

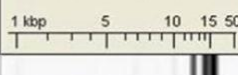


Microbial Characterization Report Guide

Thorough characterization of the microbial population in the manufacturing environment allows for rapid and definitive resolution of sterility failures and investigations into excursions. Accugenix offers automated ribotyping utilizing the DuPont Qualicon RiboPrinter® for strain-level characterization of bacterial isolates (BacRib). Characterization is a test utilized for the comparison of organisms below the species level. Isolates are assigned to a RiboGroup (a collection of banding patterns or “fingerprints”) whose similarity is ≥ 0.90 to a reference pattern. A reference pattern is a composite based on the average data of its RiboGroup members. Every time a sample is tested on the RiboPrinter® system, the RiboPrint™ pattern (“fingerprint”) generated is compared to all existing RiboGroups. If the similarity is ≥ 0.90 to an existing RiboGroup, then the sample is assigned to that RiboGroup. If the similarity is < 0.90 , a new RiboGroup will be created.

Section Descriptions

		223 Lake Dr. Newark, DE 19702 Phone +1.302.292.8888 Fax +1.302.292.8468 www.accugenix.com		RiboPrinter® Sample Report SOP-GEN-043	
Customer: ① Accugenix, Inc.		Account: ⑤ 110440 (ACC1)			
Address: ② 223 Lake Dr., Newark ,DE, 19702, USA					
Accugenix C#: ③ C1010056-20100607001		ID Request Form #: 100007 ⑥			
Customer Sample ID: CM Sample - 051010 ④		Due Date: ⑦ 2010-06-07			
EcoRI ⑧ ⑨ ⑩ ⑪ ⑫					
How Assigned	Number	Label	RiboGroup	RiboPrint™ Pattern	
ACC1	462-205-S-1	R1 - Bacterium #1	ACC1 462-140-S-1		
PvuII					
How Assigned	Number	Label	RiboGroup	RiboPrint™ Pattern	
ACC1	462-206-S-1	R1 - Bacterium #1	ACC1 462-145-S-5		
⑬ Additional Comments					
N/A					
⑭ Prepared By Danielle Robinson-Harvey on 2011-06-16 14:00:26 Reviewed By Emily Huang on 2011-06-16 14:12:02 QA Approved By Geraldine P. Ang on 2011-06-16 14:29:59 Rev. 01Jun10 JDB					

1. Your company name
2. “Ship To” address from your Identification Request Form
3. Unique sample code (C#) assigned by Accugenix
4. Your sample ID, as provided on the Identification Request Form
5. Your 6-digit Account #, followed by a 4-digit alpha-numeric code in ()
6. Each ID Request Form received with samples has a unique number
7. The due date of your Identification Report
8. Customer code
9. Number automatically assigned by the RiboPrinter®, consisting of instrument, batch and lane numbers
10. Unique C# and Customer Sample ID (R# in this example)
11. Customer code and current RiboGroup assigned
12. RiboPrint™ pattern obtained after digestion with restriction enzymes (*EcoRI* or *PvuII*, both are utilized and shown separately)
13. Place holder for additional comments
14. Electronic signatures in compliance with FDA regulation CFR 21 Part 11