

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1067616	(X3) Date Survey Completed 02/11/2025
Name of Provider or Supplier Emergent Health Partners	Street Address, City, State 1200 State Circle, Ann Arbor, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow manufacturer's instructions for the use Piccolo Xpress chemistry analyzer indoors only for one (February 2024 to February 2025) of one year since the laboratory started testing. Findings include: 1. An interview on 2/11/25 at 9:26 am with the waived testing personnel revealed the Piccolo Xpress instrument is kept in a carrying case in the vehicle while on duty and stored inside when not needed. Testing using the Piccolo Xpress instrument is sometimes performed outside using the vehicle's power source. 2. A review of the "Piccolo Xpress chemistry analyzer Operator's Manual" manufacturer's instructions revealed the operating temperature range is "15-32 degrees C" and only for indoor use. 3. An interview on 2/11/25 at 12:59 pm with the Director of Mobile Integrative Health confirmed the Piccolo Xpress is only to be used indoors.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Mobile Integrative</p>

	<p>Health, the laboratory failed to establish competency assessment policies for one (February 2024 to February 2025) of one year since the laboratory started testing. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of competency assessment policies. 2. A review of laboratory personnel records revealed a lack of competency assessments performed between February 2024 and February 2025. 3. An interview on 2/11/25 at 10:07 am with the Director of Mobile Integrative Health confirmed the laboratory had not established competency assessment policies to assess testing personnel and consultant competency.</p>
<p>D5391</p>	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to establish a Quality Assessment Plan to include preanalytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP) since it was approved on 2/6/25. Findings include: 1. A review of the Siemens epoc blood gas analyzer IQCP approved by the laboratory director on 2/6/25 revealed a lack of a Quality Assessment Plan to include how the laboratory will monitor its preanalytic systems. 2. An interview on 2/11/25 at 10:02 am with the Director of Mobile Integrative Health confirmed a Quality Assessment Program was not implemented in the Siemens epoc blood gas analyzer IQCP.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to demonstrate the stability of the Siemens epoc blood gas analyzers to support the frequency of quality control performance as written in the Individualized Quality Control Program (IQCP) (refer to D5425), failed to perform calibration verification at least every six months on the Siemens epoc blood gas analyzers (refer to D5439), failed to perform control procedures at least each date of patient testing (refer to D5445), and failed to evaluate the relationship between its Siemens epoc blood gas analyzers at least twice annually (refer to D5775).</p>
<p>D5425</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>(b)(3) The laboratory must determine the test system's calibration procedures and</p>

control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to demonstrate the stability of the Siemens epoc blood gas analyzers to support the frequency of quality control performance as written in the Individualized Quality Control Program (IQCP) since it was approved on 2/6/25. Findings include: 1. A review of the laboratory's Quality Control Plan (QCP) revealed a section stating, "Test and document analyzer/cartridge stability by running external controls per manufacturer's instructions for the following: every 30 days, for a new shipment, whenever laboratory conditions have changed significantly, when training or retraining of personnel is indicated, and when test results do not match patient symptoms or clinical findings." 2. A review of the laboratory's IQCP, approved by the laboratory director on 2/6/25, the laboratory performed quality controls over a 10-day period between 2/6/24 and 2/15/24. The laboratory did not demonstrate the system was stable for at least 30 days. 3. An interview on 2/11/25 at 12:47 pm with the Director of Mobile Integrative Health confirmed the laboratory had not demonstrated the Siemens epoc blood gas test system was stable for at least 30 days.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to perform calibration verification at least every six months on the Siemens epoc blood gas analyzers for one (February 2024 to February 2025) of one year since the laboratory started testing. Findings include: 1. A review of the laboratory's "EPOC BLOOD ANALYSIS SYSTEM PROCEDURE MANUAL" revealed a section titled "Calibration Verification" stating, "Commercially available five (5) Level Calibration Verification Sets can be used for verification of calibration of epoc Test Cards with reportable ranges." and "Follow the calibration verification procedure to verify accuracy of test results over an extended measurement range of a test. Performance of this procedure at defined intervals may be required by regulatory

or accreditation bodies." 2. An interview on 2/11/25 at 12:59 pm with the Director of Mobile Integrative Health confirmed the laboratory had not performed calibration verification on its Siemens epoc blood gas analyzers.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to perform control procedures at least each date of patient testing for 10 (February 2024 to December 2024) of 10 months reviewed. Findings include: 1. A review of patient test records and quality control records revealed a lack of controls performed each date of patient testing on the following dates between February 2024 and December 2024: a. 02/27/24 b. 02/28/24 c. 03/14/2024 d. 03/19/2024 e. 03/20/2024 f. 03/26/2024 g. 03/27/2024 h. 04/02/2024 i. 04/06/2024 j. 04/07/2024 k. 05/20/2024 l. 06/19/2024 m. 06/22/2024 n. 06/29/2024 o. 07/08/2024 p. 07/09/2024 q. 07/12/2024 r. 07/14/2024 s. 07/15/2024 t. 07/31/2024 u. 08/03/2024 v. 08/07/2024 w. 08/08/2024 x. 08/09/2024 y. 08/10/2024 z. 08/11/2024 aa. 08/12/2024 bb. 08/16/2024 cc. 08/16/2024 dd. 08/18/2024 ee. 08/19/2024 ff. 08/20/2024 gg. 08/21/2024 hh. 08/23/2024 ii. 08/25/2024 jj. 09/02/2024 kk. 09/13/2024 ll. 09/14/2024 mm. 09/22/2024 nn. 09/26/2024 oo. 09/30/2024 pp. 10/06/2024 qq. 10/07/2024 rr. 10/08/2024 ss. 10/13/2024 tt. 10/13/2024 uu. 10/18/2024 vv. 10/31/2024 ww. 11/07/2024 xx. 11/08/2024 yy. 11/09/2024 zz. 11/10/2024 aaa. 11/11/2024 bbb. 11/16/2024 ccc. 11/22/2024 ddd. 12/21/2024 eee. 12/22/2024 fff. 12/23/2024 ggg. 12/27/2024 hhh. 12/29/2024 2. A review of the laboratory's Individualized Quality Control Plan (IQCP) revealed it had not been approved for use until 2/6/25. 3. An interview on 2/11/25 at 12:59 pm with the Director of Mobile Integrative Health confirmed control procedures were not performed on each instrument each date of patient testing for the dates listed above.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to evaluate the relationship between its Siemens epoc

	<p>blood gas analyzers at least twice annually for one (February 2024 to February 2025) of one year since the laboratory started testing. Findings include: 1. A review of the laboratory's testing data revealed a lack of twice annual comparison of the laboratory's five Siemens epoc blood gas analyzers. 2. An interview on 2/11/25 at 11:09 am with the Director of Mobile Integrative Health confirmed the laboratory had not performed comparisons of the laboratory's five Siemens epoc blood gas analyzers.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to establish a Quality Assessment Plan to include analytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP) since it was approved on 2/6/25. Findings include: 1. A review of the Siemens epoc blood gas analyzer IQCP approved by the laboratory director on 2/6/25 revealed a lack of a Quality Assessment Plan to include how the laboratory will monitor its analytic systems. 2. An interview on 2/11/25 at 10:02 am with the Director of Mobile Integrative Health confirmed a Quality Assessment Program was not implemented in the Siemens epoc blood gas analyzer IQCP.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Mobile Integrative Health, the laboratory failed to establish a Quality Assessment Plan to include postanalytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP) since it was approved on 2/6/25. Findings include: 1. A review of the Siemens epoc blood gas analyzer IQCP approved by the laboratory director on 2/6/25 revealed a lack of a Quality Assessment Plan to include how the laboratory will monitor its postanalytic systems. 2. An interview on 2/11/25 at 10:02 am with the Director of Mobile Integrative Health confirmed a Quality Assessment Program was not implemented in the Siemens epoc blood gas analyzer IQCP.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p>

This CONDITION is not met as evidenced by:

- . A. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to establish a Quality Assessment Plan to include preanalytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP) (refer to D6020 A), failed to ensure the laboratory demonstrated the stability of the Siemens epoc blood gas analyzers to support the frequency of quality control performance as written in the Individualized Quality Control Program (IQCP) (refer to D6020 B), failed to ensure control procedures were performed at least each date of patient testing (refer to D6020 C), failed to establish a Quality Assessment Plan to include analytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP) (refer to D6020 D), failed to establish a Quality Assessment Plan to include postanalytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP) (refer to D6020 E), failed to ensure calibration verification was performed at least every six months on the Siemens epoc blood gas analyzers (refer to D6023 A), failed to ensure the relationship between its Siemens epoc blood gas analyzers was evaluated at least twice annually (refer D6023 B), failed to ensure it had employed a qualified technical consultant to oversee its chemistry and hematology testing (refer to D6028 A), failed to ensure it had employed qualified testing personnel to perform moderate complexity testing (refer to D6028 B), and failed to establish competency assessment policies (refer to D6030).

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

- . A. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to establish a Quality Assessment Plan to include preanalytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP). Refer to D5391. B. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to ensure the laboratory demonstrated the stability of the Siemens epoc blood gas analyzers to support the frequency of quality control performance as written in the Individualized Quality Control Program (IQCP). Refer to D5425. C. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to ensure control procedures were performed at least each date of patient testing. Refer to D5445. D. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to establish a Quality Assessment Plan to include analytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP). Refer to D5791. E. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to establish a Quality Assessment Plan to include postanalytic systems as part of its Siemens epoc blood gas analyzer Individualized Quality Control Plan (IQCP). Refer to D5891.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(6)

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

. A. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to ensure calibration verification was performed at least every six months on the Siemens epoc blood gas analyzers. Refer to D5439. B. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to ensure the relationship between its Siemens epoc blood gas analyzers was evaluated at least twice annually. Refer to D5775.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

. A. Based on record review and lack of documentation, the laboratory director failed to ensure it had employed a qualified technical consultant to oversee its chemistry and hematology testing. Refer to D6035. B. Based on record review and lack of documentation, the laboratory director failed to ensure it had employed qualified testing personnel to perform moderate complexity testing. Refer to D6065.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Mobile Integrative Health, the laboratory director failed to establish competency assessment policies. Refer to D5209.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:

. Based on record review and lack of documentation, the laboratory failed to ensure it had employed a qualified technical consultant to oversee its chemistry and hematology testing. Refer to D6065.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

. Based on record review and lack of documentation, the laboratory failed to ensure it had employed a qualified technical consultant to oversee its chemistry and hematology testing for one (February 2024 to February 2025) of one year since the laboratory started testing. Findings include: 1. A review of the qualification documentation for the technical consultant revealed a Bachelor of Science degree in

	<p>Clinical Laboratory Science and a lack of at least two years' documented training or experience or both in nonwaived testing in chemistry and hematology specialties. 2. The surveyor requested the additional experience records on 2/11/25 at 10:26 am and they were not made available. 3. The laboratory was granted an additional seven days to provide the missing records and none were received.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and lack of documentation, the laboratory failed to ensure it had employed qualified testing personnel to perform moderate complexity testing. Refer to D6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: . Based on record review and lack of documentation, the laboratory failed to ensure it had employed qualified testing personnel to perform moderate complexity testing for two (testing personnel #5 and #6) of eight testing personnel listed on Form CMS-209. Findings include: 1. A review of the qualification documentation for the testing personnel revealed the following degrees and no additional qualification documentation: a. Testing personnel #5 had a Master of Psychology degree. b. Testing personnel #6 had an Associate of Arts degree. 2. The surveyor requested the additional experience records on 2/11/25 at 10:39 am and they were not made available. 3. The laboratory was granted an additional seven days to provide the missing records and none were received.</p>