Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D1020051	09/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rm Lab Llc Dba Express Lab	7988 W Marigold St Ste 100, Boise, ID	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the general supervisor, the laboratory failed to retain the 2018 cytology PT records and signed attestation statements from the College of American Pathologist (CAP) for two out of three cytotechnologists. Findings: 1. A review of the 2018 CAP cytology PT records revealed 2 out of 3 cytotechnologists failed to maintain the signed attestations statements and proficiency records from 2018. 2. An interview on September 11, 2019 at 10:35 AM, with the general supervisor, confirmed the laboratory failed to retain 2 out of 3 cytologist PT records from CAP.
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 a record review of personnel competency assessments, a review of the procedure manual, and an interview with the laboratory general supervisor, the laboratory failed to establish and follow procedures to evaluate the competency assessments for testing personnel, general supervisor, and technical supervisor in the specialties and subspecialties of bacteriology, mycology, parasitology, virology, immunology, Syphilis serology, chemistry, endocrinology, toxicology, hematology,

	immunohematology, and histopathology since the last survey on November 30, 2017. Findings: 1. A review of the procedure manual revealed the laboratory failed to establish a policy or procedure to evaluate the competencies for 15 out of 15 testing personnel, 1 general supervisor, and 2 technical supervisors as listed on the CMS-209 Personnel Report form. 2. A review of personnel competency assessments revealed the laboratory failed to evaluate the competencies of the testing personnel, the general supervisor, and the technical supervisors for the laboratory since the last survey. 3. An interview on September 12, 2019 at 3:35 PM, with the general supervisor, confirmed the laboratory failed to establish in writing and failed to evaluate the competency assessments for the testing personnel and the supervisors.
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 a record review and an interview with the general supervisor, the laboratory failed to verify the accuracy of 52 out of 52 immunohistochemical (IHC) stains, 20 out of 20 special stains, and brain natriuretic peptide (BNP) analyte at least twice a year since the last survey on November 30, 2017. This is a repeat deficiency from the last survey on November 30, 2017. Findings: 1. A document review revealed the laboratory failed to verify the accuracy of IHC stains, special stains, and BNP at least twice a year since the last survey. 2. The laboratory performed approximately 34 BNP tests during the past year. 3. The laboratory performed approximately 5700 IHC and special stains during the past year. 4. An interview on September 13, 2019 at 12:35 PM, with the general supervisor, confirmed the laboratory failed to document the accuracy of the stains and BNP at least twice a year.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a procedure manual review and an interview with laboratory staff member A, the laboratory failed to establish in writing a procedure or policy for the acceptability criteria when receiving client's specimens since the last survey on November 30, 2017. Findings: 1. A review of the specimen processing procedure revealed the laboratory failed to include the client specimen acceptability criteria such as specimen labeling, specimen source, processing, and referral. 2. An interview on September 12, 2019 at 3:35 PM, with laboratory staff member A, confirmed the client specimen processing procedure failed to include criteria for acceptability of specimens.

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 a review of the histology procedure manual and an interview with laboratory staff member A, the laboratory failed to include acceptability requirements for patient specimen acceptability, labelling, storage, processing, control procedures and control adequacy, test procedures, corrective actions when controls fail, rejection criteria, reference intervals, literature references, and patient reporting protocols since the last survey on November 30, 2017. This is a repeat deficiency from the last survey on November 30, 2017. Findings 1. A review of the Fungal Plate, Tzanck, Potassium hydroxide (KOH), Frozen Section Staining, and the Direct Immunofluorescence procedures revealed the laboratory failed to include in each procedure the requirements and acceptability for patient specimen labelling and identification, storage, processing, analytic control and control procedures, test procedures, corrective actions when controls fail, rejection criteria, reference intervals, literature references, and patient reporting. 2. An interview on September 11, 2019 at 11:35 AM, with the laboratory staff member A, confirmed the histology processing procedures failed to include the procedure requirements.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Vitek 2 microbiology test system and an interview with the microbiology lead, the laboratory director failed to approve, sign, and date the aerobic gram-negative and gram-positive identification and susceptibility Individualized Quality Control Plans (IQCP) since the last survey on November 30, 2017. This is a repeat deficiency from the last survey on November 30, 2017. Findings: 1. A review of the IQCPs for the Vitek 2 aerobic gram-negative and gram-positive identification

	and susceptibility tests revealed the laboratory director failed to approve, sign, and date the procedures. 2. An interview on September 12, 2019 at 10:55 AM, with the microbiology lead, confirmed the laboratory director failed to approve and sign the IQCPs in use by the microbiology laboratory.
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 a record review and an interview with laboratory staff member A, the laboratory failed to include the acceptable temperature ranges for the refrigerators, room temperatures, heat blocks, and the processor for the histology and molecular microbiology laboratories on the laboratory worksheets or in the procedure manuals since the last survey on November 30, 2017. This is a repeat deficiency from the last survey on November 30, 2017. Findings: 1. A review of the Histology Temperature Log sheets and the refrigerator temperature log sheets in the molecular microbiology laboratory revealed the temperature logs failed to state the criteria for acceptable temperature ranges. 2. A review of the laboratory procedure manuals revealed the molecular microbiology and histology manuals failed to include the temperature criteria for the test systems. 3. An interview on September 11, 2019 at 11:55 AM, with laboratory staff member A, confirmed the procedure manuals and the laboratory worksheets failed to include the temperature criteria for the tests performed in histology and molecular microbiology
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 a record review and an interview with the microbiology lead, the laboratory failed to establish the performance specifications for the yeast identification panel, anaerobic identification and susceptibility panel, and the Streptococcus susceptibility panel performed on the Vitek 2 test system since the last survey on November 30, 2017. Findings: 1. A review of microbiology documents revealed no performance verification data for the Vitek panels prior to reporting patient test results. 2. The laboratory performed approximately 1800 identification and susceptibility tests on the

	Vitek the past year. 3. An interview on September 11, 2019 at 10:55 AM, with the microbiology lead, confirmed the laboratory failed to have performance specifications for the yeast, anaerobic, and Streptococcus panels.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with laboratory staff member B, the laboratory failed to establish the performance specifications for 'ComStar Pure Lye' used to perform Potassium hydroxide (KOH) microscopic fungal examinations since the last survey on November 30, 2017. Findings: 1. An observation on September 11, 2019, at 10:00 AM, of the histology laboratory revealed 'ComStar Pure Lye' used to perform microscopic fungal examinations on patient specimens. 2. A review of the histology procedure manual revealed a procedure titled 'KOH Preparations' with instructions to prepare a 10% Pure Lye solution. 3. The laboratory performed approximately 12 microscopic fungal examinations in the past year. 4. An interview on September 11, 2019 at 10:55 AM, with the laboratory staff member B, confirmed the laboratory failed to establish the performance specifications for the 'Pure Lye'.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review, a procedure review, and an interview with the chemistry lead technician, the laboratory failed to document corrective actions when the test systems for coagulation, hematology, and chemistry failed to meet the laboratory's performance specifications. Findings: 1. A review of laboratory records revealed corrective actions failed to be taken or documented by the testing person when 1 out

	of 1 patient's complete blood count, reported on 09/12/2019, from the Horiba Pentra hematology analyzer, indicated morphologic and pathologic suspect flags for microcytes, red blood cell indices, and platelets. 2. A review of the hematology procedure revealed directions to repeat testing or refer the specimen if unable to perform the test. 3. A review of quality control records for fibrinogen revealed the testing person failed to document corrective actions when 2 out of 2 levels of external control materials failed to meet the acceptability criteria prior to reporting 1 patient fibrinogen result on May 3, 2019. 4. A review of quality control records for IgE revealed the testing person failed to document corrective actions when 2 out of 2 levels of external control materials failed to meet the acceptability criteria. 5. An interview on September 13, 2019 at 12:15 PM, with the chemistry lead technician, confirmed the laboratory failed to document corrective actions for when errors occurred in quality control and patient testing.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with laboratory staff member B, the laboratory failed to record the dates of fungal cultures set-up in the histology laboratory, as well as the identity of the personnel performing all steps of the tests since the last survey on November 30, 2017. Findings: 1. An observation on September 11, 2019 at 10:15 AM, of the histology laboratory, revealed 3 fungal cultures of nail clippings on Hardy Diagnostics DTM media that failed to state the date the cultures were set-up and the identity of the testing person through all steps of testing. 2. A review of laboratory records revealed the laboratory failed to record the set-up of fungal cultures in the histology laboratory. 3. The laboratory performed approximately 120 fungal cultures in histology during the past year. 4. An interview on September 11, 2019 at 10:15 AM, with laboratory staff member B, confirmed the dates and identity of the testing personnel through all phases of testing were not recorded.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 a record review and an interview with the microbiology lead, the laboratory director failed to establish the performance specifications for the yeast identification panel, anaerobic identification and susceptibility panel, and the Streptococcus susceptibility panels performed on the Vitek 2 test system prior to reporting patient

	results since the last survey on November 30, 2017. Findings: 1. A review of microbiology documents revealed no performance verification data for the Vitek panels prior to reporting patient test results since 2017. 2. The laboratory performed approximately 1800 identification and susceptibility tests on the Vitek the past year. 3. An interview on September 11, 2019 at 10:55 AM, with the microbiology lead, confirmed the laboratory director failed to ensure the Vitek 2 panels met the manufacturer's performance specifications for the yeast, anaerobic, and Streptococcus panels prior to reporting patient results.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 record review, a procedure review, and interviews with laboratory staff, the laboratory director failed to ensure the quality assessment activities for the laboratory were established and maintained in order to identify and correct errors when indicated for the laboratory test systems since the last survey on November 30, 2017. This is a repeat deficiency from the last survey on November 30, 2017. Findings: 1. A review of the Individualized Quality Control Plans (IQCPs) for the Vitek 2 aerobic and anaerobic gram-negative and gram-positive panels, yeast, Streptococcus susceptibility panel, BD Affirm VPIII Microbial identification system, and the Quidel Amplivue test system revealed the laboratory director failed to ensure the Quality Assessment Plans for the IQCPs were established and maintained in order to identify and correct errors in the test system. 2. A review of the laboratory procedure manual revealed the laboratory failed to establish and maintain a procedure or policy for the pre-analytic, analytic, and post-analytic quality assessment activities for histopathology, virology, microbiology, and the core laboratory. 3. An interview on September 12, 2019 at 3:30 PM, with the chemistry lead, confirmed the laboratory failed to identify a system for reviewing the laboratory hematology quality control and patient hematology test results. 4. An interview on September 12, 2019 at 9:50 AM, with the molecular microbiology lead, confirmed the laboratory director failed to establish the Quality Assessment Plans for the BD Affirm VPIII Microbial identification system, and the Quidel Amplivue test systems. 5. An interview on September 13, 2019 at 1:15 PM, with the microbiology lead, confirmed the laboratory director failed to establish the Quality Assessment Plans for the identification and susceptibility panels on the Vitek 2.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on a record review and an interview with the general supervisor, the laboratory director failed to specify in writing the duties and responsibilities of each supervisor and testing person engaged in the performance of patient testing since the last survey on November 30, 2017. This is a repeat deficiency from the last survey on November 30, 2017. Findings: 1. A review of policies and procedures revealed the laboratory director failed to specify in writing the responsibilities and duties of each general supervisor, technical supervisor, and testing personnel involved in the performance and oversight of patient testing. 2. An interview on September 13, 2019 at 1:35 PM, with the laboratory director, confirmed the laboratory director failed to delegate in writing the responsibility for each supervisor and testing person engaged in testing.