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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D1008641 | (X3) Date Survey Completed 06/10/2021 |
| Name of Provider or Supplier Flushing Road Internal Medicine & Pediatrics | Street Address, City, State 1201 Flushing Road, Flint, MI | |
| 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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| D5022 | <p>TOXICOLOGY CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Consultant (TC) #2, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to verify the performance specifications for 6 drug analytes - Barbiturates, 6-Monoacetylmorphine, Methadone, Ecstasy, Opiates, and Oxycodone. Refer to D5421. .</p> |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with Technical Consultant (TC) #2, the laboratory failed to verify the accuracy of its chemistry prostate specific antigen (PSA) testing at least twice annually for 3 (2019 and 2020) of 4 events for 2 years reviewed. Findings include: 1. A record review of the "Test Check List" compared to the documentation of 2 times a year verification of accuracy revealed a lack of documentation for the PSA testing as follows: a. 2019 - no documentation for December b. 2020 - no documental for June and December 2.</p> |

When requested, the laboratory was not able to provide documentation showing the verification of accuracy was completed at least twice annually for 1 event in 2019 and 2 events in 2020 for the PSA testing. 3. An interview on 6/10/2021 at 11:11 am, TC2 confirmed the laboratory had not performed the twice annually verification of accuracy for the PSA testing.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

. Based on record review, lack of documentation, and interview with Technical Consultant (TC) #2, the laboratory failed to verify the performance specifications for 6 analytes (Barbiturates, 6-Monoacetylmorphine (6-AM), Methadone, Ecstasy, Opiates, and Oxycodone) of 6 toxicology analytes during the 3 (March to June 2021) months of operation. Findings include: 1. A review of the laboratory's patient test reports revealed the laboratory was performing and reporting out drug testing for 6 analytes (Barbiturates, 6-AM, Methadone, Ecstasy, Opiates, and Oxycodone) from March to June 2021. 2. A review of the laboratory's performance verification documentation for the new Hobra Pentra 400 chemistry analyzer revealed a lack of documentation of verification of performance specifications for the 6 analytes (Barbiturates, 6-am, Methadone, Ecstasy, Opiates, and Oxycodone) prior to the reporting of patient drug tests. 3. When requested on 6/10/2021 at 11:11 am by the surveyor, the verification of performance specification data for the 6 drug analytes was not available. 4. An interview on 6/10/2021 at 12:45 pm, TC2 confirmed the verification of performance specification data was not made available to the surveyor or completed prior to testing and reporting out patient results.

D5803

TEST REPORT
CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

. Based on record review, lack of documentation, and interview with Technical Consultant (TC) #2, the laboratory failed to have available for the surveyor the patient's final test report maintained as part of the patients' electronic medical record (EMR) for 1 (#4) of 14 patient records reviewed. Findings include: 1. A record review for 1 (#4) of 14 patient records reviewed revealed a lack of documentation in the EMR system for bacteriology Clostridium difficile testing. 2. An interview on 6/10 /2021 at 11:45 am, TC2 confirmed the final patient test results were not available in the EMR system for the surveyor to review on the day of the survey.