



Accustrata, Inc.

Market Report: Handheld/Portable Fluorometers
Prepared by PROSSIS

Market Report



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February 26th 2015

As instructed by Accustrata Inc., PROSSIS has conducted a review of the market for a Handheld/Portable Fluorometer competitive with the EnZtech "EnZquik" unit. and prepared this report dated February 26th 2015.

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Yours faithfully,

A handwritten signature in black ink that reads "Peter Rossi". The signature is stylized, with the first letters of the first and last names being large and prominent.

Peter Rossi
Executive at Large PROSSIS.

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Introduction

PROSSIS has over thirty years of experience in Instrumentation, Monitoring and Control related businesses in various capacities ranging from Sales and Marketing to Engineering and Manufacturing. We have been involved in mergers and acquisition of companies and technology along with day to day operation and strategic planning. PROSSIS has worked in various types of industries ranging from the entrepreneurial to the highly regulated.

PROSSIS core strengths include:

- ▶ Market analysis, segmentation, and forecasting.
- ▶ Product development, life cycle management, product positioning, brand awareness.
- ▶ Innovation, strategic analysis and planning, tactical implementation.
- ▶ Company due diligence, merger and acquisition.
- ▶ Intellectual property protection & technology evaluation.
- ▶ Lean manufacturing, value chain analysis, quality systems.

The report's author has been intimately involved in the development and commercialization of sensor, instrumentation, and monitoring systems. PROSSIS is fully cognizant of the many and varied problems and opportunities that face companies looking to introduce new products into existing and developing market segments.

In preparation of this report extensive research has been conducted through use of web searches, information obtained in discussions with instrument manufacturers, suppliers, distributors and end users, along with the authors inherent knowledge of the markets, products and technology.

Scope of Report

Accustrata has been asked to provide EnZtek with a fluorometer to replace their existing unit. This report takes an independent look at the potential for Accustrat Inc, ("Accustrata" or the "Company") as an instrumentation business to enter a new market. In particular this report looks to evaluate the Company's opportunities within the Handheld/Portable Fluorometer (competitive with the EnZtech "EnZquik" unit) market space. IP freedom to operate is not covered in the scope of this report.

Specifically the following has been addressed:

1. Estimated of the Handheld Fluorometer Market (revenue and units)
2. Current applications, key trends and growth potentials.
3. Existing Handheld Devices by manufacturer.
4. Top 10 potential customers' requirements (technical and application specifications unique to customer).
5. SWOT analysis.
6. Is there a Market opportunity for Accustrata?

Background on EnZtek and the EnZquik Fluorometer

EnZtek makes propriety enzyme based rapid microbiological ("rapid-micro") tests. The test results are evaluated by color change or fluorescence, the later providing lower detection capabilities. EnZquik fluorometers are used for determining test results and they need to be reliable and easy to use.

The EnZquik fluorometers are available as two single (low and high wavelength) channel units and as a two channel instruments that incorporates both high and low channels. All units have a touch screen display, data logging capabilities, a USB data port, and run off rechargeable batteries. 500µl PCR or centrifuge tubes are used for measurement. The

EnZquik fluorometer is purchased as an OEM instrument from AmiSciences and will be covered in detail in this reports section on Competitive Instruments.

EnZtek is having problems with the EnZquik Fluorometers, in particular with replicating results when the sample tubes are moved or repositioned. A positive test result is recorded, at the end of a 10 minute enzyme reaction with the reader being zeroed at the start of the enzyme reaction, if the reading on the fluorometer shows greater than 500 relative fluorescence units (RFU).

EnZtek forecast for EnZquik sales is currently less than 200 units per year. The two channel instrument sells for roughly \$1,500 and the single channel just over \$1,000. Clearly the ROI for developing a fluorometer requires a larger opportunity than that provided by current EnZtek sales.

The possible opportunities for additional sales come from:

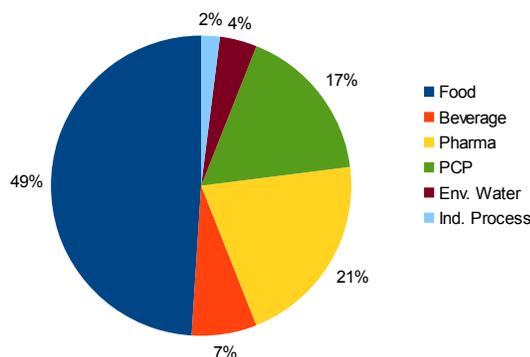
1. Increased acceptance and sales of EnZtek products.
2. Sales to companies with similar products to EnZtek.
3. Use of the basic product in other Fluorometer applications

To understand the potential opportunities a review and analysis of the markets for a handheld/portable fluorometer is needed.

Markets for Handheld/Portable Fluorometers

Overview

\$6.5 Billion Global Microbiological Testing Market



The applications for a Handheld/Portable Fluorometer falls within the larger horizontal spectroscopy market space and opportunities for such a device can be evaluated based on the trend within that horizontal market space and the vertical markets it crosses (See Figure 1).

The Global market for Microbiological testing, the market space addressed by EnZtek, is by one estimate \$6.5 Billion¹. Within this market, rapid-micro testing is becoming increasingly dominant over traditional testing

Figure 1: Microbiological Testing Market by Vertical

methodologies, with 67% of the routine testing in the food industry now being done using rapid-micro assays. With so many new rapid-micro assays it is difficult to pick one over another.

The Global report also points out that pathogen detection and identification is increasingly gaining importance as food safety is of growing visibility and concern to the public, food companies and regulators. The heightened awareness is driven by factors that include increasing food recalls, evolving pathogens, more educated consumers and heightened press coverage.

\$5.5 Billion USA Spectroscopy Market

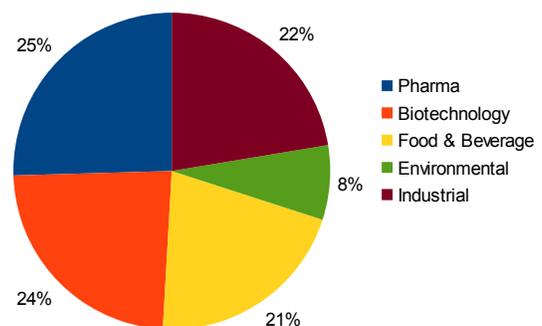
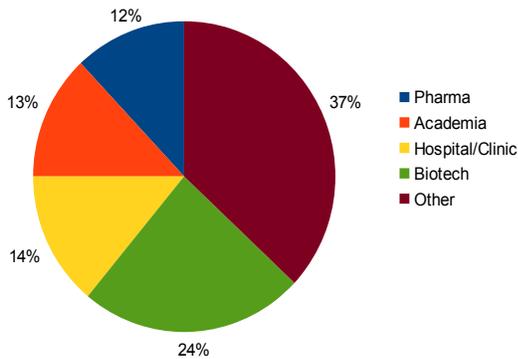


Figure 2: US Spectroscopy Market by Vertical

\$15 Million Lab Fluorescence & Luminescence Market



• *Figure 3: Lab Fluorometers & Luminometers by Vertical*

The same report also quantifies the Global handheld fluorometer market to be \$10 Million (see Figure 4). Interestingly the report looks at different vertical markets for the handheld instruments to those used in the laboratory.

As Figure 4 shows The most common application for handheld fluorometers is within the Agriculture. The report further identifies chlorophyll fluorescence measurement as a large part of the segment. However, the fluorometers being used are for plant health monitoring and are specialized instruments using pulse amplitude modulation (PAM) fluorescence techniques, very different to the unit under consideration for EnZtek and outside of the scope of this report.

The Environmental Testing vertical in Figure 4 include evaluation of water quality by way of algae levels with regard to cyanobacteria in ponds, lakes and coastal waters. Here chlorophyll and phycocyanin intrinsic fluorescence, along with fluorescent tracing dyes, are measured. Much of this market makes use of insitu instruments (Sondes). For the handheld portion of the market application wavelength and cell size changes, from the EnZtek unit, would need to be made. Addition of turbidity measurement would be advantageous, as would oil dispersion measurement.

Ballast water checking is a subset of this environmental testing application. There is a need of chlorophyll and pathogen monitoring in this niche application.

While the reports have different time frames and splits with regard to vertical market segments they still provide an insightful overview when the trends identified in the reports are taken into consideration. In addition to the key trends identified, the various reports also highlight important market drivers and potential barriers to entry. All of which will be covered in later segments of this report.

The biggest barrier to entry is the number of well established players with strong brands, existing distribution channels, available marketing and technical resources, and the ability to leverage existing infrastructure and systems. Additional barriers in the regulated vertical market segments include accreditation and verification.

The existing market for a handeld/portable EnZquik type fluorometer is estimated to be under \$4 Million . However, there could be opportunities in emerging segments for a differentiated device.

The use of spectrophotometers as part of the rapid-micro space is also growing with the USA market for spectroscopy instruments alone being worth \$5.5 Billionⁱⁱ (see Figure 2).

However, single tube fluorometers and luminometers only contribute a small proportion (\$15 Million, see Figure 3) of the overall spectroscopic laboratory instruments market identified in the Global Assessment Reportⁱⁱⁱ. Within laboratories multi-plate readers and automated systems are displacing single tube fluorometers, except in very small labs, and some critical process control points.

\$10 Million Global Handheld Fluorometer Market

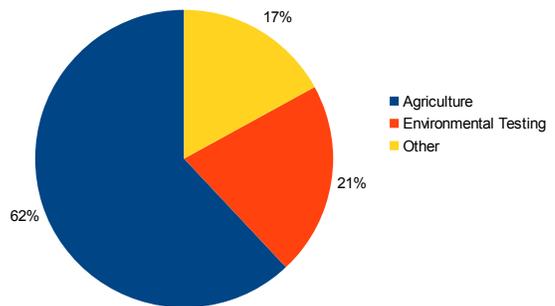


Figure 4: Handheld Fluorometer by Vertical

New Market Opportunities.

Agricultural Food Market Trends

The routine testing of foods & beverages for HACCP (Hazard Analysis Critical Control Point) verification has been dominated by Adenosine Triphosphate (ATP) systems using luminometers and luciferase testing. The main players in this \$10M space for handheld instruments (~10% of total ATP revenue) are:

- 3M Clean-Trace
- Hygiena
- BioControl
- Charm
- LuminUltra
- Neogen
- Celsis (big player in ATP but more into automation than Handhelds)

In the Food and beverage industry there has been a fast moving trend to contract laboratory testing and automation, resulting in a decline of handheld instrument sales. While HACCP needs have safeguarded handheld luminometer sales in food many processing plants, ATP testing has been limited in agricultural critical control point testing due to the simple fact that ATP is found in plant cells. Farms and their produce's supply chain to the consumer is increasingly in need of rapid pathogen testing and getting governments attention. The CDC recently estimated that perhaps 5 million cases of foodborne illness each year in the USA are attributed to fresh fruits and vegetables. With the total value of fresh market vegetables worth an estimated \$25 billion in 2013 (up from \$15 billion in 2001) this is a significant concern.

There is also a rising Concern Over Salmonella. Salmonella is a major pathogen of concern and the reports show that it is the most frequently tested pathogen. While outbreaks of other major pathogens have been reduced, Salmonella has remained stubbornly at historic levels.

In addition to recent high profile outbreaks and recalls, there is also the growing concern about antibiotic resistant Salmonella strains. At some point it seems likely that Salmonella, or at least some serotypes of Salmonella, will be treated in the same manner as E. coli O157, that is, as an adulterant, and as such, not acceptable at any level in food. For all of these reasons and more, Salmonella will factor more heavily in food safety discussions going forward.

Two years ago on January 16, 2013, the U.S. Food and Drug Administration (FDA) published its original draft rule on produce safety under the Food Safety Modernization Act (FSMA). The rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule), was aimed to prevent or at least to reduce contamination of produce with biologically hazardous material. The standards in the proposed rule sought to further efforts which already existed in the agriculture industry to reduce the incidence of food-borne illness.

The proposed rule is currently under public comment and review, it is anticipated to be enacted on October 31st 2015 with the following implementation timetable:.

- Farming entities with more than \$25,000, but no more than \$250,000 in annual produce sales have 4 years after the rule's effective date to comply with most provisions.
- Businesses with more than \$250,000 and no more than \$500,000 in annual produce sales have 3 years after the effective date of the rule to comply with most of the rule.

- All other farming entities have 2 years after the effective date of the rule to comply with most of the rule.
- The provisions of the Produce Safety Rule pertaining to agricultural water quality standards, including the testing and record keeping provisions it carries, will require compliance within 2 years after compliance with the other standards.

The new regulations has potential to have a large impact on rapid-micro testing sales. Product & Marketing managers for 3M^{iv} and Hygiena anticipating growth for their systems and competition from rapid molecular testing systems (e.g. polymerase chain reaction (PCR) based assay). Hygiena has introduced its own enzyme based rapid-micro testing system "MicroSnap" to complement their ATP assays.

The trend to the use of locally produced "organic" Produce will remove many farmers from the impact of the new regulations. They however might still want to monitor their produce from a quality perspective and will be looking at low investment options.

In 2002, the U.S. Department of Agriculture's Agricultural Research Service published an article entitled "On-Farm Testing for Pathogens on the Horizon." The article outlines a detection method using fluorescent real-time PCR to detect pathogens. Although the detection was possible in 30 to 45 minutes, the instrumentation and cost make systems like this less practical for routine testing by a farmer.

To design assays to be conducted on a farm, one needs to account for the farming environment and resources. Innovation in the testing device is needed. An innovative system focused on the farm worker as the target user will reduce the barriers to entry and open up sales for a simple reader with an appropriate rapid pathogen detection system.

Ballast Water

The 2004 International Convention for the Control and Management of Ships Ballast Water & Sediments was adopted by consensus at a Diplomatic Conference at International Maritime Organization (IMO) in London on Friday 13 February 2004. In 2014, Japan and Turkey were among those states to ratify, and one or two of the major flags (e.g. Italy, UK, Singapore, China, Hong Kong, Bahamas, Malta, Greece, Cyprus) would be enough to end the 10 year wait.

60,000 -65,00 ships worldwide are expected to have to install ballast water treatment systems in the next five to seven years to comply with the convention

- Insitu or field monitoring systems will be needed for the installed filtration systems.
- Bacteria (tests available from EnZtek) and Algae monitoring will be required
- Tests are divided into 2 particle size classes and indicator organisms (Annex 3, adopted in 2008)

Modern ships operate with minimum crew, so any ballast water monitoring system needs to be either online or assay need to be accomplished by semi skilled crew without traditional laboratory facilities.

While the Ballast Water application is identified as an opportunity it will not be addressed directly in this report. A pathogen detection fluorometer will meet some of the needs, but the type of instrument needed to make an impact in the application would involve a considerable and significant design initiative.

Market Segmentation

There are many ways to segment the market and a user segmentation, as outlined in the above market opportunities, would be an appropriate choice here. The available market could also incorporate other applications that had a similar user set.

That user set can be defined by:

- In a regulated, or soon to be regulated, market, or a market where quality is valued and quality feedback is required in a timely manner.
- In a work environment where skilled scientific labor is not freely available.
- In an environment with no access to laboratory facilities.
- Start-up investment costs are required to be low.

Market Drivers

Regulation, Guidelines & Standardization

Regulations drive markets as much or even more so than productivity, mainly because they provide some standardization, and usually are only put in place when productivity goal start to impact on peoples well-being. Regulated markets also provide suppliers with some stability as they are not as vulnerable to external fluctuations in consumer demand and generally have higher barriers to entry.

New emerging regulations, as those highlighted, do however offer new potential entrants an opportunity to break into a market space. The above identified market opportunities are attractive mainly because of the regulatory phase they are in.

Accuracy & Speed

Getting the produce to market or getting animals back into production in a timely manner deeply influences a farmers profitability. While a false positive result will negatively impact profitability a false negative will have far greater ramifications.

As the testing get closer to the source, the person administrating the test need to be able to quickly and definitively make the call. Potential error sources need to reduced if not eliminated.

Cost

The general cost to outsource a 100mL water sample for an Escherichia coli/coliform assay to a microbiological lab ranges from \$15 to \$28 per sample. Due to the complexity of the test, currently this is the only option available for farmers.

On site rapid-micro testing can cost \$5-8 per sample, not factoring in labor or overhead, and an ATP test \$2-3 per sample. While there looks to be a cost saving and a gain in the time to obtain a result with use of a rapid-micro assay in the field, additional overhead and initial capital investment often hinders small enterprises from undertaking their own testing.

In regulated markets the cost associated with verification of performance and record keeping is significant. It should not be overlooked.

Market Barriers

The barriers to entry into the markets are significant and the following barriers need to be considered:

- Established brands
- Fragmentation in the rapid-micro space – Too many choices
- Distribution channel
- Validation certification (AOAC is a accreditation is necessary for wide market acceptance)

Competition & Market Share

If we look at the established players in the handheld market they are clearly divided into two main sets. The first set are geared to the pharmaceutical and biotechnology market segment and focus on molecular biology (sample volume 1 μ l - 200 μ l). They find applications in small life science laboratories that lack the test volume to justify automated systems or multi-plate readers.

Fluorometer for these applications are provided by companies line Thermo Fisher, Quagen and Promega. The later company acquired the handheld unit, and other table top fluorometers, with the purchase of Turner BioSystems Inc. in 2009. Turner Design now serve the smaller environmental markets segment.

Handheld Fluorimeter focused on Life Science Focused market segments are not being included in this report. This includes units supplied by Promega, Quagen and Thermo Fisher Scientific. While these units could find application in the segments being explored their price point, and their low sample volume,generally excludes them in the food market segment.

Note: the Thermo Fisher LifeTechnologies Qubit has been include to highlight the difference between the handheld/portable and the single tube laboratory fluorometer.

It is the authors strong belief, based on years of experience, that a fluorometer that matches, or even surpasses the performance of relatively generic instruments, will have limited growth opportunity. In a small market this equates to no, or a marginal, ROI. Even with a lower price point the long term prospects are not promising. Competition will respond to lower pricing and quickly nullify any temporary advantage, unless it is a significant price drop with sustainable high margins – breakthrough development.

The competition should not be viewed as other handheld fluorometer manufacturers, but the players in the rapid-micro space withing the food industry, of which there are many. To be competitive in the space the product should be viewed in totality, with sample collection and handling fully integrated with the detection system and data handling.

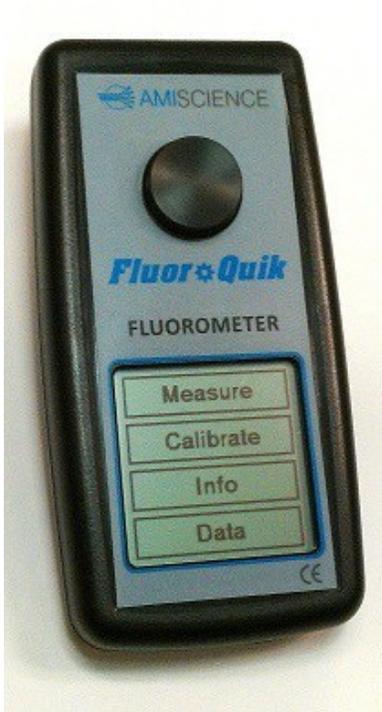
Also taken into consideration should be the fact that many of the existing rapid-micro tests are based on simple visual changes. Devices like lateral flow strips provide a very simple test and are familiar to non technical users. Coupled with a reader these strips can provide sensitive detection and data handling.

Note: operational manuals for the competitive fluorometer have been provided.

Universal, Environmental and Industrial Focused Fluorometers

AmiScience

Makes the unit used by EnZtek and others (Sigma Aldrich, BioAssay Systems, Beagle etc.)
The units are manufactured in China and the company is owned by a Chinese entity.



Quick Facts:

- Sells the single channel unit for ~\$1K
- Two channel unit for \$1.5K
- Additional cost for UV ~\$100 for UV LED.
- They offer a 30% discount to OEM and distributors with no minimum volume.
- Introducing a temperature controlled unit.
- Also offers a colorimeter & luminometer
- Sells and distributes EnZtek assays
- Made in China from Standard components.
- Estimated unit cost \$300-400.
- Revenue <\$1M

Specifications:

Product Type:	Single Tube Fluorometer
Read Type:	Discrete
Sample Volume:	
Model A	100 μ L using mini glass tube, 200 μ L using PCR tube
Model B	500 μ L using micro-centrifuge tube.
Excitation Wavelength (nm):	360, 440, 480, 530, 600
Detection Wavelength (nm):	460, 530, 590, 650, 670
Dynamic Range:	> 6 Orders of Magnitude, Assay Dependent
Temperature Range:	10-50°C (and above Ambient)
Temperature Accuracy:	+/-1°C
Temperature Stability:	+/-0.5°C
Read Out:	RFU or Direct Concentration
Calibration:	Two-Point Calibration
User Interface:	Touch Screen LCD Display
Power:	4 AA Batteries or 9V DC Power Adapter
Computer Interface:	USB Interface to Retrieve up to 80x2 Data Points
Dimensions (L x W x H):	185mm x 90mm x 35mm

ANDalyze

What looks to be a specifically designed cell to accept their color coded sensors for heavy metal detection using enzyme substrates.



Benefits:

- Simple, one button push for on-site, detection and analysis of heavy metals in water
- No specialized user training
- Less than 2 minutes to test result (from sample to result)
- Highly sensitive and selective
- Test results can be downloaded via USB connection to a computer
- Capability to re-sample quickly
- Reduces time to begin remediation action
- No harmful reagents, environmentally friendly

Features:

- Color Display with Video Functionality
- Push button keypad
- Easily navigated testing and menu
- Long Life Li-Polymer battery, rechargeable through USB connection
- Carrying case provided with each unit
- 1-year Warranty

Specifications:

Dimensions:

Width:	3.6 inches/9.14 cm
Depth:	8.0 inches/ 20.3 cm
Height:	2.25 inches/ 5.72 cm
Weight:	1.25 lb/565 g
IP Rating:	IP54 (water resistant)
Certifications:	CE Marked

Complies with the following European Union Directives:

- Low Voltage Electrical Equipment Directive 2006/95/EC
- Electromagnetic Compatibility (EMC) Directive 2004/108/EC

Pysix

The Pysix SP-900 series portable analyzer combines photometer, PTSA fluorometer, and turbidity meter into a single handheld device.



- Real Time Kinetic Display
- Intuitive Operation
- Designed for Water Treatment Industry
- Price \$1,700

Specifications

Colorimeter Wavelength:	420,525, 560, 570, and 610nm
Turbidity Excitation Wavelength:	White LED
Fluorescence Excitation Wavelength:	365 nm LED
Fluorescence Emission Wavelength:	410 nm
Wavelength Accuracy:	±1 nm
Absorbance Reproducibility:	0.005 au in the range of 0 to 1.0 au (3 sigma)
Absorbance linearity range:	0 to 1.0 au
Turbidity Reproducibility:	2 NTU (3 sigma)
Fluorescence Reproducibility:	1 ppb PTSA (3 sigma)
Fluorescence Detection Limit:	1 ppb
Turbidity Detection Limit:	2 NTU
Battery:	4 AA alkaline
Typical Battery Life:	3 months
Display:	Dot-matrix LCD display, visible in direct sunlight
Dimension:	H265 W88 H69 (mm)
Weight:	600g (without batteries)
Temperature Range:	40 to 106 °F (4 to 41 °C)
Humidity:	85% at 106 °F (41 °C)
Environmental:	IP67, dustproof and waterproof

This instrument is specifically designed to meet an identified group of users.

Thermo Fisher



Key features of the Qubit® 3.0 Fluorometer include:

- Powerful, dual-core processor quickly and accurately quantifies DNA, RNA, and protein, in <5 seconds per sample
- Uses as little as 1 µL of sample
- Stores up to 1,000 sample results
- Large 5.7-inch state-of-the-art color touch screen for easy workflow navigation
- Ability to personalize your Qubit® Fluorometer with the assays you run most, add new assays, or even create your own with MyQubit
- Language of your choice including English, French, Spanish, German, Italian, simplified Chinese, and Japanese



Select assay

Select output

View results

Specifications:

Instrument dimensions	5.4 in (w) x 10 in (l) x 2.2 in (h) (13.6 cm x 25 cm x 5.5 cm)	
Weight	743 g	
Dynamic range	5 orders of magnitude	
Processing time	≤5 seconds/sample	
Light sources	Blue LED (max ~470 nm)	Red LED (max ~635 nm)
Excitation filters	Blue 430–495 nm	Red 600–645 nm
Emission filters	Green 510–580 nm	Red 665–720 nm
Detectors	Photodiodes: measurement capability from 300–1,000 nm	
Warm-up time	<35 seconds	
USB drive	4 GB	
Qubit® 3.0 Fluorometer	\$2,350.00	

Turner Designs

Acknowledged as the market leader in the non-pharmaceutical space (PicoFluor unit acquired in the purchase by Promega and now sold as QuantiFluor). Three handheld models, focused on different applications, makes up their handheld product offering. The three models can be ordered in various configurations with the basic unit prices in the \$1-2.5K range.

AquaFluor: water and environmental including Blue-Green algae:



- Dual channels allow for quick toggling between two applications
- Small size easily fits in shirt or jacket pocket
- Dustproof and watertight for field use, it even floats!
- Single-point plus blank calibration
- 12 bit resolution
- Operates using AAA batteries for >1,000 measurements per set
- 5 second warm up
- Low maintenance field fluorometer

Specifications:

Ammonium	0.1 μM	100 μM^*
CDOM/FDOM	0.1 ppb	0 - 1000 ppb
Chl <i>a</i> Extracted - Acidification	0.5 $\mu\text{g/L}$	0 - 300 $\mu\text{g/L}$
Chl <i>in vivo</i>	0.3 $\mu\text{g/L}$	0 - 300 $\mu\text{g/L}$
Fluorescein Dye	0.4 ppb	0 - 400 ppb
Optical Brighteners	0.5 ppm	0-30,000 ppm
Phycocyanin (Freshwater Cyanobacteria)	150 cells/ml	0-150,000 cells/ml
Phycoerythrin (Marine Cyanobacteria)	150 cells/ml	0-150,000 cells/ml
Rhodamine Dye	0.4 ppb	0 - 400 ppb
Turbidity	0.5 NTU	0 - 1000 NTU
Weight in Air	13.9 oz; 0.4 kg	
Size	1.75" x 3.5" x 7.25"; 4.45 cm x 8.9 cm x 18.4 cm	
Warm-up Time	5 seconds	
Case	IP 67 standard; dustproof/waterproof	
Temperature	41-104°F; 5-40°C	
Power	4 AAA batteries	
Detector	Photodiode 300nm-1,000 nm capable	

Opti-Check: general purpose and industrial:



- Dustproof, watertight, highly durable case
- Small size easily fits in shirt or jacket pocket
- Operates using AAA batteries for >1,000 measurements per set
- Dual channels allow for quick toggling between two applications
- Single-point plus blank calibration
- 12 bit resolution
- 5 second warm up
- Low maintenance field fluorometer

Specifications:

Linear Range	0 to 400 ppb typical for fluorescein 0 to 1000 ppb typical for PTSA
Sensitivity	< 1 ppb typical for fluorescein and PTSA
Power	4 AAA batteries
Light Source	LED
Detector	Photodiode
Weight	13.9 oz; 0.4 kg
Size	1.75" x 3.5" x 7.25"; 4.45 cm x 8.9 cm x 18.4 cm
Warm-up Time	5 seconds
Case	IP 67 standard; dustproof/waterproof
Temperature	41-104°F (5-40°C)

Balast-Check: PAM (Pulse Amplitude Modulated) Fluorometer measures Chlorophyll health.



- Rapid Measurements
 - Algal Activity
 - Algal Abundance
- Portable, Handheld Fluorometer
 - Dustproof, Waterproof
 - Pocket-sized
 - Battery-powered
- Internal Data Logging
 - 1,000 data points can be logged and downloaded
- Low Maintenance
 - Easy Calibration Check

Specifications:

Maximum Range:	100 cells/mL
Sensitivity:	< 10 cells/mL
Temperature:	41° - 104°F (5° - 40°C)
Case: IP 67 standard;	dustproof/waterproof
Power:	4 AAA batteries
Light Source:	LED
Detector:	Photodiode
Weight:	13.9 oz; 0.4 kg
Size:	1.75"x 3.5"x 7.25"; 4.45 cm x 8.9 cm x 18.4 cm
Internal Memory:	1000 data measurements
Data Output:	ASCII

Turner Designs' Handhelds

Turner claims to have sold "20,000 handhelds" but the period over which these sale were achieved is not given. Turner has be around for about 40 years, so this number and the price range fits in with other estimates of handheld revenue of about \$1 -1.5 per year.

Adenosine Triphosphate (ATP) Handheld Luminometers

While not a direct competitor the to a Fluorimeter the Luminomiter is used in the ubiquitous ATP test for HACCP. As stated earlier; ATP testing has been limited in agricultural critical control point testing due to the simple fact that ATP is found in plant cells. Farms and their produce's supply chain to the consumer is increasingly in need of rapid pathogen testing and getting governments attention.

The key ATP test suppliers in the \$10M handheld market were also noted earlier. In this section we will take a closer look at the companies existing products and how they are preparing for the move towards more rapid-micro testing.

Most of the ATP companies offer a range of testing solutions for the food industry. In addition to hygiene testing through ATP assay, microbiological indicator and pathogen testing, they offer tests for food allergies and other possible contaminants.

The luminometers shown here provide a useful set of user requested and tested features, some of which, could be incorporated into a handheld fluorometer.

Note 3M, Celsis and LuminUltra are not reviewed here. Celsis is predominately in the automated space and LuminUltra is relatively new in the market and shows no obvious desire to move in pathogen detection. 3M is a large player in microbiology market mainly through its wide range of convenience or prepackaged media. 3M acquired Biotrace, the original ATP monitoring company and now markets the product line under the Clean-Trace brand.

Hygiena

The only unit on the market that uses the same platform for the ATP testing and indicator organism testing. MicroSnap E. coli is a rapid test for detection and enumeration of E. coli bacteria. The test uses a novel bioluminogenic test reaction that generates light when enzymes that are characteristic of E. coli bacteria react with specialized substrates. The light generating signal is then quantified in the EnSURE luminometer. Results are available in 8 hours or less, depending on the required level of detection. Single figure organisms can be detected in 8 hours, enabling MicroSnap E. coli to give results in the same working day or shift



- Reads standard ATP samples.
- Stores up to 5,000 locations, 200 User ID's and 100 test plans.
- Runs on 2 AA batteries for several months.
- Advanced photodiode is stable and robust.
- No required calibration or yearly maintenance.
- PC compatible via USB.
- Data imported into SureTrend data analysis software.
- Positive control kits available for validation
- AOAC accredited.

The new MicroSnap platform bridges the time gap between ATP and bacterial culture results with convenient, 8-hour or less tests for E. coli, Coliform, Enterobacteriaceae, and TVC.

MicroSnap tests are read by the EnSURE monitoring system and results are recorded with SureTrend software. EnSURE measures both ATP monitoring and organisms tests, enabling food and beverage processors to acquire an accurate status of plant hygiene and product quality during the same working day or shift.

Sampling system, reagents and reading tube are all packaged in a single test are



Indicator test available:

- MicroSnap E. coli
- MicroSnap Coliform
- MicroSnap Enterobacteriaceae
- MicroSnap Total
- MicroSnap Listeria spp.



	Cost Per Test
MicroSnap	\$4.30
Enricher	\$2.58
Ensure	\$1,700.00

Hygiena also offers a simple color change InsSite test for Salmonella.

BioControl



Features:

- Sample plans organize multiple test points as a subset of data and create testing efficiencies
- Re-test verification ensures test points with high ATP readings are re-cleaned and re-tested
- Randomization of test points eliminates testing bias
- Advanced data analysis software enables Quality Assurance managers to efficiently manage their HACCP and hygiene monitoring programs
- Additional probes available for pH, temperature, and conductivity/concentration
- Manual on-site calibration for all parameters satisfies HACCP and GMP requirements that all systems can be calibrated and documented

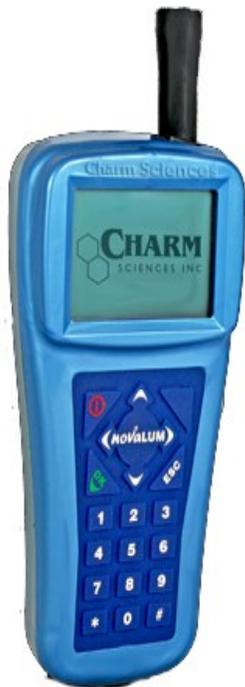
BioControl has a range of rapid-micro test:

- Campylobacter
- Cronobacter
- E. coli O157:H7
- Listeria spp.
- Listeria monocytogenes
- Salmonella
- Shiga Toxin Genes
- Staphylococcal Enterotoxins
- STEC (Shiga Toxigenic E. coli)

All the above assay makes use of a different platform to their ATP test. Many of the tests do not require any instrumentation and rely only on a visual change in the test device.

Charm

The Charm novaLUM ATP detection system luminometer used for:



- ATP sanitation hygiene monitoring with the PocketSwab Plus, FieldSwab, WaterGiene, and AllerGiene
- Pasteurization verification of dairy products with the PasLite and F-AP tests
- Pesticide detection with CideLite
- Sensitive photomultiplier
- Versatile; reads rapid tests for ATP sanitation hygiene monitoring, pasteurization verification, pesticide detection, and undercooked meat detection
- Results in five seconds
- Ergonomic, rugged design
- Patented, open-chamber design; no lids, latches, or doors
- Random sampling
- Fully customizable with novaLINK software

Charm offers its Fast Phage product for rapid-micro pathogen detection. Fast Phage and other rapid-micro assays do not make use of the novaLUM luminometer.

Neogen

Intuitive interface and an easy-to-use format.



- AccuPoint 2 boasts powerful technology, from cutting edge circuitry to the latest in photodiode technology
- RFID technology makes it easy to collect ATP test results. It drastically cuts testing time by allowing the AccuPoint reader to scan and automatically pull appropriate test site information. After initially placing RFID tags, all it takes is a quick scan to instantly associate that tag with related sites
- AccuPoint's Data Manager software provides a better way to interpret test data.
- Establish a performance objective for cleaning and then track results against that objective.
- Automatically sync the reader to the software when it senses a change in the test plan or new test results

Neogen offers Colitag™ for the determination of the presence or absence of total coliforms and E. coli in drinking water, and surface and source water samples. AccuPoint is not required for this test.

Product

Based on the market analysis and the competitive product offering, any product looking to compete needs at the very least to be:

- Robust & reliable, including being water proof.
- Fit in a pocket and be used one handed.
- Minimum user interaction
- Can be safely held/placed/supported for long tests.
- Test timer and/or progress indicator.
- Simple and easy to understand the result: Pass, Warning, Fail
- Unobtrusive calibration and system verification.
- Requires minimum training to use.
- Provide for data logging and uploading of data for record keeping and trending (unspoken here could be 21CFR requirements).
- Offer some WOW differentiation factor that will make it stand out from the crowd.

The importance of integrating the test and the sampling system into a single cohesive package is required, and cannot be stressed enough.

Additionally, advantage should be taken of the familiarity end users now have with commercially available technology. Any product should take advantage of converging technologies. Technologies that potentially could be called into play include, outside of those already being incorporated (LED, battery, microprocessors, displays etc.):

- Web and cloud interoperability
- Wifi, Bluetooth, USB
- Inductive, solar charging
- RFID, bar code
- Smart phones, tablets, E Readers

SWOT Analysis

The SWOT analysis for the Food & Beverage market segment is presented below along with SWOT for an EnZquik Replacement unit. Both SWOT analysis are from an Accustrata view point.

Food & Beverage Market Segment.

Accustrata	Favorable	Unfavorable
Internal	<ul style="list-style-type: none"> • Partner exists (EnZtek) • Partner has experience in market • Partner has proprietary IP • Clean slate – no legacy products • No sales to cannibalize 	<ul style="list-style-type: none"> • Partner's resources are limited • No Fluorometer applicable IP • Unknown resource availability
	Strengths	Weaknesses
External	<ul style="list-style-type: none"> • Increase need for reliable rapid-micro testing: <ul style="list-style-type: none"> • Public awareness – food safety • Fresh produce growth • Time to market & production costs • New regulations for fresh produce about to come into effect • New user segment developing • Converging technology offers potential design solutions 	<ul style="list-style-type: none"> • Established Brands ability to leverage existing market position. • Too many new rapid-micro test being introduced • Conservative nature of customers • Considerable price pressure on testing • Customer acquisition cost are high
	Opportunities	Threats

Q) Is there a Market Opportunity for Accustrata?

A) Yes, but:

1. For any significant capture of market share Accustrata, in partnership with EnZtek, needs to be innovative in their product offering and bring a differentiated product to market, that has some WOW factor.
2. The product should be aimed at a user with a non scientific background and should be robust in both physical design and usage (eliminate potential errors).
3. The product should simplify: Sample handling, result decision making, record keeping and necessary testing verification requirements.
4. The Fluorometer should not be financial barrier to testing.

Such a product could look to access the new markets opening up and take a share of the existing ATP HACCP market. It would also be well positioned, with customization, to find applications in other environmental markets.

An innovative product concept could address a potential \$ 50-75M market. Without the concept it is difficult to estimate market size and % share available.

EnZquik Replacement Fluorometer (EQRF): Food Safety & Environmental Testing

Accustrata	Favorable	Unfavorable
Internal	<ul style="list-style-type: none"> • Prototype sensor designed • Partner exists for Interface and housing. • Partner for production identified 	<ul style="list-style-type: none"> • No defined product specifications • Limited immediate volume identified ~200 units/year • No Fluorometer applicable IP • Limited resources compromises design
	Strengths	Weaknesses
External	<ul style="list-style-type: none"> • Converging technology offers potential design solutions 	<ul style="list-style-type: none"> • TM <\$4, potential TAV< \$2M • Established market leader (Turner) • New low cost entrant (AmiScience) • Market price elasticity limited (\$1,000-\$1,500) • Limited small volume customers base • No identified continuing revenue stream
	Opportunities	Threats

Q) Is there a Market Opportunity for Accustrata?

A) No.

1. Total Available market is small 200-2,000 units/year. The table below shows the cost of goods at various sales prices and achieved margins

EQRF COGS & Potential Margin Analysis														
Market Price	\$500	Profit	\$750	Profit	\$1,000	Profit	\$1,250	Profit	\$1,500	Profit	\$1,750	Profit	\$2,000	Profit
OEM 30% Discount	\$350	\$150	\$525	\$225	\$700	\$300	\$875	\$375	\$1,050	\$450	\$1,225	\$525	\$1,400	\$600
Cost (20% Margin)	\$280	\$70	\$420	\$105	\$560	\$140	\$700	\$175	\$840	\$210	\$980	\$245	\$1,120	\$280
Cost (25% Margin)	\$263	\$88	\$394	\$131	\$525	\$175	\$656	\$219	\$788	\$263	\$919	\$306	\$1,050	\$350
Cost (30% Margin)	\$245	\$105	\$368	\$158	\$490	\$210	\$613	\$263	\$735	\$315	\$858	\$368	\$980	\$420
Cost (35% Margin)	\$228	\$123	\$341	\$184	\$455	\$245	\$569	\$306	\$683	\$368	\$796	\$429	\$910	\$490
Cost (40% Margin)	\$210	\$140	\$315	\$210	\$420	\$280	\$525	\$350	\$630	\$420	\$735	\$490	\$840	\$560
Cost (45% Margin)	\$193	\$158	\$289	\$236	\$385	\$315	\$481	\$394	\$578	\$473	\$674	\$551	\$770	\$630
Cost (50% Margin)	\$175	\$175	\$263	\$263	\$350	\$350	\$438	\$438	\$525	\$525	\$613	\$613	\$700	\$700
Cost (55% Margin)	\$158	\$193	\$236	\$289	\$315	\$385	\$394	\$481	\$473	\$578	\$551	\$674	\$630	\$770
Cost (60% Margin)	\$140	\$210	\$210	\$315	\$280	\$420	\$350	\$525	\$420	\$630	\$490	\$735	\$560	\$840
Cost (65% Margin)	\$123	\$228	\$184	\$341	\$245	\$455	\$306	\$569	\$368	\$683	\$429	\$796	\$490	\$910
Cost (70% Margin)	\$105	\$245	\$158	\$368	\$210	\$490	\$263	\$613	\$315	\$735	\$368	\$858	\$420	\$980
Cost (75% Margin)	\$88	\$263	\$131	\$394	\$175	\$525	\$219	\$656	\$263	\$788	\$306	\$919	\$350	\$1,050

Best case (50% margin at a market price of \$2,000, for 2000 units) provides a total of \$700 gross profit per unit or \$1.4M of revenue. (Put the EQRF on par with Turner's estimated business for Handheld)

Most Probable (40% margin at a market price of \$1,500, for 800 units) provides a total of \$420 gross profit per unit or \$336K of revenue.

Customers/Channel Partners

There is very little demand for the larger sample volume handheld Fluorometer units outside of academia and research. Sales would need to be through lab suppliers, or OEM channels. Individual customer acquisition cost will be high and a significant discount (30%) would need to be offered to distributor.

In trying to quantify the market the existing distributors were of little help and generally unwilling to provide sales data. Those that were willing to provide some input made statements like "Much less than you would think" (Beagle Bioscience), or have quantified it as a "handful" (Bioassay Systems). Sigma Aldrich, who recently started selling the AmiScience unit under the FluoroSelect (Fluka) brand, is currently "underwhelmed". This could of course change, but they are not prepared to look at other suppliers until they have a better idea of demand.

Channel partners will be the main customers as this most certainly will be an OEM play, if any, with the fluorometer/colorimeter/luminometer needing to be tailored to the assay and the chemistry in use.

In addition to partners like EnZtek, current ATP test providers could be viable partners along with ELISA reagent producers looking to enter into the new emerging markets.

Other channel partners could be found within the water quality segment in the form of Hach, LaMotte, Taylor Diagnostics and others. Of course an innovative and successful EnZtek product would lead to sales, to some of the above, through EnZtek itself.

Providing 10 defined customers' specifications for a replacement EnZtek is problematic as basically the customer for such a unit would be the existing AmiScience and Turner Diagnostics customer base. The specifications for the customer needs to match or be better than the product currently offered for the application. These specifications are shown in the earlier section showing the Turner and AmiScience products. Below is a list of the 10 largest customers (evaluated by web presence) with their application segment(sorted alphabetically).

Company	Application
AquaPhoenix Scientific	Water
Beagle Bioproducts	BGA
Bioassay Systems	Biotech
Biocompare	Biotech
Biotium	Biotech
Cole Parmer	All
EquipCo	All
Sigma Aldrich	Biotech
Topac	Biotech
VWR	All

Summary & Conclusions

There exist a niche opportunity in the fresh Produce food chain with regard to pathogen and indicator organism detection, brought about by pending regulation. However, to take advantage of this opportunity, and leverage the product into adjacent spaces, there needs to be substantially more innovation in the product than simply producing a better EnZquik Replacement Fluorometer (EQRf).

Pursuing an EQRf, in the authors opinion, does not provide a good ROI for Accustrata as an

independent entity. The cost of customer acquisition is too high. In providing EnZtek a product every effort should be made to keep the cost low and meet only the basic needs. A low cost product would be attractive to some of AmiSciences and Turner Designs existing customers. A list of the top 10 customers is provided.

Pursuing the market opportunity with an innovative concept has some merit, but if a potentially viable concept cannot be quickly conceived, then again the author recommends against investing heavily in the opportunity.

Note: The Food Safety Summit is taking place in Baltimore April 28-30, 2015

Additional Market Growth & Opportunities

Food & Beverage

- Farm Produce
- Dairy
- Poultry & egg
- Ready to eat sandwiches etc.
- Food bars, trucks and restaurants
- Grocery perishable and fresh food

Environmental

- Ballast Water
- Drinking Water
- HAB (Harmful Algal Blooms)

Medical & Personal Care

- Clinic & Hospital janitorial services
- Medical device cleaning (endoscopes etc.)

Consumer

- Home Cleanliness (immune compromised)
- Pool & Spa monitoring (colorimeter version)
- Well water

Third World

i) Food Micro, Eight Edition—Microbiology Testing in the Global - Food Industry, June 2013, Strategic Consulting, Inc.

ii) BCC Research Report Spectroscopy (IAS004D) published in May 2010

iii) Global Assessment Report, 10th Edition: The Laboratory Life Science and Analytical Instrument Industry, September 2008 - Strategic Directions International, Inc.

iv) Jenie Marlind (3M ClearTrace), Lauren Roady (Hygiena)