

DEMONSTRATING STATE OF CONTROL

Tracking and Trending of Environmental Isolates

EVERY STEP OF THE WAY

WHY TREND ORGANISMS?

Do isolates present risk to patient, product or process?

Are isolates transient or resident?

Can contaminants be tracked into controlled areas, in-process materials or finished products?

Do cleaning procedures remediate contamination?

Demonstrate State of Control

ENVIRONMENTAL MONITORING DATABASES

Critical to success

Trend the data

Review data trends with management and regulators

Commercial Solutions

Spreadsheet

Dedicated Database Programs

PURPOSE OF T&T TOOL

Measures the state of control of the manufacturing facility

- Acts as a surveillance – early warning system

Evaluate level of risk

Root cause analysis

CAPA planning to mitigate risk

Measure the effects of CAPA plans

Evaluating objectionable organisms

Analyze fluctuations in microflora month to month; year to year; seasonal

Value of T&T

24/7 access to information

Proactive monitoring

Easily perform deep dives

No manual data entry

Customize reports to fit business requirements

Improve compliance position

FEATURE ATTRIBUTES

Define the source of the recovered isolate

Product related

Air sample

Surface sample

Gowning

Raw material

Water

Quality Control Organisms

Environmental

Personnel samples

Rinse Water, Swabs

Other (Custom Input)

Product Lot # (SKU#)



Use your standardized nomenclature

FEATURE ATTRIBUTES

Define the sampling method

Static

Dynamic

Routine

Filling Operation

Active air sampling

SAS

SMA

Settle plate

Contact plate

Swab

Bioburden

Filling Operation

Media Challenge



Use your standardized nomenclature

FEATURE ATTRIBUTES

Define the location, collection date and who

Location Demographics

Plant Number

Floor Number

Room Number

Unique Sampling Point Code

Collection date/time

Samples Collected By (name or initials) Lab#/
Batch#

Batch#

Sample Name/#/Bar-code

Other: 3 Custom Input Fields



Use your standardized nomenclature

FEATURES - REPORTING

Reports	v.1	v.2
A list of all species identified within your facility and by origin/type of the sample	X	√
A frequency of occurrence report of all species identified at your facility and by origin/type of the sample	X	√
Trending the microflora by room or manufacturing location and by origin/type of the sample	X	√
A grouping of the identifications of isolates by genus level within your facility and by origin/type of the sample	X	√
A grouping of the identifications of isolates by Gram stain reaction, morphology and spore forming capability within your facility and by origin/type of the sample	X	√
A frequency of occurrence report of all species identified	√	√
Trending the microflora by Species	√	√
Trending microflora by Genus	√	√
Trending by Morphology Types	√	√
Trending by Time Periods	√	√
Gram Reaction	√	√
Spore Formers	√	√
Morphology	√	√
All of the above	√	√
Trending microflora by Type (Bacteria;Fungi;Yeast)	√	√
Dashboard	√	√
Trending for a specific Species or Genus (up to 3 selections)	√	√
Report by Sample # Range or Collection Date		√

OTHER FEATURES

Data Import – Import/Export

Ability for data upload for IRF

Simplify ability to upload T&T data to other Information Mgt Systems.

Tables & Graphs

Administrative Rights

3 - Levels of Users (Adm. responsible for settings and user status)

Global Site Access to Data for Reports Between Sites

Other Features

Customized fields

Allowable characters for entries up to 40

Attributes can be entered at time or IRF or back entered by customer post sample submission

Entries could be made on historical data



Your standardized nomenclature is saved and becomes drop down choices

OTHER FEATURES

Improved Compliance

Audit trail & reporting to track attribute changes made by submitters

3 – Levels of use within/site

- Site Admin - responsibility to manage users access, passwords, etc.
- Submitters – Data entry
- Viewers only

Super User for global viewing of sites

Objectionable Organisms

Custom creation of “Bad Bug” list

Flagged ID reports

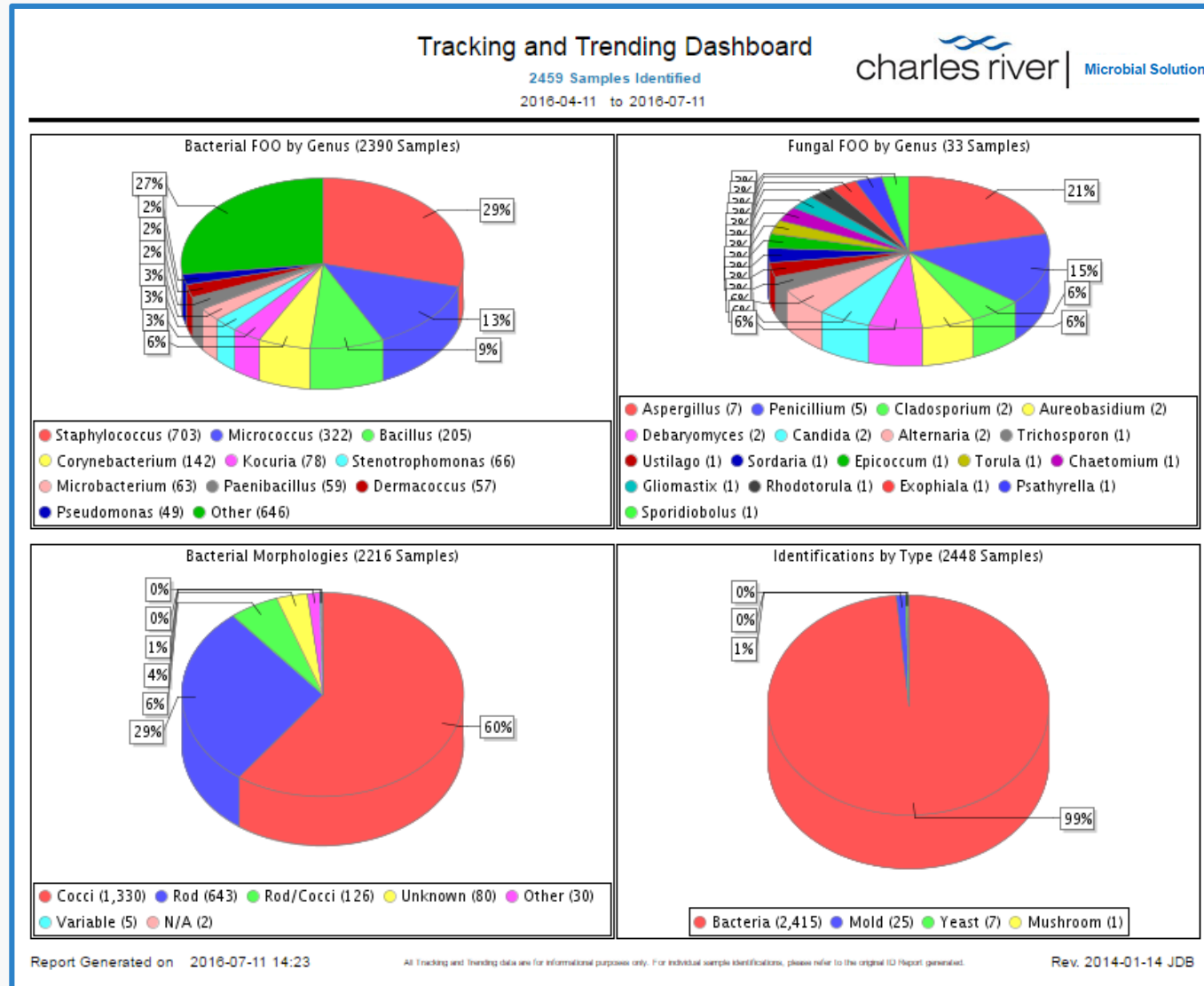


CUSTOMER WEB PORTAL LANDING PAGE

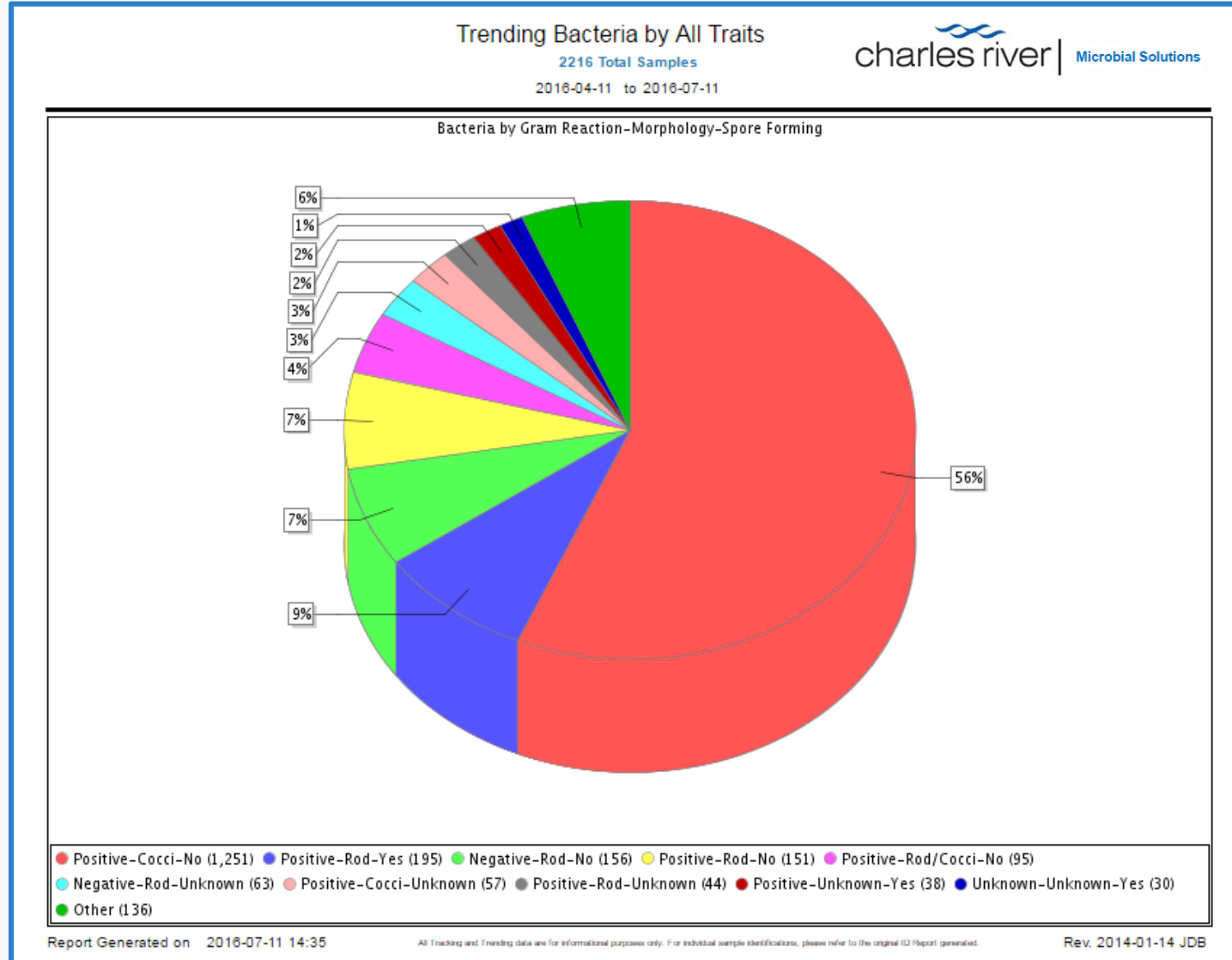
User Name: Missy Ruch Customer Account: 111555

<ul style="list-style-type: none"><input type="checkbox"/> New Request<input type="checkbox"/> View Request<input type="checkbox"/> View Access Request<input type="checkbox"/> View Invoice<input type="checkbox"/> View C# Reports<input checked="" type="checkbox"/> Tracking & Trending<input type="checkbox"/> Contact Information<input type="checkbox"/> Change Password<input type="checkbox"/> Customer Support<input type="checkbox"/> Current Pricing<input checked="" type="checkbox"/> Help<input type="checkbox"/> Logout <p>Useful Documents</p> <ul style="list-style-type: none"><input type="checkbox"/> Accugenix Customer Web Portal Manual<input type="checkbox"/> ID Request Form File Upload Instructions<input type="checkbox"/> ID Request Form Example Tab-delimited File<input type="checkbox"/> AccuBLAST Request Form File Upload Instructions<input type="checkbox"/> AccuBLAST Request Form Example Tab-delimited File<input type="checkbox"/> Sample Preparation	<h3>Help</h3> <ul style="list-style-type: none">▪ Click on New Request to submit a new ID Request form or AccuBLAST Request form.▪ Click on View Requests to view the requests submitted.▪ Click on View Access Requests to view the access requests submitted.▪ Click on View Invoice to view invoice and payment information for various requests submitted.▪ Click on View C# Reports to download C# reports for a selected request.▪ Click on Tracking & Trending to access tracking and trending reports.▪ Click on Contact Information to view and edit contact information.▪ Click on Change Password to change your password.▪ Click on Customer Support to view Customer Support contact information.▪ Click on Current Pricing to view Current Pricing information.
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TRACKING & TRENDING DASHBOARD




BACTERIA BY ALL TRAITS



POSITIVE COCCI, NON-SPORE FORMERS

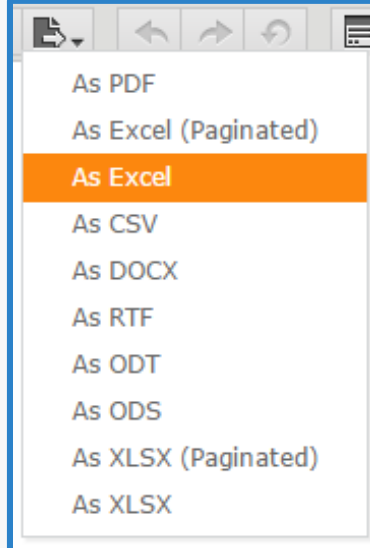
Sample Data Export
773 Total Samples
2016-06-15 to 2016-09-15



Organism Types: All Gram Reaction: All
Cell Morphology: All Spore Forming: All
Confidence Level: All

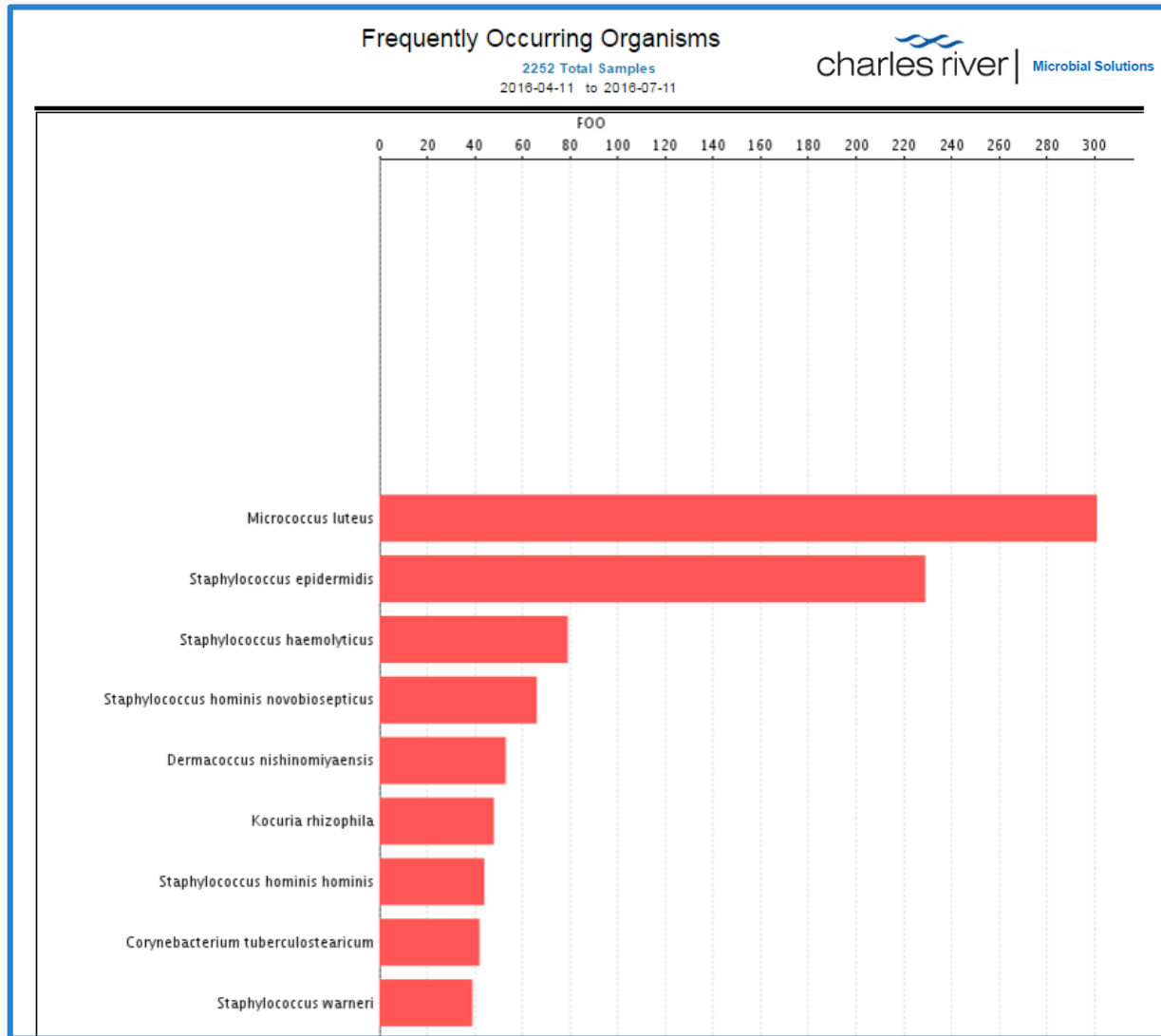
C Number	Sample ID	IRF #	Received	Identification	Confidence	Gram Reaction	Spore Forming	Morphology	Org. Type
2354959	090230116-E632655	245905	2016-09-14	Staphylococcus caprae	Species	Positive	No	Cocci	Bacteria
2354958	090200016-E632507	245905	2016-09-14	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2353429	090170116-E632284	245695	2016-09-13	Staphylococcus hominis novobiosepticus	Species	Positive	No	Cocci	Bacteria
2353428	090160216-E632297	245695	2016-09-13	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2353427	090160116-E632287	245695	2016-09-13	Staphylococcus hominis novobiosepticus	Species	Positive	No	Cocci	Bacteria
2353424	090120216-E632182	245695	2016-09-13	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2353422	090110216-E632181	245695	2016-09-13	Staphylococcus hominis novobiosepticus	Species	Positive	No	Cocci	Bacteria
2353421	090110116-E632181	245695	2016-09-13	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2352538	090130016-E632140	245589	2016-09-12	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2352532	082700016-E631682	245589	2016-09-12	Staphylococcus hominis hominis	Species	Positive	No	Cocci	Bacteria
2352530	082680216-E631682	245589	2016-09-12	Staphylococcus warneri	Species	Positive	No	Cocci	Bacteria
2352529	082680116-E631682	245589	2016-09-12	Staphylococcus haemolyticus	Species	Positive	No	Cocci	Bacteria
2352528	082670316-E629886	245589	2016-09-12	Staphylococcus haemolyticus	Species	Positive	No	Cocci	Bacteria
2352527	082670216-E629886	245589	2016-09-12	Staphylococcus warneri	Species	Positive	No	Cocci	Bacteria
2352525	082650216-E628215	245589	2016-09-12	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2350547	082640016-E631718	245433	2016-09-09	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2350546	082630016-E631595	245433	2016-09-09	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2350545	082620016-E631491	245433	2016-09-09	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2350544	082610216-E631635	245433	2016-09-09	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria
2350543	082610116-E631635	245433	2016-09-09	Staphylococcus hominis novobiosepticus	Species	Positive	No	Cocci	Bacteria
2350541	082600216-	245433	2016-09-09	Staphylococcus epidermidis	Species	Positive	No	Cocci	Bacteria

Report Generated on 2016-09-15 11:52 All Tracking and Trending data are for informational purposes only. For individual sample identifications, please refer to the original ID Report generated. Rev. 2014-01-14 JDB



- As PDF
- As Excel (Paginated)
- As Excel
- As CSV
- As DOCX
- As RTF
- As ODT
- As ODS
- As XLSX (Paginated)
- As XLSX

FREQUENTLY OCCURRING ORGANISMS (FOO)



ORGANISMS OVER TIME

