

MICROBIAL SOLUTIONS: CHARLES RIVER (THE “COMPANY”) ACCUGENIX® SHIPMENT CONDITIONS



1.877.criver1 | www.criver.com | askcharlesriver@crl.com

Services: AccuGENX-ID®, AccuPRO-ID®, AccuBLAST®, AccuGENX-ST™, RiboPrinter® and Access®

SAMPLE SUBMITTAL

Samples may be shipped to any of the Company's global Accugenix® laboratories. Sample submission options and sample preparation methods for each service can be accessed at <https://www.criver.com/products-services/qc-microbial-solutions/microbial-id-strain-typing/accugenix-sample-submission>.

AccuBLAST® Request Form (ARF) can be completed at <https://myaccount.accugenix.com/acgy>. AccuBLAST® microbial identification can only be performed from file formats ending in .ab1 and must be obtained from a sequence-based identification system. Only 500bp 16S and ITS2 sequences are accepted.

Microbial identification can only be performed with pure colonies. Purchasers may ship cultures with more than one colony type, provided that the colony to be identified is separated from other colonies. Samples too highly mixed to test directly from the original culture must be re-cultured, thereby delaying the requested turnaround time (TAT). To ensure testing is not delayed, the colony to be identified should be clearly marked and listed individually on the request form.

TAT is based on business days and begins upon the receipt of a sample. Same-day TAT is available for samples received by the facility prior to 8:30am Monday through Friday. If, upon arrival, the request form is incorrect or incomplete, samples are mixed or old, contain no visible growth, and/or require testing for clarification, the TAT will begin when colonies are isolated, there is sufficient growth, and/or additional information is received. If Purchaser cancels a sample after testing has begun, Purchaser will incur full charge for the test. The Purchaser is invoiced for all colonies for which testing is initiated.

Samples submitted for AccuPRO-ID® or ribotyping must be fresh cultures (24-72 hours). Cultures exceeding seventy-two (72) hours upon receipt by the Company must be subcultured, thereby delaying the requested TAT. Samples will be ineligible for these services if fresh, isolated growth is unattainable.

Additional fees apply with the following:

- Samples returned to the Purchaser
 - The client will provide a carrier account number
 - There is a handling fee for all returns
 - Contact technical support for detailed information
- Saturday Same Day Testing
 - AccuGENX-ID® testing only
 - Contact technical support to schedule

Charles River Delaware Facility TAT Requests and Results Reporting

AccuGENX-ID®, AccuPRO-ID®, AccuGENX-ST™, RiboPrinter®, and Access®

The contact information for Technical Support in Delaware (USA) is +1.302.292.8888 or del-customersupport@crl.com.

Results are issued by 6:30 PM Eastern Time (ET) on the due date. If samples are received at the facility in Delaware (USA) after 3:00 PM ET, TAT will begin the following business day. For same day TAT, samples must arrive at the facility in Delaware (USA) by 8:30 AM ET. The Company does not guarantee results by 5:00 PM ET for samples received later than 8:30 AM ET. For same day TAT samples received after 8:30 AM ET, results will be sent as soon as available, however, no later than 12:00 PM ET the next business day. A same-day TAT charge will apply. For a Saturday same-day TAT, contact Technical Support by 1:00 PM ET on the prior Friday to schedule; additional fees will apply.

Charles River Australia Facility TAT Requests and Results Reporting

AccuGENX-ID®, AccuPRO-ID®, Access®

The contact information for Technical Support in Australia is MEL-office@crl.com. Please call us at +613 87616116. TAT options include one-day, two-day, and five-day.

Charles River Europe Facilities (France and Ireland) TAT Requests and Results Reporting

AccuGENX-ID®, AccuPRO-ID®, Access® processed in EU facilities.

AccuGENX-ST™, RiboPrinter®, forwarded to Newark, Delaware facility for processing.

The contact information for Technical Support in Europe is Accugenix.labEU@crl.com. Should you need to contact us by phone: Dial +33 (0)4 37 50 29 15 for our Accugenix® lab in Ecully, France or dial +353 (0)1 506 9775 for our Accugenix lab in Dublin, Ireland. Results are issued by 11:59 PM local time on the due date. If samples are received at a European facility after 1:00 PM local time, TAT will begin the following business day. For same-day TAT, samples must arrive at any of our European facilities by 8:30 AM local time. The Company does not guarantee results by 11:59 PM for samples received later than 8:30 AM local time. For same-day TAT samples received after 8:30 AM local time, results will be sent as soon as available, however, no later than 11:59 PM local time the next business day. A same day TAT charge will apply.

Charles River Laboratories China Facility TAT Requests and Results Reporting

AccuGENX-ID® and AccuPRO-ID®

The contact information for Customer Support in Charles River China is +86. 21. 3973.9878.

Results are issued by 5:30 PM China Standard Time on the due date.

Charles River Laboratories India Facility TAT Requests and Results Reporting

AccuGENX-ID® and AccuPRO-ID®

The contact information for Customer Support in Charles River Laboratories India Pvt. Ltd., (INDIA) is 1800-102-9876.

Results are issued by 5:30 PM Indian Standard Time (IST) on the due date.

Charles River Korea Facility TAT Requests and Results Reporting

AccuGENX-ID® and AccuPRO-ID®

The contact information for Technical Support in Korea is +82.32.209.8101.

Results are issued by 11:59 PM Korea Standard Time (KST) on the due date. If samples are received at the facility in Korea after 3:00 PM KST, TAT will begin the following business day. For same-day TAT, samples must arrive at the facility in Korea by 3:00 PM. The Company does not guarantee results by 11:59 PM KST for samples received later than 3:00 PM KST. For same day TAT samples received after 3:00 PM KST, results will be sent as soon as available, however, no later than 11:59 PM ET the next business day. A same day TAT charge will apply.

Charles River Singapore Facility TAT Requests and Results Reporting

AccuGENX-ID® and AccuPRO-ID®

The contact information for Technical Support in Singapore is +65 8721 8933.

Results are issued by 11:59 PM Singapore Standard Time (SST) on the due date. If samples are received at the facility in Singapore after 3:00 PM SST, TAT will begin the following business day. For 1-day TAT, samples must arrive at the facility in Singapore by 12:00 PM SST.

**Earliest required delivery times are subject to change. Please check our website for details specific to your shipping location.*

AccuBLAST®

TAT Requests and Results Reporting

The contact information for Technical Support in Delaware is +1.302.292.8888 or del-customersupport@crl.com.

TAT is based on business days and begins on the day and time a file is received at the Company. Results are issued by 6:30 PM Eastern time (ET) on the due date. Same-day TAT sequence files must arrive at the Company by 12:00 PM ET. The Company does not guarantee results by 6:30 PM ET for samples received later than 12:00 PM ET. For Saturday same-day TAT, contact Technical Support by 1:00 PM ET on the prior Friday to schedule data analysis; additional fees will apply.

The contact information for Technical Support in Delaware is +1.302.292.8888 or del-customersupport@crl.com.

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Access® System

After Purchaser submits samples on its Access® system for identification, the following applies:

ID Type	Eligibility Code and ID Type Description
Access® Species Match (Bacterial)	[1] MALDI Species ID – species-level identification achieved; for genotypic identification at an additional charge, check “Submit for Charge” box to request “BacSeq” test.
Access® Species* Match	[2] MALDI Species* – sample matches two or more species; check “Submit for Charge” box to request a “BacSeq” test, for an additional charge, to attempt to resolve the identification by 16S rDNA sequencing (see below).
Access® Species Match (Fungal)	[3] MALDI Fungal – Access® is not validated for fungal identification; however, a species-level identification was achieved; for genotypic identification at an additional charge, check “Submit for Charge” box to request “FunITS” test.
Access® No Match	[4] MALDI Identification Unsuccessful – no match in the reference library; only charge for classification if “Submit for ID” checked and sample submitted for Accugenix® identification services.
Access® No Spectra	[5] MALDI Identification Unsuccessful – no spectra; only charge for classification if “Submit for ID” checked and sample submitted for Accugenix® identification services.

Category	How Determined	Impact
Species Match (Bacterial or Yeast)	Bacterial Species Match ≥ 1.750 ID is Bacterial	Not Eligible for Follow-up ID services at your tiered Access® classification rate.
Species* Match (Bacterial or Yeast)	Multiple Bacterial Matches ≥ 1.750 ID is Species*	Not Eligible for Follow-up ID services at your tiered Access® classification rate.
Species Match (Filamentous Fungi)	Fungal Match ≥ 1.750 ID is Filamentous Fungi (mold) or mushroom	Not Eligible for Follow-up ID services at your tiered Access® classification rate.
No Match	Match < 1.750 and Match > 0.000	Eligible for Follow-up ID services at your tiered Access® classification rate.
No Spectra	Match = 0.000	Eligible for Follow-up ID services at your tiered Access® classification rate.

If there is a species or species* match for a bacteria or yeast, the Purchaser will be invoiced based on their classification rate. If a sample is submitted to the Company for additional testing with AccuGENX-ID® (BacSeq/FunITS), there will be an additional charge. If a sample matches two or more species (species* confidence), resolution may be accomplished by AccuGENX-ID® sequencing. If the rDNA sequence (16S or ITS2) cannot differentiate between the colonies, Purchaser may request the ProSeq service for further analysis if available for the defined species* group by contacting their Technical Support Specialist.

With Access®, if there is a species match for a filamentous fungus, the Purchaser will be invoiced based on the Purchaser’s tiered Access® classification rate. If a sample is submitted for additional testing with AccuGENX-ID® (FunITS), there will be an additional charge. The Access® system is not validated for filamentous fungal identification. The Company evaluated the MALDI-TOF technology and determined that it is not acceptable for filamentous fungal identification due to the clinical focus of the reference library, which includes limited environmental fungal species and poor reproducibility of data acquisition from filamentous fungal samples. The Company does not verify the accuracy of species identification of filamentous fungi when using the Access® system.

The Purchaser is not invoiced for samples that result in Access® No Match or No Spectra outcomes. The Purchaser may submit the sample to the Company for identification at its Access® tiered classification rate. The Purchaser must submit samples to the Company by clicking the appropriate box in the web portal within two (2) days of initiating an IRF. If the Company determines that a filamentous fungal sample was submitted for identification, the Purchaser will be invoiced based on their discounted rate for the identification (FunITS). Samples submitted to the Company for follow-up identification may be submitted on plates or as ethanol preparations. These preparations must be prepared from cultures that are less than seventy-two (72) hours old. The Purchaser will receive the identification results within five (5) business days of submittal of sample to the Company.

SAMPLE SUBMISSION VIA THE PURCHASER WEB PORTAL

The Accugenix® web portal (<https://myaccount.accugenix.com/>) permits the Purchaser to prepare and submit an IRF electronically. The Purchaser represents that the IRF is accurate and complete.

TRACKING AND TRENDING

Information contained in the Laboratory Information Management System (LIMS™) is obtained from the naming convention applied to samples by the Purchaser and the identifications resulting from processing performed by the Company. The auxiliary data associated with the Company’s species library (e.g., cell morphology and Gram reaction) is obtained from the primary literature or from reference material including, but not limited to, the *International Journal of Systematic and Evolutionary Microbiology*, *Bergey’s Manual of Systematic Bacteriology*, The Westerdijk Fungal Biodiversity Institute (Centraalbureau voor Schimmelcultures), and MycoBank, and does not reflect testing conducted by the Company. The tracking and trending data in the web portal are for informational purposes only. For an individual sample identification, refer to the original identification report generated. The Company only ensures data integrity up to the point of export from the web portal.

MISCELLANEOUS

Sample processing and/or data analysis may be performed by any of the Company’s affiliates that are accredited to ISO 17025 for the services requested. The Company does not perform sterility testing. Failure to obtain a result does not indicate or imply sterility of sample. Once samples arrive, processing is initiated based on requested TAT. Special project testing procedures developed between the Company and Purchaser may be outside of the scope of the Company’s validated processes. Special projects are performed with Purchaser’s completion of the special project form, where the special project testing instructions and results are recorded. The Company does not perform any product release or compendial testing. The Company automatically releases 21 CFR Part 11 compliant reports on their due date. Each facility recognizes their respective national holidays and will be closed.

Contact Technical Support with questions regarding holiday observances and resulting effect on TAT. The Company’s sample retention policy is to hold Purchaser samples for a minimum of three (3) weeks after the result due date. Requests for longer retention must be made in writing to Technical Support at: accugenix-customersupport@crl.com. Pricing is subject to change without notice.