| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>25D2282355 | (X3) Date Survey Completed<br>02/27/2025 |
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| **Name of Provider or Supplier**<br>Express Care Of Starkville, Llc | **Street Address, City, State**<br>606 Hwy 12 East, Starkville, MS | |

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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| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the operator's manual for the Abaxis Piccolo Xpress Chemistry Analyzer, patient test results, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., and interview with Technical Consultant #2 (TC #2), listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to perform routine chemistry testing following manufacturer's instructions for acceptable specimens on the Abaxis Piccolo Xpress Chemistry Analyzer. Findings include: 1. Review of the operator's manual for the Abaxis Piccolo Xpress Chemistry Analyzer revealed the manufacturer's instructions state, "Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." 2. Review of patient test results in the Abaxis Piccolo Xpress Chemistry Analyzer revealed the last thirty patient specimens, whose specimens could have potentially been collected in sodium heparin tubes, were tested from 11/1/2024 through 2/25/2025, four of fourteen months since the last survey on 12/13/2023. 3. Observation of green-top specimen collection tubes, in use by the laboratory on 2/27/2025 at 10:30 a.m., revealed the anticoagulant in the green-top tubes in use was sodium heparin. There were 70 tubes remaining from a pack of 100 sodium heparin tubes, received on 6/18/2024. 4. In an interview on 2/27/2025 at 10:30 a.m., Technical Consultant #2 stated the laboratory used whole blood specimens from green-top tubes for routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer. |
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| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>(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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(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 the operator's manual for the Abaxis Piccolo Xpress Chemistry Analyzer, patient test results, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., and interview with Technical Consultant #2, the laboratory failed to establish performance specifications for performing routine chemistry testing on the Abaxis Piccolo Xpress Chemistry Analyzer with whole blood specimens drawn in sodium heparin collection tubes. Findings include: 1. The manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer stated, "Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." Review of the operator's manual revealed the laboratory had modified routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer, by using whole blood specimens drawn in sodium heparin collection tubes. A modified test is considered uncategorized by the Food and Drug Administration (FDA) and therefore, becomes a high complexity test. 2. Review of patient test results in the Abaxis Piccolo Xpress Chemistry Analyzer revealed the last thirty patient specimens, whose specimens could have potentially been collected in sodium heparin tubes, were tested from 11/1/2024 through 2/25/2025, four of fourteen months since the last survey on 12/13/2023. 3. Observation of green-top specimen collection tubes, in use by the laboratory on 2/27/2025 at 10:30 a.m., revealed the anticoagulant in the green-top tubes in use was sodium heparin. There were 70 tubes remaining from a pack of 100 sodium heparin tubes, received on 6/18/2024. 4. In an interview on 2/27/2025 at 10:30 a.m., Technical Consultant #2 stated the laboratory used whole blood specimens from green-top tubes for routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the CMS 209 personnel form, documentation of personnel qualifications, manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., and interview with Technical Consultant |

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| | #2, the laboratory director, listed on the CMS 209 personnel form, does not meet the qualification requirements of 493.1443 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the personnel file of the laboratory director, listed on the CMS 209 personnel form, revealed this individual did not meet the qualification requirements of 493.1443 of this subpart for a laboratory performing high complexity testing. 2. Review of the operator's manual for the Abaxis Piccolo Xpress Chemistry Analyzer, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., and interview with Technical Consultant #2 on 2/27/2025 at 10:30 a.m., revealed the laboratory had modified routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer, by using whole blood specimens drawn in sodium heparin collection tubes. The manufacturer's instructions for the Abaxis Piccolo Xpress Analyzer stated, "Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." A modified test is considered uncategorized by the Food and Drug Administration (FDA) and therefore, becomes a high complexity test. Refer to D6078 (Laboratory Director Qualifications). |
| **D6078** | LABORATORY DIRECTOR QUALIFICATIONS<br>CFR(s): 493.1443<br><br>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 (b)(2)(i) Be a doctor of medicine, a 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 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of |

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| | Pathology.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS 209 personnel form, documentation of personnel qualifications, manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer, interview with Technical Consultant #2 on 2/27/2025 at 10:30 a.m., observation of green-top sodium heparin specimen collection tubes in use by the laboratory and patient test results, the laboratory director, listed on the CMS 209 personnel form, does not meet the qualification requirements of 493.1443 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the personnel file of the laboratory director, listed on the CMS 209 personnel form, revealed this individual did not meet the qualification requirements of 493.1443 of this subpart for a laboratory performing high complexity testing. 2. The manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer stated, "Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." Review of the operator's manual revealed the laboratory had modified routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer, by using whole blood specimens drawn in sodium heparin collection tubes. A modified test is considered uncategorized by the Food and Drug Administration (FDA) and therefore, becomes a high complexity test. 3. In an interview on 2/27/2025 at 10:30 a. m., Technical Consultant #2 stated the laboratory used whole blood specimens from green-top tubes for routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer. 4. Observation of green-top specimen collection tubes, in use by the laboratory on 2/27/2025 at 10:30 a.m., revealed the anticoagulant in the green-top tubes in use was sodium heparin. There were 70 tubes remaining from a pack of 100 sodium heparin tubes, received on 6/18/2024. 5. Review of patient test results in the Abaxis Piccolo Xpress Chemistry Analyzer revealed the last thirty patient specimens, whose specimens could have potentially been collected in sodium heparin tubes, were tested from 11/1/2024 through 2/25/2025, four of fourteen months since the last survey on 12/13/2023. |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the CMS 209 personnel form, documentation of personnel qualifications, manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., and interview with Technical Consultant #2, the testing personnel, listed on the CMS 209 personnel form, do not meet the qualification requirements of 493.1489 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the personnel files of the testing personnel, listed on the CMS 209 personnel form, revealed these individuals did not meet the qualification requirements of 493.1489 of this subpart for a laboratory performing high complexity testing. 2. Review of the operator's manual for the Abaxis Piccolo Xpress Chemistry Analyzer, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., |

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| | and interview with Technical Consultant #2 on 2/27/2025 at 10:30 a.m., revealed the laboratory had modified routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer, by using whole blood specimens drawn in sodium heparin collection tubes. The manufacturer's instructions for the Abaxis Piccolo Xpress Analyzer stated, "Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." A modified test is considered uncategorized by the Food and Drug Administration (FDA) and therefore, becomes a high complexity test. Refer to D6171 (Testing Personnel Qualifications). |
| **D6171** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1489(b)<br><br>(b) Meet one of the following requirements: (b)(1) 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; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS 209 personnel form, documentation of personnel qualifications, manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer, interview with Technical Consultant #2, observation of green-top sodium heparin specimen collection tubes in use by the laboratory on 2/27/2025 at 10:30 a.m., and patient test results, the testing personnel, listed on the CMS 209 personnel form, |

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| | do not meet the qualification requirements of 493.1489 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the personnel files of the testing personnel, listed on the CMS 209 personnel form, revealed these individuals did not meet the qualification requirements of 493.1489 of this subpart for a laboratory performing high complexity testing 2. The manufacturer's instructions for the Abaxis Piccolo Xpress Chemistry Analyzer stated, "Lithium heparin is the only anticoagulant recommended for use with the Piccolo Xpress." Review of the operator's manual revealed the laboratory had modified routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer, by using whole blood specimens drawn in sodium heparin collection tubes. A modified test is considered uncategorized by the Food and Drug Administration (FDA) and therefore, becomes a high complexity test. 3. In an interview on 2/27/2025 at 10:30 a.m., Technical Consultant #2 stated the laboratory used whole blood specimens from green-top tubes for routine chemistry testing with the Abaxis Piccolo Xpress Chemistry Analyzer. 4. Observation of green-top specimen collection tubes, in use by the laboratory on 2/27/2025 at 10:30 a.m., revealed the anticoagulant in the green-top tubes in use was sodium heparin. There were 70 tubes remaining from a pack of 100 sodium heparin tubes, received on 6/18/2024. 5. Review of patient test results in the Abaxis Piccolo Xpress Chemistry Analyzer revealed the last thirty patient specimens, whose specimens could have potentially been collected in sodium heparin tubes, were tested from 11/1/2024 through 2/25/2025, four of fourteen months since the last survey on 12/13/2023. |