| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2299444 | 08/07/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Michael G Valpiani Md Az Ltd | 16922 Telge Rd, Suite 2b, Cypress, 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 |
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| **D0000** | An announced survey of the laboratory was conducted on 08/07/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's policies/procedures, test establishment studies and staff interview, the laboratory failed to follow its own policy for verification of interfering substances for one of one toxicology testing platforms used by the laboratory, the Sciex 4000 LC-MS/MS. Findings included: 1. Review of laboratory's policy "Analytic Method Validation v2" (approved for use 03/01/2024) revealed: "During the method validation, the analyte will be quantified with other similar drugs or chemical compounds in chemical and physical properties to test if there is an interference exist (sic) and how the interferences affect the quantitation of the analyte being tested." 2. Review of laboratory's test establishment studies for each analyte (completed 03/02/2024) revealed: Sample name: Interference Sample type: Unknown |

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| | Results: Area (cps) = N/A RT (min) = N/A Target concentration (ng/mL): N/A Calculated concentration (ng/mL): N/A There was no documentation of the interfering substances used in the study, nor how it affected the results. 3. In an interview on 08 /07/2024 at 1005 hours in the laboratory, the general supervisor (as indicated on submitted Form CMS 209) confirmed the findings. Key: cps - Counts per second RT - Retention time min - Minutes N/A - Not applicable ng/mL - Nanograms per milliliter CMS - Centers for Medicare and Medicaid |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's quality assurance/quality control records, policies /procedures and staff interview, the laboratory failed to document evaluation of quality control to detect errors over time for one of one test platforms used by the laboratory, the Sciex 4000 LC-MS/MS. Findings included: 1. Review of laboratory's Sciex 4000 LC-MS/MS quality control and quality assurance records from March to July 2024 revealed the laboratory did not document evaluation of quality control to detect errors over time. 2. Review of laboratory's policies/procedures revealed there were no protocols in place for evaluation of quality control to detect potential errors over time. 3. In an interview on 08/07/2024 at 1145 hours in the laboratory, the general supervisor (as indicated on submitted Form CMS 209) confirmed the findings. |