Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0968323	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Care Emergi Center & Occupational Health	2339 S Us Hwy 1, Fort Pierce, FL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in proficiency testing for 1 out of 3 endocrinology analytes tested for the 2nd and 3rd events of 2018 and the 1st event of 2019. Findings:t Review of the laboratory's proficiency testing with American Proficiency Institute (API) showed that the laboratory failed to enroll in proficiency testing for Free Thyroxine (FT4) for the 2nd and 3rd events of 2018 and the 1st event of 2019. During an interview on 5/15/19 at 11:17 AM, Technical Consultant stated they started endocrinology testing on 4/4/18 and that the laboratory failed to enroll in proficiency testing for FT4.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2)

	The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in proficiency testing (PT) that resulted in a score of zero (0) percent on the Hematology /Coagulation third event in 2017. Findings: Review of the American Proficiency Institute (API) records for the 2017 Hematology/Coagulation 3rd event showed the laboratory received a score of 0% for all analytes to be tested. Notes on the API "Performance Summary" sheet stated "Failure to Participate". During an interview on 5/15/19 at 11:15 AM, the Technical Consultant acknowledged that the laboratory failed to get the test results submitted on time.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document annual competency assessment on 1 out of 3 testing personnel for 2018. Findings: Review of the competency records showed that the laboratory failed to have document the annual competency assessments for 1 out of 3 testing personnel in 2018. During an interview on 5/15/19 at 1128 AM, the Technical Consultant who is also a testing personnel stated that she didn't have a competency evaluation performed on herself.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findgins: Cross Reference D5403. Based on record review and interview, the laboratory's written procedure manual was incomplete. Cross Reference D5413. Based on observation, record review, and interview, the laboratory failed to store frozen Chemistry control material at the correct freezer temperatures from 1/01 /18 to 5/15/19. Cross Reference D5421. Based on record review and interview, the instrument verification for the Beckman Coulter Access 2 installed in July 2017 was

	incomplete. Cross Reference D5469. Based on record review and interview, the laboratory failed to perform quality control lot to lot comparison from 5/15/17 to 5/15 /19. Cross Reference D5481. Based on record review and interview, the laboratory failed to have the 2 levels controls within acceptable range for CBC's (Complete Blood Count) prior to testing patients on 1 testing date (5/29/17) in 2017 and 2 testing dates (4/02/18 and 12/03/18) in 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's written procedure manual was incomplete. Findings: Review of the laboratory's procedure manual, signed by the laboratory directory on 3/15/19, showed that there was not a list of alert (critical) values for hematology testing. During an interview on 5/15/19 at 3:37 PM, the Laboratory Director acknowledged that they did not have the critical values listed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to store frozen chemistry controls, calibrators and reagents at the correct freezer temperatures from 1/01/18 to 5/15/19. Findings: Observation of materials stored in the laboratory freezers on 5/15/19 at 1:40 PM showed that chemistry controls, calibrators and

	reagents stored in the freezer required a storage temperature of -20 to -70 degrees Celsius per the manufacturer's label. Review of the temperature logs for the freezer indicated that the laboratory was using an acceptable range of -10 to -20 degrees Celsius. The Daily Temperature Chart 1/01/81 to 5/15/19 showed that the temperature of the freezer ranged from -6 to -10 degrees Celsius. During an interview on 5/15/16 at 1:47 PM, the Technical Consultant confirmed that the manufacturer's requirements for storage temperatures were not met for the materials stored in the freezer.
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 and interview, the instrument verification for the Beckman Coulter Access 2 installed in July 2017 was incomplete. Findings: The laboratory uses the Access 2 for TSH (Thyroid Stimulating Hormone), FT3 (Free Ttriiodothyronine) and FT4 (Free Thyroxine) testing. Review of the Access 2 instrument verification records show that the laboratory had only the linearity and precision records available. The laboratory started testing patient on 4/04/18. During an interview on 5/15/19 at 1:47 PM, the Technical Consultant acknowledged that she did not know where the documentation for accuracy, reportable ranges, and reference intervals were located.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform quality control lot to lot comparison from 5/15/17 to 5/15/19. Findings: Review of procedure titled "ABX Micros 60 New Lot of QC Parallel Testing" notes that new levels of control levels must be run in parallel for a minimum of 5 days. Review of the quality control logs showed that lot to lot comparisons of the Horiba ABX Micros 60 hematology

	analyzer were not available. During an interview on 5/15/19 at 3:30 PM, the Technical Consultant acknowledged that the laboratory had not performed lot to lot comparisons of the hematology controls.
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 record review and interview, the laboratory failed to have the 2 levels controls within acceptable range for CBCs (Complete Blood Count) prior to testing patients on 1 testing date (5/29/17) in 2017 and 2 testing dates (4/02/18 & 12/03/18) in 2018. Findings: The laboratory use the Horiba ABX Micros 60 hematology analyzer to perform CBCs which included the tests for RBC (Red Blood Cells), PLT (Platelets) and MPV (Mean Platelet Volume). The manufacturer of the Horiba ABX Micros 60 hematology analyzer states that out of range parameters will be shown on the display or the printout as an "H" (High) or "L" (Low). The manufacturer recommends verifying that there are no out of range results before accepting results and to re-run out of range results. The laboratory's procedure titled "ABX Micros 60 Procedure" notes that any controls outside the acceptable ranges should be re-run and that "no patient results can be reported until the problem is resolved and all 3 levels of QC are acceptable." Review of the QC results for laboratory showed that the controls performed on days where the QC was out of range were not re-run. Review of the patient logs showed that CBC results were reported on days when the QC was out of range. The QC results for the hematology analyzer showed that the following out of range control results: 5/29/17 Normal Control - RBC 4.61 L High Control - RBC 5.56 L 2 out of 2 patients with laboratory tests had CBC's 4/02/18 Normal Control - RBC 4.31 L High Control - RBC 5.29 L 4 out of 6 patients with laboratory tests had CBC's 12/03/18 Low Control - PLT 23 L Normal Control - PLT 110 L High Control - PLT 214 L Normal Control - MPV 4.7 L High Control - MPV 4.7 L 5 out of 8 patients with laboratory tests had CBC's During an interview on 5/15/19 at 1 PM, Testing Personnel B thought that it was acceptable if they had one CBC analytes per control level out they did not need to re-run it.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction. Findings: Cross Reference D6007. Based on observation, interview, and record review, the Laboratory Director failed to ensure that the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic and analytic phases of testing from 5/15/17 to 5/15 /19. Cross Reference D6013. Based on record review and interview, the Laboratory

	Director failed to ensure that the instrument verification for the Beckman Coulter Access 2 installed in July 2017 was complete. Cross Reference D6015. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enroll in proficiency testing for 1 out of 3 endocrinology analytes tested for the 2nd and 3rd events of 2018 and the 1st event of 2019. Cross Reference D6017. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory return proficiency testing (PT) within the timeframe established by the proficiency testing program. Cross Reference D6020. Based on record review and interview, the Laboratory Director failed to ensure that the quality control program provided quality laboratory services. The laboratory failed to perform quality control lot to lot comparison from 5/15/17 to 5/15/19. The laboratory failed to have the 2 levels controls within acceptable range for CBC's (Complete Blood Count) prior to testing patients on 1 testing date (5/29/17) in 2017 and 2 testing dates (4/2/18 and 12/3/18) in 2018.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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; This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the Laboratory Director failed to ensure that the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic and analytic phases of testing from 5/15/17 to 5/15 /19. Findings: Preanalytic: Review of the competency records showed that the laboratory failed to have document the annual competency assessments for 1 out of 3 testing personnel in 2018. During an interview on 5/15/19 at 1128 AM, the Technical Consultant who is also a testing personnel stated that she didn't have a competency evaluation performed on herself. Analytic: Review of the laboratory's procedure manual, signed by the laboratory directory on 3/15/19, showed that there was not a list of alert (critical) values for hematology testing. During an interview on 5/15/19 at 3: 37 PM, the Laboratory Director acknowledged that they did not have the critical values listed.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the instrument verification for the Beckman Coulter Access 2 installed in July 2017 was complete. Findings: The laboratory uses the Access 2 for TSH (Thyroid Stimulating Hormone), FT3 (Free Ttriiodothyronine) and FT4 (Free Thyroxine) testing. Review of the Access 2 instrument verification records show that the laboratory had only the linearity and precision records available. The laboratory started testing patient on 4/4/18. During an interview on 5/15/19 at 1:47 PM, the Technical Consultant acknowledged that she did not know where the documentation for accuracy, reportable ranges, and reference intervals were located.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enroll in proficiency testing for 1 out of 3 endocrinology analytes tested for the 2nd and 3rd events of 2018 and the 1st event of 2019. Findings: Review of the laboratory's proficiency testing with American Proficiency Institute (API) showed that the laboratory failed to enroll in proficiency testing for Free Thyroxine (FT4) for the 2nd and 3rd events of 2018 and the 1st event of 2019. During an interview on 5/15/19 at 11:17 AM, Technical Consultant stated they started endocrinology testing on 4/4/18 and that the laboratory failed to enroll in proficiency testing for FT4.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the laboratory return proficiency testing (PT) within the timeframe established by the proficiency testing program. Findings: Review of the American Proficiency Institute (API) records for the 2017 Hematology/Coagulation 3rd event showed the laboratory received a score of 0% for all analytes to be tested. Notes on the API "Performance

	Summary" sheet stated "Failure to Participate". During an interview on 5/15/19 at 11: 15 AM, Technical Consultant acknowledged that the laboratory failed to get the test results submitted on time.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the quality control program provided quality laboratory services. Findings: 1. The laboratory failed to perform quality control lot to lot comparison from 5/15/17 to 5/15 /19. Review of procedure titled "ABX Micros 60 New Lot of QC Parallel Testing" notes that new levels of control levels must be run in parallel for a minimum of 5 days. Review of the quality control logs showed that lot to lot comparisons of the Horiba ABX Micros 60 hematology analyzer were not available. During an interview on 5/15/19 at 3:30 PM, the Technical Consultant acknowledged that the laboratory had not performed lot to lot comparisons of the hematology controls. 2. The laboratory failed to have the 2 levels controls within acceptable range for CBC's (Complete Blood Count) prior to testing patients on 1 testing date (5/29/17) in 2017 and 2 testing dates (4/02/18 and 12/03/18) in 2018. The laboratory use the Horiba ABX Micros 60 hematology analyzer to perform CBC's (Complete Blood Count) which included the tests for RBC (Red Blood Cells), PLT (Platelets) and MPV (Mean Platelet Volume). The manufacturer of the Horiba ABX Micros 60 hematology analyzer states that out of range parameters will be shown on the display or the printout as an "H" (High) or "L" (Low). The manufacturer recommends verifying that there are no out of range results before accepting results and to re-run out of range results. The laboratories procedure titled "ABX Micros 60 Procedure" notes that any controls outside the acceptable ranges should be re-run and that "no patient results can be reported until the problem is resolved and all 3 levels of QC are acceptable." Review of the QC results for laboratory showed that the controls performed on days where the QC was out of range were not re-run. Review of the patient logs showed that CBC results were reported on days when the QC was out of range. The QC results for the hematology analyzer showed that the following out of range control results: 5/29/17 Normal Control - RBC 4.61 L High Control - RBC 5.56 L 2 out of 2 patients with laboratory tests had CBC's 4/02/18 Normal Control - RBC 4.31 L High Control - RBC 5.29 L 4 out of 6 patients with laboratory tests had CBC's 12/03/18 Low Control - PLT 23 L Normal Control - PLT 110 L High Control - PLT 214 L Normal Control - MPV 4.7 L High Control - MPV 4.7 L 5 out of 8 patients with laboratory tests had CBC's During an interview on 5/15/19 at 1 PM, the Testing Personnel B thought that it was acceptable if they had one CBC analytes per control level out they did not need to re-run it. 3. The laboratory failed to store frozen chemistry controls, calibrators and reagents at the correct freezer temperatures from 1 /1/18 to 5/15/19. Observation of materials stored in the laboratory freezers on 5/15/19 at 1:40 PM showed that chemistry controls, calibrators and reagents stored in the freezer required a storage temperature of -20 to -70 degrees Celsius per the

	manufacturer's label. Review of the temperature logs for the freezer indicated that the laboratory was using an acceptable range of -10 to -20 degrees Celsius. The Daily Temperature Chart 1/01/81 to 5/15/19 showed that the temperature of the freezer ranged from -6 to -10 degrees Celsius. During an interview on 5/15/16 at 1:47 PM, the Technical Consultant confirmed that the manufacturer's requirements for storage temperatures were not met for the materials stored in the freezer.