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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D2059771 | (X3) Date Survey Completed 03/30/2018 |
| Name of Provider or Supplier I2b Lab Llc | Street Address, City, State 4631 Teller Ave Ste 100, Newport Beach, CA | |
| 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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| 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 review of 2017 CAP (College of American Pathologists, DMPM-- Drug Monitoring for Pain Management) proficiency testing reports, laboratory proficiency testing records, laboratory documents correlating split specimen testing, and patients test reports; the lack of laboraotry documetns, and interview with laboratory personnel, the laboratory failed to verify the accuracy of testing at least twice annually. Findings include: a. Laboratory documents revealed the laboratory tested for 76 different drugs in 2017. b. To satisfy the requirement to verify the accuracy of testing at least twice annually, the laboratory chose to participate in CAP's proficiency testing program, and perform split sample testing for results correlations with two other CLIA-certified reference laboratories utilizing LC/MS-MS methods. c. Review of CAP reports and both correlation studies revealed drugs that were not included in the CAP survey or the other laboratories test menus; and thus, the laboratory failed to verify the accuracy of testing at least twice annually as follows: MDEA Methylphenidate 3,4 Methylenedioxypropylamphetamine (MDPV) Methylone Mephedrone Norpropoxyphene Lamotrigine Lurasidone MDA Doxepin Fluoxetine Flunitrazepam Ketamine Cocaine Citalopram Clonazepam Diazepam Acetylmorphine Aripiprazole Buspirone Bupropion Quetiapine Paroxetine Pregabalin Olanzapine Zopiclone Zaleplon Venlafaxine Trimipramine Ritalinic acid Amobarbital Pentobarbital Phenobarbital Secobarbital d. Laboratory personnel affirmed (11/30/17; 3/22/18) no other alternate means of verifying the accuracy of testing in 2017; and thus, the laboratory's failure to verify all drugs at least twice annually. e. The reliability and quality of results reported could not be assured. Based on the stated estimated annual tests volume, the laboratory reported approximately 350,000 results each year for</p> |

drugs tested. A few examples are as follows: Accession Date of Date Date Collection Received Reported ----- 5274 2/17/17 3 /20/17 3/21/17 5318 1/12/17 3/20/17 3/23/17 6059 4/12/17 4/27/17 4/28/17 9914 8/21 /17 9/12/17 9/14/17

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of laboratory documents establishing performance specifications for testing drugs using laboratory-developed-test procedures for the Agilent LC/MS (Liquid chromatography-tandem mass spectrometry) system with MassHunter Workstation Software for data analysis, and the laboratory's criteria for specimen acceptability; the lack of laboratory documents, and interview with the Technical Supervisor, the laboratory failed to establish criteria for specimen stability for acceptability. Findings include: a. The laboratory document titled "LC/MS Method Validation Plan", implemented 1/25/15, limited testing of refrigerated samples to 5 days. b. Laboratory written procedures effective 2/03/17, titled "Specimen Collection and Storage" and "Processing of Samples and Rejection" stated urine specimen are stable for 1 week at ambient room temperature, 2 weeks when refrigerated, and 1 year when frozen. And the written procedures failed to specify acceptable temperatures for "room temperature", "refrigerated", and "frozen". c. The Technical Supervisor affirmed (3/30/18) that the criteria in the written procedures were based on the publications of other laboratories and that the laboratory did not validate the stability of the drugs in the specimen beyond 5 days refrigerated; specifically, the laboratory failed to establish stability at 1 week room temperature, 2 weeks refrigerated, and 1 year frozen. d. The reliability and quality of results reported could not be assured.

Based on the stated estimated annual tests volume, the laboratory reported approximately 350,000 results each year for drugs tested. A few examples are as follows: Accession Date of Date Date Collection Received Reported ----- 5274 2/17/17 3/20/17 3/21/17 5318 1 /12/17 3/20/17 3/23/17 6059 4/12/17 4/27/17 4/28/17 9914 8/21/17 9/12/17 9/14/17

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory documents establishing performance specifications for testing drugs using laboratory-developed-test procedures for the Agilent LC/MS (Liquid chromatography-tandem mass spectrometry) system with MassHunter Workstation Software for data analysis, the laboratory's list of current drugs tested, and patients test reports; the lack of laboratory documents, and interviews with laboratory personnel including an Administrator and the Technical Supervisor, the laboratory failed to validate 8 drugs. Findings include: a. Laboratory validation documents and the laboratory "Current Drugs List" included testing for 76 drugs. However, the laboratory was unable to provide validations for 8 drugs, as follows: Methyphenidate 3,4 Methylenedioxypropylamphetamine (MDPV) Methylone Mephedrone Lurasidone Quetiapine Paroxetine Zopiclone b. The Technical Supervisor affirmed (3/22/18) the aforementioned lack of validations; and thus, the laboratory's failure to establish Accuracy, Precision (reproducibility), Analytical Sensitivity (limits of detection), Stability, and Analytical Specificity including interfering substances, prior to testing patients specimen and reporting results. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual tests volume, the laboratory reported approximately 350,000 results each year for all drug tests, including the 8 that were not validated. A few examples are as follows:
Accession Date Reported ----- 5274 3/21/17 5318 3/23/17 6059 4/28/17 9914 9/14/17 .

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory written policy for quality controls and interview with laboratory personnel, the laboratory failed to require results of control materials to meet the laboratory's criteria for acceptability before reporting patient test results. Findings include: a. The laboratory QC policy stated the following: "In some circumstances, patient data can be released even if the control result is not within the specified limit, provided patient care is not compromised." b. The Technical Supervisor affirmed (3/22/18) the policy needed clarification to ensure compliance with requirements for acceptable QC results prior to reporting. c. The reliability and quality of results reported could not be assured. Based on the stated estimated annual tests volume, the laboratory reported approximately 350,000 results each year for drugs tested.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

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| | <p>This CONDITION is not met as evidenced by: Based on the serious and cumulative nature of survey findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in providing overall management and direction to meet the Conditions required for performing high complexity laboratory-developed-testing (LDT). See D6082, D6086, and D6093. .</p> |
| <p>D6082</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: The Laboratory Director is herein cited for deficient practice in ensuring the development and validation of tests to establish quality in all aspects of testing, including preanalytic, analytic, and postanalytic. Findings include: a. Laboratory validation studies for LC/MS-MS failed to establish criteria for specimen stability prior to testing and reporting results. See D5311. b. The laboratory failed to validate testing for 8 drugs to establish performance specifications prior to reporting results. See D5423. . .</p> |
| <p>D6086</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: The Laboratory Director is herein cited for deficient practice in ensuring that verification methods are adequate to determine the accuracy of testing, and at least twice annually. Findings include: a. The laboratory's methods for verifying the accuracy of testing failed to include 8 drugs. See D5217. .</p> |
| <p>D6093</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: The Laboratory Director is herein cited for deficient practice in ensuring that quality control programs are established and maintained and to identify failures in quality as they occur. Findings include: a. The Laboratory Director approved the policy to report patients results when QC fails to meet criteria for acceptability. See D5481.</p> |