Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2165454	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Village Emergency Room Llc	17030 Nw Freeway, Jersey Village, TX	

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
D0000	Based on an announced validation survey, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on the laboratory's records and staff interview, the laboratory failed to have documentation of performing two of two accuracy assessments in 2024 for two non-regulated analytes: D-dimer and Myoglobin. Findings include: 1. A review of the laboratory's records revealed the laboratory performed D-dimer and Myoglobin testing in 2024 on the Triage meter. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing two accuracy assessments for the non-regulated analytes D-dimer and Myoglobin in 2024. 3. In an interview on 5/1/25 at 11:10 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings.
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 a review of laboratory records and staff interview, the laboratory failed to identify issues with analytic systems for two of four tests run on the Triage meter. Findings include: 1. The laboratory failed to have documentation of performing verification studies (accuracy, precision, reportable range, normal reference values) for two of four tests run on the Triage meter. (Refer to D5421) 2. The laboratory failed to establish an IQCP (Individualized Quality Control Plan) to support the modification in quality control testing for one of four tests run on the Triage meter. (Refer to D5445)
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of laboratory's procedure manual and staff interview, the laboratory failed to have one of one written procedure for how new test systems will be verified (studies to include: accuracy, precision, reportable range, normal patient range) prior to patient testing. Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory failed to have a written procedure for how new test systems will be verified (studies to include: accuracy, precision, reportable range, normal patient range) prior to patient testing. 2. In an interview on 5/1/25 at 10:45 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i)

	Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 a review of the laboratory's records, patient test records, staff interview, the laboratory failed to have documentation of performing verification studies (accuracy, precision, reportable range, normal reference values) for two of four test run on the Triage meter. Findings include: 1. A review of the laboratory's records revealed the laboratory started testing Myoglobin in June 2023 and D-dimer in December 2024 using the Triage meter. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of accuracy, precision, reportable range and normal reference values studies for Myoglobin and D-dimer. 3. A review of patient test records revealed the laboratory estimated performing 660 cardiac tests (including Myoglobin and D-dimer) annually. 4. In an interview on 5/1/25 at 11:10 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings.
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 the laboratory's test records, the laboratory's quality control records from December 2024 to February 2025, and staff interview, the laboratory failed to establish an IQCP (Individualized Quality Control Plan) to support the modification in quality control testing for one of four tests run on the Triage meter. Findings include: 1. A review of the laboratory's test records revealed the laboratory performed the following tests using the Triage meter (Serial Number: 00096092): - CM-MB (Creatine Kinase - Myocardial Band) - Troponin - Myoglobin - D-dimer 2. A review of the laboratory's quality control records from December 2024 to February 2025 revealed the laboratory ran two levels of quality control material once a month for all 4 tests. 3. Further review of the laboratory's records revealed there was no documentation of the laboratory developing an IQCP for the D-dimer cartridge, modifying the frequency of quality control testing from two levels of quality control material every day of patient testing to two levels of quality control material with every new shipment of test cartridges or every 30 days. 4. A random review of patient test records revealed the following 3 patients were run on the Triage meter when there was no documentation of the laboratory running 2 levels of quality control material: Account number: 63051177 Reported: 12/23/24 Test: D-dimer Account number:

	63100048 Reported: 12/28/24 Test: D-dimer Account number: 63581804 Reported: 2 /5/25 Test: D-dimer 5. In an interview on 5/1/25 at 11:00 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's Temperature Logs, and staff interview, the laboratory failed to have documentation of performing corrective action for 9 of 122 days from September to December 2024 when the refrigerator temperature readings were documented outside of the laboratory's acceptable range. Findings include: 1. A review of the laboratory's policy titled 'Care of Refrigerators and Freezers' revealed the following: "Record the temperature of the recording chart and initial every day. 2 -8 degree Celsius for refrigerators. If the temperature does not fall within the ranges listed above and unable to reach appropriate temperature after adjusting, a work order must be placed and until will not be used. This action must be noted on the recording sheet." 2. A review of the laboratory's Temperature Logs from September to December 2024 revealed the following 9 days where the refrigerator temperature readings exceeded the laboratory's acceptable range and no corrective action was documented: 9/10/24 0C 9 /25/24 0C 11/26/24 0C 11/27/24 1C 12/5/24 0C 12/11/24 0C 12/12/24 1C 12/13/24 1C 12/25/24 1C 3. In an interview on 5/1/25 at 10:30 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings. Key: C = Degrees Celsius
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient's test reports from August to December 2024 and staff interview, the laboratory failed to include the address of the testing facility on four of four patient's test reports reviewed. Findings include: 1. A random review of patient's test reports from August to December 2024 revealed the laboratory failed to include the address of the testing facility on the following 4 patient's test reports: Account number: 57030822 Reported: 8/22/24 Account number: 62530380 Reported: 11/17/24 Account number: 62699799 Reported: 12/2/24 Account number: 62878580 Reported: 12/12/24 2. In an interview on 5/1/25 at 11:20 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings.

D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, random review of patient test reports from August to December 2024, and staff interview, the laboratory failed to include the correct reference intervals for CBCs (Complete Blood Count) on the final reports for two of two pediatric patient's reports reviewed. Findings include: 1. A review of the laboratory's policy titled 'Normal Results: Hematology' revealed the laboratory had reference intervals for the following age ranges for CBCs: - Newborn (0 days - 1 month) - Pediatric (up to 12 years) - Adults (12 and older) 2. A random review of patient test reports from August to December 2024 revealed the following 2 pediatric patient's reports for CBC testing that included the adult reference intervals instead of the pediatric intervals: Account number: 57030822 Reported 8/22/24 Age: 4 years Account number: 62699799 Reported 12/2/24 Age: 7 years 3. In an interview on 5/1 /25 at 11:10 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings.
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 a review of the laboratory's records and staff interview, the laboratory director failed to provide overall management and direction for two of four tests run on the Triage meter. Findings include: 1. The laboratory director failed to ensure verification studies were performed and adequate for two of four tests run on the Triage meter. (Refer to D6013) 2. The laboratory director failed to ensure a quality control program was established and maintained for one of four tests run on the Triage meter. (Refer to D6020)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory director failed to ensure verification studies were performed and adequate for two of four tests run on the Triage meter. (Refer to D5421)
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: Based on a review of the laboratory's quality control records and staff interview, the laboratory director failed to ensure a quality control program was established and maintained for one of four tests run on the Triage meter. (Refer to D5445)
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) (b)(8)(vi) Assessment of problem-solving skills; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's annual competency assessments, patient test records, and staff interview, the technical consultant failed to assess problem solving skills for four of four annual competency assessments performed for moderate complexity testing in 2024. Findings include: 1. A review of the laboratory's annual competency assessments performed in 2024 revealed the technical consultant failed to assess problem solving skills for CBC (Complete Blood Count) testing on the Sysmex XP-300 hematology analyzer and cardiac analyte testing (CK-MB, TnI, D-Dimer, Myoglobin) on the Triage meter for the following testing personnel: - Testing Person #1 - Testing Person #2 - Testing Person #3 - Testing Person #4 2. A review of the laboratory's patient test records revealed the laboratory estimated performing 5616 hematology tests on the Sysmex XP-300 analyzer and 660 cardiac analyte tests on the Triage meter annually. 3. In an interview on 5/1/25 at 9:40 a.m. in the nurse's station, after review of the records, the laboratory director confirmed the above findings. Key: CM-MB = Creatine Kinase- Myocardial Band TnI- Troponin