X3) Date Survey Completed</b>  05/24/2018
<b>Name of Provider or Supplier</b>  Fayetteville Diagnostic Clinic	<b>Street Address, City, State</b>  3344 North Futrall Drive, Fayetteville, 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>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure for quality control, "Orchard" system quality control reports, patient result reports, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results since the last acceptable test run when results of quality control failed to meet the laboratory's established criteria for acceptability on four of four occasions of quality control failure affecting 42 patients. Findings follow: A: The laboratory failed to evaluate patient results performed on 3/9/17 when quality control for prothrombin times failed to meet the laboratory's criteria for acceptability on 3/10/17 1. The laboratory's policy and procedure for quality control states "In all cases where STOP is indicated, do not continue to report patient results until the situation is resolved" and "2-2s Rule: Two controls in the run exceed 2SD or one control in the run + one control in the preceding run exceed 2SD". 2. Review of the "Orchard" system quality control report for March 10, 2017 revealed that the abnormal prothrombin time control (lot number N0556523 with an acceptable range of 44.5 to 50.5) was reported as 52.9 at 09:47, 53.2 at 10:05, 51.8 at 11:11, and 49.9 at 12:16 with a note "Remake PT Reagent". 3. Review of the "Orchard" system quality control report revealed that the last acceptable prothrombin time quality control was performed at 09:31 on 3/9/17 4. Review of the patient result report for 3/9/17 revealed that prothrombin time tests</p>

were performed and resulted on ten patients (identified as numbers 1 through 10 on a patient identification list). 5. Upon request, the laboratory was unable to provide documentation that patient prothrombin time results performed on 3/9/17 had been evaluated. 6. In an interview on 5/23/18 at approximately 1400, the technical supervisor identified as number 3 on the CMS 209 report confirmed that quality control for prothrombin time failed to meet the laboratory's criteria for acceptability on 3/10/17 and the patient prothrombin time results since the last successful quality control run had not been evaluated. B: The laboratory failed to evaluate patient results performed on 7/6/17 when quality control for prothrombin times failed to meet the laboratory's criteria for acceptability on 7/7/17 1. The laboratory's policy and procedure for quality control states "In all cases where STOP is indicated, do not continue to report patient results until the situation is resolved" and "2-2s Rule: Two controls in the run exceed 2SD or one control in the run + one control in the preceding run exceed 2SD". 2. Review of the "Orchard" system quality control report for July 7, 2017 revealed that the abnormal prothrombin time control (lot number N0462476 with an acceptable range of 53 to 59) was reported as 52.6 at 10:33 3. Review of the "Orchard" system quality control report revealed that acceptable prothrombin time quality control was performed at 12:20 on 7/7/17 with a note "new reagent made, second bottle, different box to be opened of reagent". 4. Review of the "Orchard" system quality control report revealed that the previous acceptable quality control result was 56.2 at 09:35 on 7/6/17 4. Review of the patient result report for 7/6/17 revealed that prothrombin time tests were performed and resulted on nine patients (identified as numbers 11 through 19 on a patient identification list. 5. Upon request, the laboratory was unable to provide documentation that patient prothrombin time results performed on 7/6/17 had been evaluated. 6. In an interview on 5/23/18 at approximately 1400, the technical supervisor identified as number 3 on the CMS 209 report confirmed that quality control for prothrombin time failed to meet the laboratory's criteria for acceptability on 7/7/17 because the testing personnel had replaced the test reagents, and the patient prothrombin time results since the last successful quality control run had not been evaluated. C: The laboratory failed to evaluate patient results performed on 09/21/17 when quality control for urine creatinine failed to meet the laboratory's criteria for acceptability on 09/22/17. 1. The laboratory's policy and procedure for quality control states "In all cases where STOP is indicated, do not continue to report patient results until the situation is resolved" and "2-2s Rule: Two controls in the run exceed 2SD or one control in the run + one control in the preceding run exceed 2SD". 2. Review of the "Orchard" system quality control report for September 22, 2017 revealed that the normal control for urine creatinine (lot number 66741 with an acceptable range of 64 to 70.4 ) was reported as 63.09 at 08:50, 63.1 at 09:24, and 67.92 at 10:17. 3. Review of the "Orchard" system quality control report for September 22, 2017 revealed that the abnormal controls (lot number 66742 with an acceptable range of 137.6 to 150.8) was reported as 136.45 at 08:50 , 134.72 at 09:24, and 143.37 at 10:17. 3. Review of the "Orchard" system quality control report revealed that the last acceptable urine creatinine quality control was performed at 09:12 on 9/21/17 4. Review of the patient result report for 9/21/17 revealed that urine creatinine tests were performed and resulted on seven patients identified as numbers 36 through 42 on a patient identification list. 5. Upon request, the laboratory was unable to provide documentation that patient urine creatinine results performed on 9/21/17 had been evaluated. 6. In an interview on 5/23/18 at approximately 1400, the technical supervisor identified as number 3 on the CMS 209 report confirmed that quality control for urine creatinine failed to meet the laboratory's criteria for acceptability on 9/22/17 and the patient urine creatinine results since the last successful quality control run had not been evaluated.