| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 23D0912551 | 05/24/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Belleville Health Care Pc | 265 Main Street Suite B, Belleville, 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 |
|---|---|
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. A. Based on record review and interviews, the laboratory failed to establish a policy for the conditions of specimen transportation for its urine toxicology specimens received from outside locations for 2 (May 2021 to May 2023) of 2 years reviewed. Findings include: 1. An interview on 5/24/23 at 9:07 am with Testing Personnel #1 and #2 revealed specimens tested in the laboratory are collected in the neighboring clinic and a clinic in Rochester, MI. 2. A review of the laboratory's policies and procedures revealed a lack of specimen transportation policy. 3. An interview on 5/24 /23 at 9:43 am with the Technical Consultant confirmed a specimen transportation policy had not been established. B. Based on record review and interviews, the laboratory failed to follow the manufacturer's instructions for specimen acceptability and rejection for its qualitative urine amphetamine testing for 4 (Patients PR25882, BW206548, DE826015, and CM224097) of 10 patient test records reviewed. Findings include: 1. A review of the laboratory's "Thermo Scientific DRI Amphetamines Assay" manufacturer's instructions revealed a section titled, "Specimen Collection and Handling" stating, "The Clinical and Laboratory Standards Institute Toxicology and Drug Testing in the Clinical laboratory; Approved Guideline recommends that prior to analysis, urine specimens may be stored at 2 to 8 degrees C for five working days." 2. An interview on 5/24/23 at 11:23 am with Testing Personnel #2 revealed the laboratory only stores urine specimens refrigerated, between 2 to 8 degrees C. 3. A |

| | |
|---|---|
| | review of 10 patient test records revealed the following 4 patients had qualitative urine amphetamine testing performed more than 5 days after the specimens were collected: a. Patient PR25882 had their specimen collected on 7/21/22 and testing performed on 8/3/22, 13 days after collection. b. Patient BW206548 had their specimen collected on 1/10/23 and testing performed on 2/8/23, 29 days after collection. c. Patient DE826015 had their specimen collected on 4/14/23 and testing performed on 4/25/23, 11 days after collection. d. Patient CM224097 had their specimen collected on 4/24/23 and testing performed on 5/10/23, 16 days after collection. 4. An interview on 5/24/23 at 12:20 pm with the Technical Consultant confirmed the laboratory had reported results on specimens that had exceeded specimen stability. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>. Based on record review and interview with the Technical Consultant, the laboratory failed to ensure Technical Consultant had met the qualification requirements at 493.1411. Refer to D6035. |
| **D6035** | TECHNICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1411<br><br>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be |

| | |
|---|---|
| | acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Technical Consultant, the laboratory failed to ensure the Technical Consultant had met the qualification requirements at 493.1411 for 1 of 1 Technical Consultant listed on Form CMS-209. Findings include: 2. A review of the laboratory's personnel files revealed a lack of documentation showing the Technical Consultant's Bachelor of Science degree had been in a chemical, physical or biological science of medical technology. 3. The surveyor requested additional documentation showing the Technical Consultant's major of study on 5/24/23 at 9:49 am and it was not made available. 4. The laboratory was given an additional 7 days to provide documentation showing the Technical Consultant met the qualification requirements and it was not made available. |
| **D6047** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b(8)(i)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Technical Consultant, the Technical Consultant failed to perform direct observations as part of testing personnel competency assessments for 2 (Testing Personnel #1 and #2) of 2 testing personnel listed on Form CMS-209. Findings include: 1. An interview on 5/24/23 at 9:58 am with the Technical Consultant revealed competency assessments are performed remotely. 2. A review of the laboratory's competency assessment documentation revealed testing personnel had been assessed remotely on the following dates: a. Testing Personnel #1 on 10/26/22. b. Testing Personnel #2 on 1/20/22 and 7/18/22. 3. A review of the laboratory's "Proficiency Testing and Employee Competency" policy revealed a section titled "Employee Competency" stating, "Employee competency assessment will measure the following points to determine and measure the employee competency to perform the testing performed by the laboratory. 1. The direct observation of each test performed by the employee." 4. An interview on 5/24/23 at 12:20 pm with the Technical Consultant confirmed the competency assessment observations had not been direct. |