

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2122920	<b>(X3) Date Survey Completed</b>  05/16/2019
<b>Name of Provider or Supplier</b>  Rdb Bioinformatics	<b>Street Address, City, State</b>  2500 Crosspark Rd E233, Coralville, IA	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 9:45 am on 05/16 /2019, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (gram stain, bacterial identification, and antimicrobial susceptibility testing). The findings include: 1. Interview with laboratory personnel identifier #2 confirmed the laboratory performed gram stain, bacterial identification and antimicrobial susceptibility testing on patient specimens. 2. At the time of the survey, the laboratory did not enroll in an approved proficiency testing program for the subspecialty, bacteriology (gram stain, bacterial identification, and antimicrobial susceptibility testing) for 2019.</p>
<b>D5503</b>	<p>BACTERIOLOGY CFR(s): 493.1261(a)(2)</p> <p>(a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.</p>

	<p>This STANDARD is not met as evidenced by:  Based on review of the Gram Stain procedure, quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 5/16/2019, the laboratory failed to check gram stains for positive and negative reactivity using the appropriate control organisms for one out of one week in May 2019. The findings include: 1. Patient identifier A had bacterial identification and antimicrobial susceptibility testing performed on 5/12 /2019. 2. Laboratory personnel identifier #2, confirmed the laboratory performed a gram stain as part of the bacterial identification work-up. 3. The Gram Stain procedure stated QC would be performed, "weekly and upon opening reagents from a new lot or shipment." 4. At the time of the survey, the laboratory did not have gram stain QC records for the week of 5/12/2019.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b>  CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on review of patient test reports and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:15 on 5/16 /2019, the laboratory failed to include the patient's name and identification number on one of two patient test reports (Patient identifier A). The findings include: 1. Patient identifier A had bacterial identification and antimicrobial susceptibility testing performed on 5/12/2019. 2. At the time of the survey, laboratory personnel identifier #2 confirmed the test report for patient identifier A only had the name of the patient; it did not have an additional identification number.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the laboratory procedure manual and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11: 00 am on 5/16/2019, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.</p>
<p><b>D6127</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b></p>

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 9:45 am on 05/16/2019, the technical supervisor failed to assess the competency of individuals performing high complexity testing at least semiannually during the first year the individual tests patient specimens for one out of one testing personnel (laboratory personnel identifier #2). The findings include: 1. The laboratory completed initial training for laboratory personnel identifier #2 on 8/8/2018. 2. At the time of the survey, the laboratory did not have documentation of a semiannual competency for laboratory personnel identifier #2.