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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2291408 | (X3) Date Survey Completed 03/06/2024 |
| Name of Provider or Supplier Kelsey-Seybold Clinic Springwoods Village Campus | Street Address, City, State 22407 Holzwarth, Spring, 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 |
|---------------------------|--|
| D0000 | An announced survey of the laboratory was conducted on 03/06/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited. |
| 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 surveyor's observations, review of laboratory's analyzer verification studies and staff interview, the laboratory failed to document verification of normal/reference range for 2 of 2 analyzers used by the laboratory from November 2023 to March 2024, the VITROS XT 3400 chemistry analyzer, and the Sysmex XN-430 hematology analyzer. Findings included: 1. Surveyors observations on 03/06/2024 at 0905 hours in the laboratory revealed the laboratory used the following analyzers: One VITROS XT 3400 clinical chemistry analyzer, serial number (SN) J34500954 One Sysmex XN-430 hematology analyzer, SN 11877 2. Review of laboratory's "VITROS XT 3400 Clinical Chemistry Analyzer (SN 3450954) Verification Summary Report - Springwood Village" (document VER-064.1, approved 11/03/2023) revealed: "6.4.1. Reference ranges were established by Kalsey-Seybold clinic multisite reference establishment study." 3. Review of laboratory's " Sysmex XN-430 (SN 11877) Verification Summary - Springwood Village" (document VER-061.1, approved 10/26 /2023) revealed: "6.4.1. Reference range was adopted from established KSC ranges."</p> |

4. Laboratory was asked for documentation of verification of normal/reference range for the above instruments and no such documentation was available for review prior to survey exit. 5. In an interview of 03/06/2024 at 1010 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid KSC - Kelsey Seybold Clinic