

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2122920	<b>(X3) Date Survey Completed</b>  02/24/2021
<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 review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 02/24/2021, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (gram stain), for two out of two years from 2020-2021. The findings include: 1. Interview with laboratory personnel identifier #1 confirmed the laboratory has been performing gram stains since the last survey on 05/16/2019. 2. At the time of the survey, personnel identifier #1 confirmed the laboratory did not enroll in an approved proficiency testing program for the subspecialty, bacteriology (gram stain) for 2020 or 2021. THIS IS A REPEAT DEFICIENCY.</p>