Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2181925	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
D-Rad Mobile Imaging Services	1387 George Dieter Ste 105 - D, El Paso, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1250 Condition: Laboratories Performing Moderate Complexity Testing; Analytic Systems 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 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. This STANDARD is not met as evidenced by: Review of the manufacturer's instructions, CMS 116, patient reports, Personnel files and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions for disseminating all authorized fact sheets when using the Clarity COVID-19 Antigen Rapid Test Cassette for patient testing in 2020 and 2021. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY: A. " Authorized laboratories using the Clarity COVID-19 Antigen Rapid test kit must include with test results reports of the COVID-19, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these fact sheets may be used, which may include mass media. F. Al Operators using your product must be appropriately trained in performing and interpreting the results of your product." 2. Review of the CMS 116 found the laboratory recorded an annual volume of 4,920 Covid tests performed. 3. Review of patient reports found the laboratory did not include instructions to providers on where to obtain the fact sheets or included copies of the authorized fact sheets. 4. Review of personnel files found no documentation of

	training for the Clarity COVID-19 Antigen Rapid test cassette. 5. Interview of the Laboratory owner conducted on March 9, 2022 at 1:09 PM confirmed that the laboratory did not include the authorized Fact Sheets with the patient test results for COVID-19 and did not have documented training of testing personnel performing the tests.
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 review of policies and procedures, verification studies, quality control records, maintenance records, patient test records and interview of facility personnel, the laboratory failed to meet the analytic systems requirements to monitor and evaluate the overall quality of analytic systems and correct problems identified in Hematology, Virology, Syphilis Serology and Chemistry. (See D5411, D5421, D5441, D5449, D5469 and D5791)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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. This STANDARD is not met as evidenced by: Review of the manufacturer's instructions, CMS 116, patient reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions for disseminating all authorized fact sheets when using the FaStep COVID-19 IgG /IgM Rapid Test Device as defined in the Conditions of Authorization for Use. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the FaStep COVID-19 IgG/IgM Rapid Test Device must include with result reports of the COVID-19 IgG/ IgM all authorized Fact Sheets." 2. Review of the CMS 116 found the laboratory recorded an annual volume of 4920 COVID tests performed. 3. Review of patient reports found the laboratory did not include instructions to providers on where to obtain the fact sheets or included copies of the authorized fact sheets. 4. Interview of the General Supervisor on the CMS report 209 Laboratory Personnel Report conducted on January 18, 2022 at 11:59 AM confirmed that the laboratory did not include the authorized Fact Sheets with the patient test results for COVID-19 using the FaStep COVID-19 IgG/IgM Rapid Test Device.
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: I. Review of Laboratory records and interview of facility personnel found the laboratory failed to verify the reference ranges were appropriate for the patients when using the ABX Pentra 60 C+ Hematology Analyzer for testing patient Complete Blood Counts. The findings included: 1. Review of verification records found no verification studies for reference ranges available for review. 2. The laboratory reported an annual volume of 8,208 Hematology procedures tested on the ABX Pentra C+. 3. Interview of Testing Person one on the Form 209- Laboratory Personnel Report conducted March 9, 2022 at 12:25 PM confirmed there were no additional records for review. II. Review of Laboratory records and interview of facility personnel found the laboratory failed to verify the reference ranges were appropriate for the patients when using the Beckman AU 400 Chemistry analyzer and the Beckman Coulter Access 2 Analyzer for testing patient specimens. The findings included: 1. Review of verification records found no records available for review to verify reference ranges were appropriate for the patient population served. 2. The laboratory reported an annual volume of 20, 748 Chemistry procedures without reference range verifications prior to patient testing. 3. Interview of Testing Person one on the Form 209- Laboratory Personnel Report conducted March 9, 2022 at 12:25 PM confirmed there were no additional records for review.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records and interview of facility personnel found the laboratory failed to have a quality control procedure in place that monitored the accuracy and precision of analytic process in Chemistry, Virology, Hematology and Syphilis Serology. The findings included: 1. Review of the policy titled Quality Review (approved 01/21/2021) found under the heading PURPOSE: " The object of our Quality Review plan is to improve the reliability , efficiency and quality of laboratory services." Further review found under the heading POLICY: "

	Quality control is the sum of those procedures by which the routine precision and accuracy of each test can be assured. Action taken will depend on the type of test and equipment or material and may include any or all of the following: Correct Procedure followed Calibration and QC of instruments are in range Check stability of reagents Assurance of proper temperature requirements assurance of not interchanging original kit components with current or new kit component lot numbers. Repeat testing All quality control records will be reviewed on a monthly basis and corrective action will be documented. The laboratory Staff will be responsible for analyzing and documenting QC outliers and QC rerun. The QC for each instrument will be printed each month for review." 2. Review of the policy titled RPR Test (approved 4/14/2021) found on page 3 under the heading Quality Control: " When testing with a negative control, no aggregation would be observed. When testing with a weakly reactive control, slight aggregation should be observed. When Testing with a reactive control, moderate to large aggregates should be observed. When these reactions are found, this will indicate proper procedural technique, specimen volume, and test performance. Refer to your Standard Operating procedure and or Quality Assurance plan for all other quality control requirements. The laboratory did not define the number, type and frequency of quality control testing for each non waived test in either the Quality Review policy or the RPR policy, nor did they define a means of monitoring over time the accuracy and precision of quantitative assays. 3. Review of quality control records found: a. RPR testing using the Germaine Aim RPR test kit found no documentation of quality control procedures performed each day of patient testing. b. Review of the FaStep COVID IgG/IgM Rapid Test found no documentation of quality control procedures tested each day of patient testing. c. Review of Hematology quality control records found no documentation of review by the Laboratory Director or Technical Consultant. d. Review of quality control records for the Beckman Access 2 analyzer found no documentation of review by the Laboratory Director or Technical Consultant. e. There were no quality control records available to review for detections of immediate errors and assessing the accuracy and precision over time for the Beckman AU 400. 4. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted March 9, 2022 at 10:00 AM confirmed that the laboratory does not have a QC program to evaluate QC for immediate errors or error over time for the Beckman AU 400. She stated "the printer gets jammed up and the results don't print." She went on to say they do not print the Levy Jennings graphs or have any other means of assessing QC performance over time. At 12:25 PM that she does not verify the Hematology quality control materials are acceptable for use prior to putting them into use. At 2:28 PM, she confirmed that the laboratory does not perform quality control procedures each day of testing patients using the Aim RPR test kit, or the FaStep COVID-19 IgG/IgM test kit.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on observations, review of laboratory records, patient test records, the CMS 116 application and interview of facility personnel, the laboratory failed to test a

	negative and positive control at least once each day of testing when using the Germaine Aim RPR (Rapid Plasma Reagin) Test to test patient specimens. The findings included: 1. Observations made during the inspection found the laboratory was currently using the Germaine Aim RPR Test kit (lot 12843 Expiration 2022-12-31) for testing patient specimens. 2. Review of laboratory records found no documentation of quality control procedures each day patients were tested. 3. Review of patient test records found 48 patients tested between February 1, 2022 and March 9 , 2022 without documentation of quality control: February 1, 2022 - 5 patients tested without quality control February 4, 2022 - 4 patients tested without quality control February 7, 2022 - 1 patient tested without quality control February 8, 2022 - 4 patients tested without quality control February 10, 2022 - 1 patient tested without quality control February 11, 2022 - 2 patients tested without quality control February 14, 2022 - 1 patient tested without quality control February 15, 2022 - 1 patient tested without quality control February 17, 2022 - 1 patient tested without quality control February 18, 2022 - 2 patients tested without quality control February 21, 2022 - 2 patients tested without quality control February 22, 2022 - 2 patients tested without quality control February 23, 2022 - 2 patients tested without quality control February 24, 2022 - 2 patients tested without quality control February 25, 2022 - 4 patients tested without quality control February 28, 2022 - 1 patient tested without quality control March 1, 2022 - 5 patients tested without quality control March 2, 2022 - 2 patients tested without quality control March 3, 2022 - 2 patients tested without quality control March 4, 2022 - 3 patients tested without quality control March 7, 2022 - 1 patient tested without quality control 4. Review of the CMS 116 application provided during the inspection, the laboratory recorded an annual volume of 792 patient specimens tested for Syphilis Serology. 5. Interview of testing person one on the CMS Report 209 Laboratory Personnel Report conducted March 9, 2022 at 2:29 PM confirmed the laboratory performed quality control testing once with the opening of each new box of the RPR test kit
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: Review of the manufacturer's instructions for use, instrument records, quality control records and interview of facility personnel found the laboratory failed to verify the criteria of acceptability for the Horiba Difftrol Tri-level Hematology control material. The findings included: 1. Review of the Horiba Difftrol Tri-Level Hematology quality control instructions for use (Rev. 07/15) found under the heading Performance Characteristics - "Assigned values are presented as a Mean Value together with

	maximum and minimum ranges. The Mean value is derived from replicate testing on instruments operated and maintained according to manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account expected biological variability of the control material. Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new log when the instrument is in good working order and quality control results on the previous lot are acceptable. The laboratory recovered mean should be within the assay range." 2. Review of instrument records found no documentation of maintenance procedures for the Horiba Pentra 60C+. 3. Review of quality control records found no evidence that new lots of quality control materials were verified prior to being put into routine use. There was no documentation that the new lot of controls was tested for acceptability prior to the current lot number expiration. 4. Interview of testing person one conducted March 9, 2022 at 12:25 PM confirmed that she does not verify the new lot of control for acceptability prior to putting it into use. She stated she " loads the QC (quality control) disk after printing the data and runs the new lot."
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures, verification studies, quality control records, maintenance records, patient test records and interview of facility personnel, the laboratory failed tohave an ongoing mechanism in place to monitor, assess, identify and correct problems identified in Hematology, Virology, Syphilis Serology and Chemistry. (See D5411, D5421, D5441, D5449 and D5469)
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: The laboratory director failed to provide overall management and direction of the laboratory. (See D6013, D6020, D6021 and D6029)
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: The laboratory director failed to ensure the verification procedures were complete for each instrument and met the manufacturers specifications for accuracy, precision, reportable range and other performance characteristics. (See D 5421)
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: The laboratory director failed to establish and maintain the quality control program to ensure the quality of laboratory services. See D5441, D5449 and D5469)
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory Director failed to establish and maintain a quality assessment program to assure the quality of laboratory services. (See D 5791)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, policies and procedures,

	personnel records, and interview of facility personnel found that the laboratory director failed to ensure that all testing personnel had the appropriate education and training prior to testing patient specimens. (See D 6065)
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report, policies and procedures, personnel records and staff interview, it was revealed that one of one testing personnel did not have the appropriate documented training required to perform moderate complexity testing (see D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, policies and procedures, personnel records, and interview of facility personnel found that the laboratory failed to ensure that all testing personnel had the appropriate training prior to testing patient specimens. Findings included: 1. Review of the CMS report 209 laboratory personnel report found that the laboratory designated 1 testing personnel performing moderate complexity procedures. 2. Review of the policy titled Orientation and Training (approved 01/04/2021) found on page one under the heading PURPOSE: "Upon start of employment, each laboratory employee will attend a well-planned and structured orientation program. This program will outline information that will be beneficial to the employee's concept of the organization and its purpose." Further review found under the heading POLICY: " D-RAD that each employee from the Clinical Laboratory receive orientation within 90 days from their starting date on lab functions, procedures and safety. Orientation on all Clinical Laboratory policies and procedures will be completed prior to the employee working alone. The Laboratory Supervisor will monitor the program and complete the appropriate documentation. All orientation activities will be documented and made a part of the employees file." Continued review found under the heading PROCEDURE: "The Laboratory Supervisor will review the information in the new employee department orientation

	with the new hire. The employee will sign the orientation checklist when he/she understands all the information presented. The orientation checklist will be filed in the departments personnel file." 3. Review of personnel records found testing person one (hired 10/03/2021) had no documentation of training/ orientation available for review. 4. Interview of testing person one conducted March 8, 2022 at 09:45 AM in the laboratory confirmed that there were no training records available for review. She went on to say that "all training was verbal".