

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0520868	<b>(X3) Date Survey Completed</b>  06/26/2019
<b>Name of Provider or Supplier</b>  Rm Lab Llc DbA Express Lab	<b>Street Address, City, State</b>  3910 Washington Pkwy #B, Idaho Falls, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to follow the written procedure to perform weekly quality control testing for antimicrobial susceptibility tests using 6 gram-positive organisms on the Vitek 2 during May 2019. Findings: 1. A review of the Individualized Quality Control Plan (IQCP) revealed the laboratory failed to perform 1 out of 6 gram-positive organisms for weekly quality control used to test patient culture specimens on May 14 and 28, 2019. 2. A review of the Individualized Quality Control Plan (IQCP) revealed the laboratory failed to perform 2 out of 6 gram-positive organisms for weekly quality control used to test patient culture specimens on May 21, 2019. 3. The laboratory performed approximately 35 patient specimens between May 14 and 22, 2019. 4. An interview with the laboratory manager on June 26, 2019 at 6:00 PM, confirmed the laboratory failed to perform 6 gram-positive quality control organisms for antimicrobial susceptibility tests panels.</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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</p>

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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Individualized Quality Control Plan (IQCP) for the identification and antimicrobial susceptibility tests (AST) panels for gram-negative and gram-positive organisms on the Vitek 2, the laboratory failed to identify and evaluate potential failures in the Risk Assessments (RA) since the last review of March 2018. Findings: 1. A review of the IQCP RA for AST testing revealed the laboratory failed to include the identification and evaluation of failures for specimen, environment, personnel, reagent, and test system for the pre-analytic, analytic, and post-analytic phases of testing. 2. A review of the IQCP RA for organism identification revealed the laboratory failed to include the identification and evaluation of failures for specimen, environment, personnel, reagent, and test system for the pre-analytic, analytic, and post-analytic phases. 3. The laboratory performed approximately 4,000 cultures on the Vitek in 2018.

**D5455**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(v)(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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control records, patient reports, and an interview with the laboratory manager, the laboratory failed to perform amplification control reactions for Chlamydia trachomatis (CT), Neisseria (GC) and Trichomonas vaginalis (TV) test panel performed on the BD Max test system on May 17, 2109. Findings: 1. A review of quality control records between May 15, 2019 through May 22, 2019, revealed on May 17, 2019, 2 amplification controls failed to be performed for the CT/GC/TV test panel. 2. A review of the laboratory procedure for the BD Max CT/GC/TV assay revealed 2 amplification controls must be performed each day of patient testing. 3. The laboratory performed 4 patient test panels for CT/GC/TV on May 17, 2019. 4. An interview with the laboratory manager on June 26, 2019, at 6:00 PM, confirmed the laboratory failed to perform amplification controls on the day of patient testing.

**D5471**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and

negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control records, the Individualized Quality Control Plan (IQCP) for the Vitek 2, and an interview with the laboratory manager, the laboratory failed to check each new lot or shipment of gram-negative (GN69) and gram-positive (GP67) identification panels for the Vitek 2 test system that was received in April 2019. Findings: 1. A review of the quality control records from the Vitek 2 revealed the laboratory failed to perform quality control tests on the GN69 panel received in April 2019 prior to reporting patient culture results. 2. A review of the quality control records from the Vitek 2 revealed the laboratory failed to perform 1 out of 2 quality control tests for the GP67 identification system received in April 2019 prior to reporting patient culture results. 3. A review of the IQCP for the Vitek 2 revealed the instructions to perform quality control using 2 organisms for each GN69 and GP67 panels prior to patient testing. 4. The laboratory performed approximately 50 patient culture specimens in May 2019. 5. An interview with the laboratory manager on June 26, 2019 at 6:00 PM, confirmed the laboratory failed to perform quality control for the new lot of gram-negative and gram-positive identification panels.

**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 review of the procedure manual for the Vitek 2 and an interview with the laboratory manager, the laboratory failed to document corrective actions for 3 out of 3 consecutive days of failed quality control results for the gram-positive antimicrobial susceptibility testing panel (AST-GP67) between May 14, 2019 and May 16, 2019. Findings: 1. A review of the quality control results from the Vitek 2 for May 2019, revealed the laboratory failed to document corrective actions for the AST-GP67 *Staphylococcus aureus* 29213 control organism that failed testing for 3 consecutive days on May 14, 15, and 16, 2019. 2. A review of the written procedure for quality control performance for urine cultures performed on the Vitek 2 revealed instructions to document corrective actions and perform quality control testing for 5 days and/or perform a 20-day study for repeat quality control failures. 3. The laboratory performed approximately 35 patient culture specimens between May 14, 2019 and May 22, 2019. 4. An interview with the laboratory manager on June 26, 2019 at 5:50 PM, confirmed the laboratory failed to document corrective actions for quality control results failed on the Vitek.

**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 a review of quality control records and the Individualized Quality Control Plan (IQCP) for the Vitek 2 antimicrobial susceptibility testing (AST) testing for gram-negative and gram-positive panels, the laboratory director failed to ensure the Quality Assessment Plan for the IQCP was established and failed to ensure quality assessment activities for organism identification and susceptibility testing was performed since the last review in March 2018. Findings: 1. A review of the IQCP for the Vitek 2 AST testing revealed the laboratory director failed to establish a Quality Assessment Plan from the last review in March 2018. 2. A review of the IQCP Risk Assessments for the Vitek 2 AST and identification test system, revealed the laboratory failed to identify and evaluate failures in specimen, test system, personnel, reagent, and environment for all phases of testing. Refer to D5445. 3. A review of laboratory records revealed the laboratory failed to document corrective actions for 3 out of 3 consecutive days of failed quality control results for the gram-positive antimicrobial susceptibility testing panel (AST-GP67) between May 14, 2019 and May 16, 2019. Refer to D5781. 4. A review of patient reports revealed the laboratory failed to perform quality control activities for the Vitek 2 gram-positive and gram-negative identification test system prior to reporting patient culture results. Refer to D5471.