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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0476593 | (X3) Date Survey Completed 06/26/2018 |
| Name of Provider or Supplier Wellmed At East Forest | Street Address, City, State 2201 Forest Ln, Garland, TX | |
| 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 |
|---------------------------|--|
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) procedure and interview with facility personnel, the laboratory failed to identify the history in the laboratory's Risk Assessment (RA) for the QBC hematology analyzer. The findings included: a. At the time of the survey June 26, 2018 the laboratory failed to produce documentation for the history of Quality Control assessment of the Quality Control b. In an interview at 11:00 hours on 06/26/2018 in the office, the Testing person #1 from the CMS from 209 stated that the laboratory performed the Q C once every 3 weeks part of the IQCP risk assessment.</p> |