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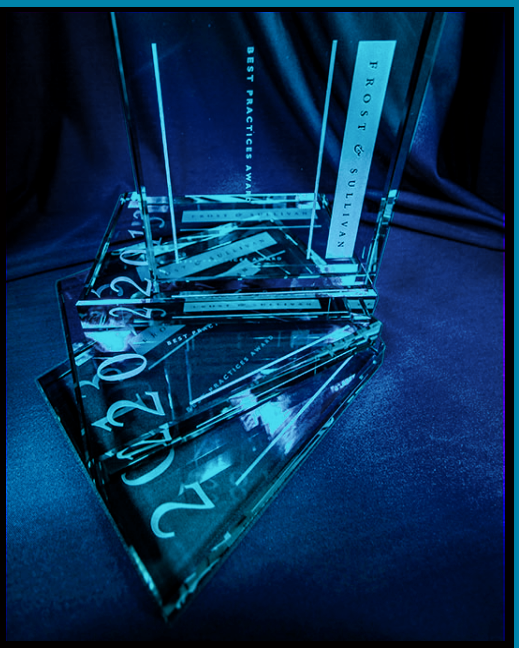
Cell Science Systems

2016 North American Food Intolerance Testing Company of the Year Award



FROST & SULLIVAN

2016 BEST PRACTICES AWARD

NORTH AMERICAN FOOD INTOLERANCE TESTING COMPANY OF THE YEAR AWARD

2016 BEST PRACTICES AWARDS

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Background and Company Performance

Industry Challenges

Food intolerance and allergies are no longer a rare occurrence but a growing epidemic in the United States that is making people rethink their eating habits. There is growing evidence that food sensitivities are more common and have a wider and more varied impact on health than was previously known. Unlike food allergies, food sensitivities are toxic reactions to certain foods, which do not involve the specific immune system responses and are often more difficult to diagnose. Food sensitivities cause immense stress, both physical and mental, with symptoms ranging from vomiting and diarrhea to migraines and eating disorders. With growing evidence that the food consumed is one of the main reasons for the growing incidence of chronic diseases such as neurological disorders, cardiovascular diseases, and rheumatoid arthritis, there is now a stronger emphasis on the need to understand one's body. While there has been an upsurge of tests offered by several labs both large and small as well as direct-to-consumer tests to understand food sensitivities, many companies still do not focus strongly on the food intolerance market and often prioritize other high-revenue-generating markets.

Very few companies are committed to understanding food intolerance, as this is the first step toward preventative care. Some of the key needs in this space are as follows:

Personalized Testing

The goal of the healthcare system in the US is personalization. With an increasing number of studies suggesting that health can be improved and maintained by knowing how food plays a role in one's body, identifying the food and chemical substances that may trigger unwanted inflammation has become necessary to prevent chronic diseases. A test that can enable the identification of a range of such substances in a cost-effective manner is expected to make a significant impact in this market.

Need for a Better Program

Currently, the only course of action to establish a link between foods and inflammation in our bodies is through arduous exacting and time consuming elimination and challenge dietary process to establish a connection; or, guesswork. In either case, the process of identification is laborious and difficult for both patients and clinicians.

Accurate and Actionable Data

Many of the direct-to-consumer tests use different methodologies for testing food intolerance and sensitivity. While some use serological assays for measurement of allergen specific IgG antibodies, others, such as the Alcat Test®, study white blood cells and inflammation using blood samples. Methodology exerts great influence on the clinical relevance of the test findings and also has an impact on the speed at which easily interpretable and actionable data can be obtained.

Commitment to Cause

Expertise in food sensitivity testing and providing actionable consulting services is rare in this space, as many companies seek to expand their portfolios into more lucrative markets such as inflammatory bowel disease (IBD) and other chronic diseases.

Visionary Innovation and Performance and Customer Impact

Cell Science Systems, Corporation (CSS) is a private company that, along with its affiliates, has been a market leader in the food intolerance space for the past 20 plus years. Introducing the Alcat Test, a cellular test for foods, chemicals molds, functional foods, additives and drugs, CSS has gained a strong foothold in the market for food sensitivity testing solutions. With strong collaborations with research institutions such as the Yale School of Medicine and a large customer base, CSS has constantly been involved in research efforts in the fields of food and chemical intolerance by collaborating with academic researchers to look at clinical reactions to foods in patients with IBS and several other conditions in order to detect possible correlation patterns and to progress the understanding of inflammation triggers and the disease processes that they can promote. The Alcat Test is the gold standard for food intolerance and also aids researchers in biomarker identification.

Criterion 1: Addressing Unmet Needs

CSS is one of the few companies focusing on curbing food habits that eventually lead to chronic diseases. The following is an account of how CSS has come to be viewed as the leader in this space for more than 20 years:

Personalization of Tests

"Our daughter has been taking Ritalin and Paxil for over 5 years to deal with hyperactivity/ADHD as well as other health, concentration and academic issues. The Alcat Test identified numerous foods that we needed to eliminate-such as beef, lemon, grapes and apples. Once we eliminated these foods, we saw a dramatic change with our daughter. Within 24 hours she was much calmer. We slowly weened her off Paxil and Ritalin, and now she is TOTALLY off of these drugs for more than 2 months. The new diet has done wonders"

–Customer of Cell Science Systems

These are just one of the many instances where CSS's Alcat Test has changed the lives of individuals. It tests for more than 450 different food and chemical substances, offering robust personalization options. Competing testing solutions have a less robust menu. Most significantly, however, is that the Alcat Test is the only technology in this field to have been clinically validated by rigorous independent studies. CSS is also the only company in this space to also be a US FDA registered medical device manufacturer that also voluntarily maintains ISO EN 13485 certification, and is fully vertically integrated; from

instrument manufacture to test reagent production, under cGMP standards, to providing expert test results consultations This makes the Alcat Test the gold standard, with many physicians recommending it; and, puts it in good stead for when the FDA begins to regulate LDT's (Lab Developed Tests) as they currently do with medical devices.

Clinically Validated Methodology

The Alcat Test is the only known test currently being used to have been independently validated through rigorous randomized placebo controlled clinical trials and lab-based technical studies, that can definitively help clinicians advocate healthy eating to ameliorate or even prevent chronic illnesses. The Alcat Test provides a cost-effective alternative to the archaic method of guessing and trial and error in identifying possible pathogens. CSS enables "in-vitro" testing that identifies changes in blood cell sizes by using a blood sample. The white blood cells are incubated with the purified food extracts, or other test substances (after the lysis or mechanical removal of red blood cells, using a gradient separation technique) using the impedance method of particle sizing and counting. The impedance method is considered the international standard for physio-chemical particle evaluation. A proprietary algorithm enables statistical comparison of a patient's normal cell (control) profile with post-incubation (test) samples.

The evaluation of a cellular response in this manner offers the advantage of being non-mechanism dependent. The change in innate immune cell structure, as measured through this technique, has been shown by research at Yale School of Medicine, to be associated with degranulation and correlated with known, mainstream immunological inflammatory pathways. This information is attainable, cost effectively, through a simple blood draw; and, reflects a final common pathway of the various pathogenic mechanisms associated with non IgE mediated adverse reactions to foods and chemicals. As the awareness of the existence of such a validated methodology for assessing patient specific individual triggers of inflammation is increased, it is likely that many more mainstream health care providers will adopt its usage.

No single immune factor, antibody or cytokine has; or, likely will, be identified as being THE biomarker of food sensitivity. Hence, the Alcat Test in vitro method, which measures the final common pathway of multiple mechanisms through direct measurement of the innate immune cells in a model that most reflects natural exposure to the test substance, is unlikely to be supplanted by any other assay that currently exists or that will be developed in the future.

Accuracy of Test

Since the first commercialization of the test in the late 1980's CSS has collaborated with a number of academic institutions and clinics that have independently assessed and validated the technical and clinical utility of the Alcat Test. Randomized and controlled trials, as well as retrospective assessment of clinical outcomes have repeatedly demonstrated test efficacy.

The assessment of a test for adverse reactions to foods must be adequately controlled for the Hawthorne and any other non-specific effect. Such a trial has been conducted at Yale School of Medicine and has reported a statistically significant improvement of symptom scores associated with IBS patients following an Alcat Test-based diet vs. a control (or sham/placebo) diet. No competing test has achieved such validation. A recent randomized placebo controlled trial conducted at Northern Illinois University reported significant improvement in body composition, pre and post measurement in levels of serum amyloid A (a reliable marker of acute phase total body inflammation) and, medical symptoms scores, vs. controls. Studies from the Univ. of Pavia, one of the oldest teaching hospitals in the world, share findings of significant improvement in dermatologic and gastrointestinal disorders. A randomized controlled study at Baylor Medical College, Sports Medicine and Performance Institute, found significant improvement in body composition, scale weight and medical symptoms associated with chronic inflammation vs. controls following a calorie restriction regimen.

Test efficiency, the measurement of sensitivity and specificity, can only be assessed by comparison with the standard of a double-blinded oral challenge test here, independent studies have demonstrated a high correlation with double-blinded food challenges (83.4%) and a placebo controlled trial demonstrated a 96% correlation with double-blinded challenges with food additives. As an aggregate, these studies underscore an important distinguisher between the Alcat test and competitive tests, such as IgG antibody tests. The former produces a specific effect whereas IgG are not distinguishable from placebo effects.

In addition to these and other controlled studies, numerous anecdotal medical and personal reports have reported on the utility of the test in resolving complex health conditions and improving general health in individuals that have failed other treatments; or, have sought enhanced wellbeing and improved performance. Many testimonials have come from professional athletes, world class celebrities as well as ordinary people, of all walks of life, age groups, nationalities and conditions.

Criterion 2: Customer Purchase Experience

"I want to take a moment and tell you how pleased I am that I had the Alcat Test done."– Customer of CSS

Customers not only find CSS's tests life-changing but also praise its consulting and support services that facilitate health improvements based on quantitatively depicted actionable data and valuable advice. As competitors only tend to focus on test results and not the transferability of the data to the patient, many customers complain of feeling overwhelmed and lost with the huge volume of information provided at a single time. CSS ensures that its results are color-coded and presented in an easy-to-understand format. The company also provides consulting services in collaboration with physicians and nutritionists.

Criterion 3: Visionary

With the success of its flagship product, CSS is expanding its portfolio in bowel disorders such as Celiac, Irritable Bowel Syndrome (IBS), and Crohn's Array with its CICA (Celiac, IBS, Chrohns' disease ARRAY). It is also strengthening its profile for chronic diseases with its MethylDetox (assaying genetic risk for compromised methylation and detoxification) product that helps customers understand their genetics constitutions and address health issues by changing their diets and nutrition intake accordingly. Another product in its portfolio looks at telomere length which is associated with the risk of age-related disorders such as rheumatoid arthritis and cardiovascular and metabolic disorders. CSS also has a functional micronutrient assay, and other assays, under development. CSS has also joined the bandwagon of direct-to-consumer testing solutions by partnering with providers such as labtestsonline.com and Walk-in labs who cater directly to customers. CSS's products are also available on the company's own Web site, cellsciencesystems.com, which links to its sister company, PreviMedica, who offers one on one counseling with registered Dietitians.

In addition, CSS is planning the release of a new analyzer that will enable the company to license other users of the test worldwide. CSS already has CE certificate for free sale of its current analyzer and reagents in the EU, as well as Ministry of Health approval in several countries. CSS also operates as a wholly owned subsidiary in Germany that offers testing to customers in Europe and the Middle East.

Criterion 4: Financial Performance and Quality of Care

Besides a specialty clinical laboratory that develops and performs laboratory testing in immunology, cell biology, and molecular diagnostics (focusing on personalized treatment and prevention of chronic diseases), CSS operates a laboratory certified by the Clinical Laboratory Improvement Amendments (CLIA). The company meets FDA and Current Good Manufacturing Practice (cGMP) regulations and ensures compliance with ISO EN13485 standards, which underscores its adherence to the highest quality control standards.

Conclusion

The robust portfolio of Cell Science Systems Corp. offers a lot more than a testing solution. This is a company that genuinely cares about chronic disease epidemics such as obesity and diabetes in the US and strives to curb their growing incidence by helping individuals eat healthy. Through its advanced testing solutions, CSS provides valuable advice and quantitative data that aid customers in changing their food habits, enabling them to lead healthier, happier lives.

With its strong overall performance, Cell Science Systems Corp. has earned Frost & Sullivan's 2016 Company of the Year Award.

Significance of Company of the Year

The Company of the Year award requires the recipient company to demonstrate excellence in growth, innovation, and leadership. This kind of excellence typically translates into superior performance in three key areas: demand generation, brand development, and competitive positioning. These areas serve as the foundation of a company's future success and prepare it to deliver on the two criteria that define the Company of the Year Award (Visionary Innovation & Performance and Customer Impact).

Understanding Company of the Year

As discussed above, driving demand, brand strength, and competitive differentiation all play a critical role in delivering unique value to customers. This three-fold focus, however, must ideally be complemented by an equally rigorous focus on visionary innovation to enhance customer value and impact.

Key Benchmarking Criteria

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated two key factors—Visionary Innovation & Performance and Customer Impact—according to the criteria identified below.

Visionary Innovation & Performance

Criterion 1: Addressing Unmet Needs
Criterion 2: Visionary Scenarios through Mega Trends
Criterion 3: Implementation Best Practices
Criterion 4: Blue Ocean Strategy
Criterion 5: Financial Performance

Customer Impact

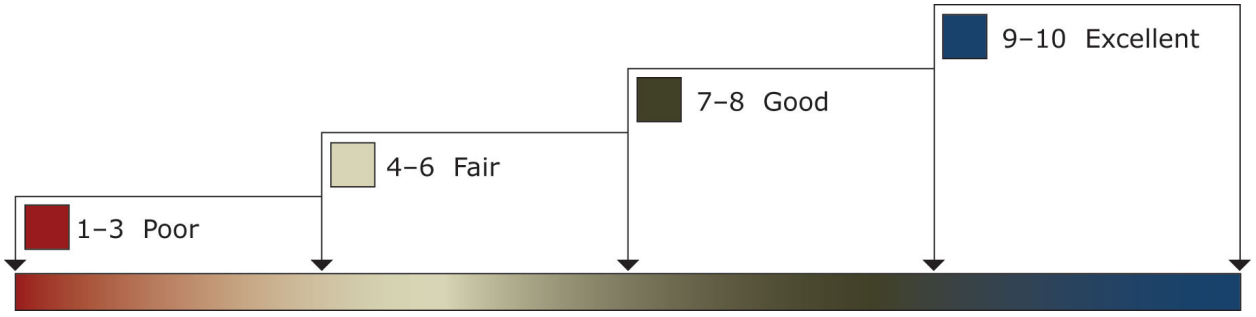
Criterion 1: Price/Performance Value
Criterion 2: Customer Purchase Experience
Criterion 3: Customer Ownership Experience
Criterion 4: Customer Service Experience
Criterion 5: Brand Equity

Best Practice Award Analysis for Cell Science Systems

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are illustrated below.

RATINGS GUIDELINES



The Decision Support Scorecard is organized by Visionary Innovation & Performance and Customer Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, we have chosen to refer to the other key players as Competitor 2 and Competitor 3.

DECISION SUPPORT SCORECARD FOR COMPANY OF THE YEAR AWARD

Measurement of 1–10 (1 = poor; 10 = excellent)			
Company of the Year	Visionary Innovation & Performance	Customer Impact	**Average Rating**
Cell Science Systems	**9.0**	**10.0**	**9.5**
Competitor 2	8.0	8.0	8.0
Competitor 3	7.0	8.0	7.5

Visionary Innovation & Performance

Criterion 1: Addressing Unmet Needs
Requirement: Implementing a robust process to continuously unearth customers' unmet or under-served needs, and creating the products or solutions to address them effectively

Criterion 2: Visionary Scenarios through Mega Trends
Requirement: Incorporating long-range, macro-level scenarios into the innovation strategy, thereby enabling "first to market" growth opportunities solutions

Criterion 4: Implementation of Best Practices
Requirement: Best-in-class strategy implementation characterized by processes, tools, or activities that generate a consistent and repeatable level of success.

Criterion 3: Blue Ocean Strategy
Requirement: Strategic focus in creating a leadership position in a potentially "uncontested" market space, manifested by stiff barriers to entry for competitors

Criterion 5: Financial Performance
Requirement: Strong overall business performance in terms of revenues, revenue growth, operating margin and other key financial metrics

Customer Impact

Criterion 1: Price/Performance Value
Requirement: Products or services offer the best value for the price, compared to similar offerings in the market

Criterion 2: Customer Purchase Experience
Requirement: Customers feel like they are buying the most optimal solution that addresses both their unique needs and their unique constraints

Criterion 3: Customer Ownership Experience
Requirement: Customers are proud to own the company's product or service, and have a positive experience throughout the life of the product or service

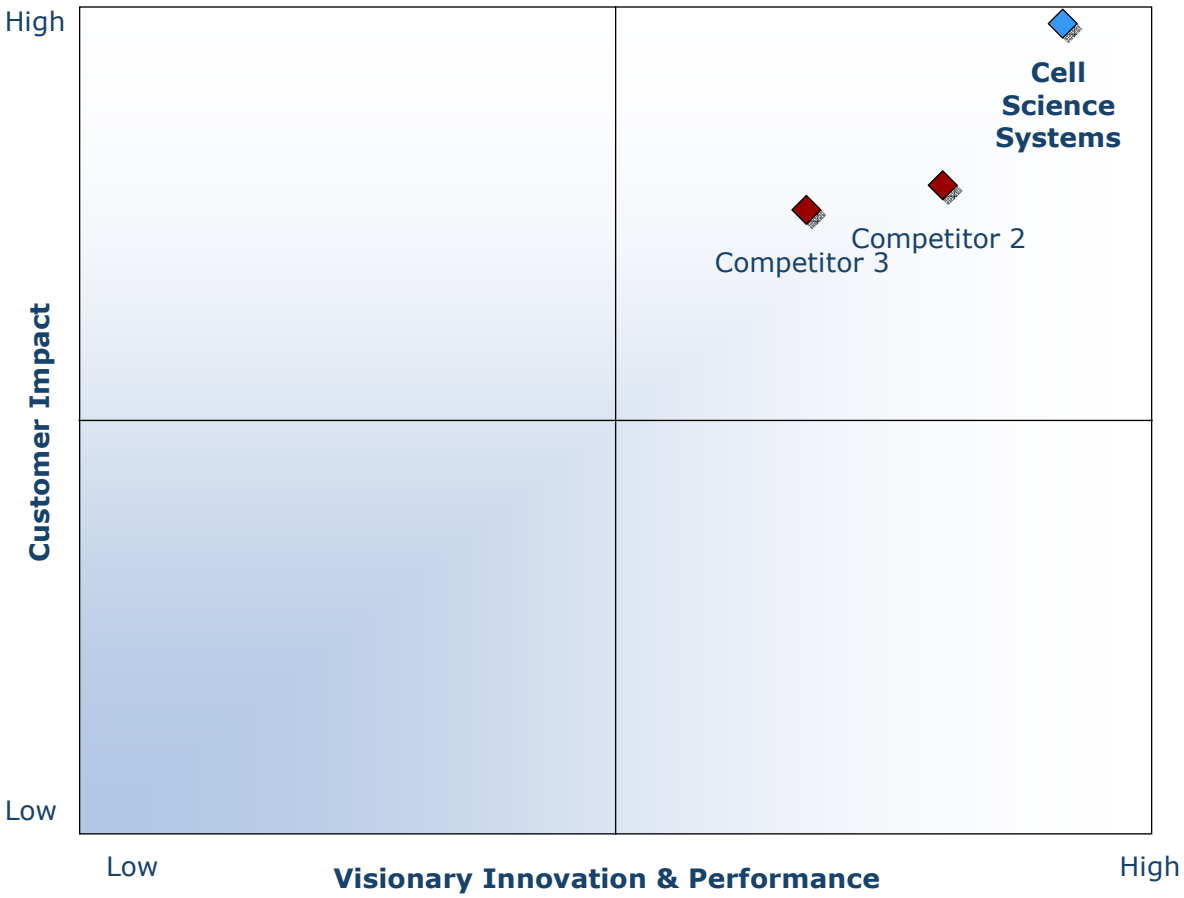
Criterion 4: Customer Service Experience
Requirement: Customer service is accessible, fast, stress-free, and of high quality

Criterion 5: Brand Equity
Requirement: Customers have a positive view of the brand and exhibit high brand loyalty

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts can then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.

DECISION SUPPORT MATRIX FOR COMPANY OF THE YEAR AWARD



The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan Awards follow a 10-step process to evaluate award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

	STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1	**Monitor, target, and screen**	Identify award recipient candidates from around the globe	• Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies	Pipeline of candidates who potentially meet all best-practice criteria
2	**Perform 360-degree research**	Perform comprehensive, 360-degree research on all candidates in the pipeline	• Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates	Matrix positioning all candidates' performance relative to one another
3	**Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps	Detailed profiles of all ranked candidates
4	**Initiate research director review**	Conduct an unbiased evaluation of all candidate profiles	• Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles	Final prioritization of all eligible candidates and companion best-practice positioning paper
5	**Assemble panel of industry experts**	Present findings to an expert panel of industry thought leaders	• Share findings • Strengthen cases for candidate eligibility • Prioritize candidates	Refined list of prioritized award candidates
6	**Conduct global industry review**	Build consensus on award candidates' eligibility	• Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates	Final list of eligible award candidates, representing success stories worldwide
7	**Perform quality check**	Develop official award consideration materials	• Perform final performance benchmarking activities • Write nominations • Perform quality review	High-quality, accurate, and creative presentation of nominees' successes
8	**Reconnect with panel of industry experts**	Finalize the selection of the best-practice award recipient	• Review analysis with panel • Build consensus • Select winner	Decision on which company performs best against all best-practice criteria
9	**Communicate recognition**	Inform award recipient of award recognition	• Present award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance	Announcement of award and plan for how recipient can use the award to enhance the brand
10	**Take strategic action**	Upon licensing, company may share award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess award's role in future strategic planning	Widespread awareness of recipient's award status among investors, media personnel, and employees

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