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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 17D0450852 | (X3) Date Survey Completed 04/19/2022 |
| Name of Provider or Supplier Great Plains Of Smith County | Street Address, City, State 921 Us-36, Smith Center, KS | |
| 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 |
|---------------------------|---|
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Sysmex XS 450 verification documentation, Complete Blood Count (CBC) policy and interview, the laboratory failed to verify reference ranges (normal values) for ten CBC calculations were appropriate documented for the laboratory's patients' male/female population prior to reporting patient test results at time of survey. Findings: 1. No documentation demonstrating the present of reference ranges of the CBC calculations: Mean Corpuscula Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell Distribution Width (RDW), Mean Platelet Volume (MPV), Neutrophil Absolute (#), Lymphocyte #, Monocyte #, Eosinophil #, and Basophil #. 2. Based on a review of a Male and Female CBC patient report with reference ranges for MCV, MCH, MCHC, RDW, MPV, Neutrophil #, Lymphocyte #, Monocyte #, Eosinophil # and Basophil #, the reference range documentation could not be presented from the Sysmex XS 450 validation/verification or the CBC policy 3. Interview with the technical consultant on April 19, 2022 at 11:00 a.m. confirmed, the laboratory failed to verify the reference ranges(normal values) were appropriate for the laboratory's patient population prior to reporting patient test results at time of suvey.</p> |