

F R O S T & S U L L I V A N

# BEST PRACTICES

## AWARDS

F R O S T & S U L L I V A N

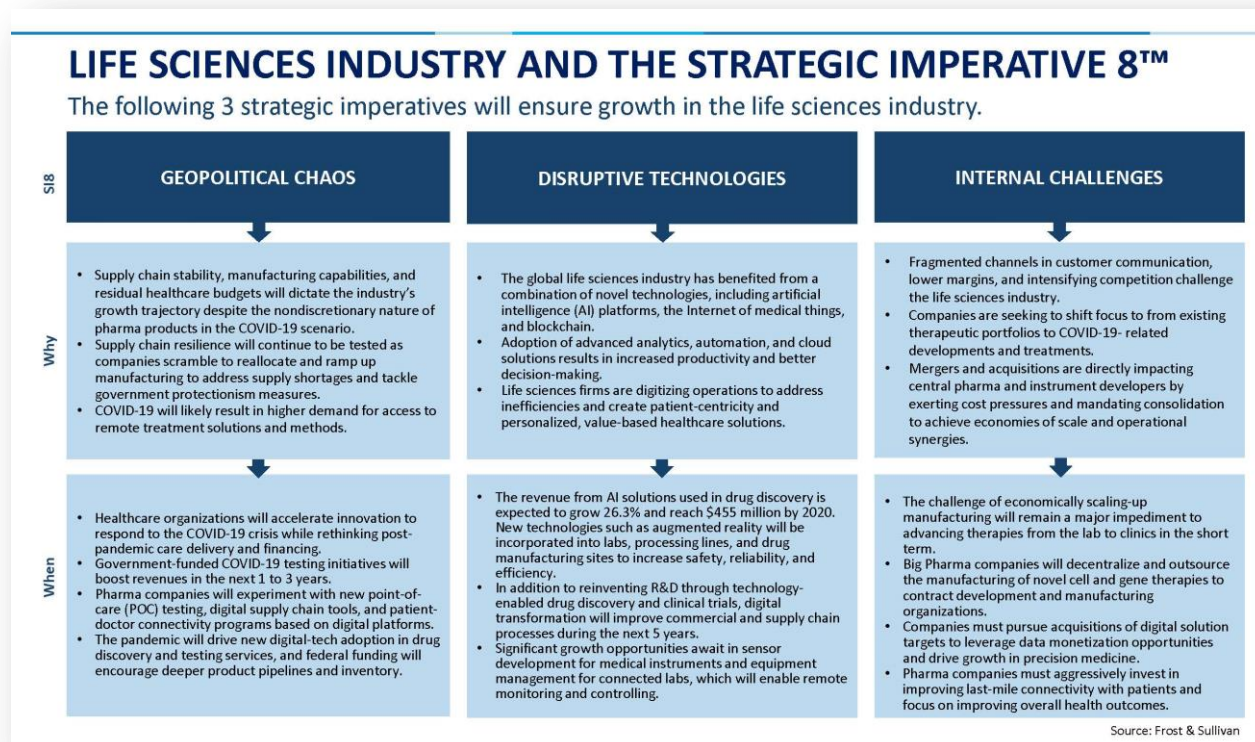
BEST  
2020 PRACTICES  
AWARD

 R E A G E N A  
*Visible Difference*

**2020 EUROPEAN ZOONOTIC  
POINT-OF-CARE DIAGNOSTICS  
COMPANY OF THE YEAR AWARD**

## Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the life sciences industry: geopolitical chaos, disruptive technologies, and internal challenges. Every company that is competing in the life sciences space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan's recognition of Reagent is a reflection of how well it is performing against the backdrop of these imperatives.



## Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each Award category before determining the final Award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated companies. Reagent excels in many of the criteria in the zoonotic point-of-care diagnostics space.

# AWARD CRITERIA

| <i>Visionary Innovation &amp; Performance</i> | <i>Customer Impact</i>        |
|---|-------------------------------|
| Addressing Unmet Needs                        | Price/Performance Value       |
| Visionary Scenarios Through Mega Trends       | Customer Purchase Experience  |
| Implementation of Best Practices              | Customer Ownership Experience |
| Leadership Focus                              | Customer Service Experience   |
| Financial Performance                         | Brand Equity                  |

## *Infectious Disease Point-of-care Testing: Snapshot*

According to the World Health Organization, zoonotic diseases, also known as zoonoses, constitute a significant portion of existing and newly transmitted infections to humans, including rabies, Lyme disease, influenza, dengue, and emerging coronaviruses.<sup>1</sup> Animals can transfer infectious pathogenic microorganisms, e.g., bacteria, viruses, parasites, and fungi, to other animals and people (sometimes mutating into human-only strains), causing illnesses.

Point-of-care testing (POCT), in particular, is evolving into the preferred testing mode. Timely pathogen detection and identification, proper therapy determination, treatment response monitoring, prognosis assessment, and Integrated Disease Surveillance and Response implementation upend the prevailing empiric antibody treatment paradigm. While saving many lives and substantially decreasing mortality rates over the last several decades, Frost & Sullivan points out that hypothesis-based therapies are at odds with value-driven, patient-centric care, typically using broad-spectrum antibiotics with no longer sustainable trade-offs.

With a spectrum of socio-economic disruptions, the notorious COVID-19 epidemic abruptly introduced the world to the need for affordable, rapid, accurate, and easy-to-use POCT for practical infectious diseases clinical management and control - whether tending to an individual patient or responding to a worldwide pandemic. Frost & Sullivan estimates the global infectious disease POCT market at nearly \$2.4 billion in 2020, growing at a compound annual growth rate of 27.3% from 2019 to 2024.<sup>2</sup>

A high-growth ecosystem boosted further by the high global economic burden, Frost & Sullivan notes that POCT offers lucrative opportunities for vendors increasing availability and access to more patient-centric and cost-effective systems against infectious diseases. Highly competitive, and with large multinationals dominating the market, Frost & Sullivan concludes that smaller participants must explore

<sup>1</sup> <https://www.who.int/zoonoses/diseases/en/>

<sup>2</sup> *Smartphone-based Solutions Spur the Global Infectious Disease Point-of-Care Testing Market, Forecast to 2024* (Frost & Sullivan, September 2020)

growth avenues through innovation, converging technologies, and novel business models using technology as building blocks to capture market share.

### ***The Zoonoses Specialist***

Founded in 1987, Finland-based Oy Reagentia Ltd (Reagentia) is a trusted, well-known, and established innovator specializing in point-of-care diagnostics for zoonotic diseases. Reagentia's product portfolio includes enzyme immunoassay (EIA) tests and the new ReaScan®+ diagnostic system including POC rapid tests.

Committed to high-quality products and solutions since inception, the company conforms to strict international quality and medical device standards, such as Quality Management System ISO 9001:2015 and ISO 13485:2016, completing continuous regulatory audits successfully over the decades. Reagentia's 2001 in vitro diagnostic (IVD) CE-marking for its ReaScan® rapid testing system marked an inflection point, fueling its pioneering innovation journey.

*"Reagentia's mission is to provide high-value solutions to healthcare customers. For instance, when it comes to the CXCL13 rapid test, it is not just a better product to replace other products, but it actually changes the patient pathway for improved outcomes."*

*-Anu Mickels, Chief Executive Officer, Oy Reagentia Ltd*

Beyond its high-quality diagnostic product portfolio, the company also offers liquid-based solutions, EIA reagents, and contract development and manufacturing services to the life sciences industry. Reagentia operates globally through strategic distribution partners, delivering over 500 products across more than 20 countries.

### ***Pioneering Leadership: Visible Difference***

Reagentia's new ReaScan®+ diagnostic system serves unmet clinical needs in infectious disease diagnostics. The company focuses on high-need and high-cost niche segments, working closely with academic universities and hospitals to bring high value to the marketplace through innovative POC solutions.

Powered by its ReaScan+ technology, and purposefully designed for POC applications, the automated system delivers reliable qualitative (detect) and quantitative (quantify) results in less than 20 minutes. Reported numerically on the readers' screen, clinicians can compare test values within seconds against stated threshold values. Effective, i.e., high sensitivity and specificity, and consistent, with a variation coefficient of less than 10%, the ReaScan®+ product line enables objective, swift, and confident clinical decision-making at the POC.

In line with its motto, "Visible Difference," Reagentia offers high value-added POCT to healthcare customers. It pioneered POC rapid immunoglobulin IgM diagnostic tests for Hantavirus, 2001, and tick-borne encephalitis (TBE), 2014, well-known diseases in Europe. Previously under-diagnosed and under-

treated, these conditions compounded the staggering infectious disease public health burden beyond morbidity and mortality.

*“Reagent’s ReaScan®+ diagnostic system serves unmet clinical needs in infectious disease diagnostics. The company focuses on high-need and high-cost niche segments, working closely with academic universities and hospitals to bring high value to the marketplace through innovative POC solutions.”*

**- Norma Vela-Roch, Best Practices Research Analyst**

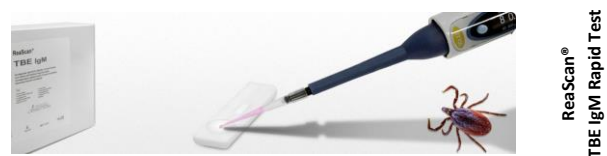
In another industry-first, the company launched the ReaScan®CXCL13 rapid test for Lyme neuroborreliosis (LNB) in 2017. Also known as neurological Lyme disease, it is the most dangerous Lyme disease manifestation. Remarkably, the unique POC test detects elevated chemokine CXCL13 levels in cerebrospinal fluid (CSF), helping clinical treatment decisions in patients suspected with LNB.

Neurological Lyme disease occurs in 10% to 15% of infected individuals with causative agents varying depending on geography, e.g., *Borrelia burgdorferi*, in the United States (US), *Borrelia afzelii*, in the European Union (EU), and *Borrelia garinii*, in Asia.<sup>3</sup>

In the EU, LNB is one of the leading bacterial infections affecting the human nervous system. It is an acute tick-borne inflammatory condition with painful clinical manifestations, e.g., meningo-radiculitis, meningitis, peripheral facial palsy, and life-limiting sequela, e.g., pain, fatigue, and cognitive impairments. The European Commission recently added LNB to its communicable disease surveillance list. LNB’s public health burden continues to grow quite substantially, with incidence and prevalence severely underestimated due to testing performance limitations and subsequently delayed treatment at best and non-treatment at worst.

Notwithstanding, most patients reportedly respond to antibiotic therapy within four weeks of infection.<sup>4</sup> Economical, accessible, fast, and with a user-friendly format, Frost & Sullivan believes that Reagent’s Chemokine CXCL13-ReaScan® will help improve patient outcomes and overall quality of life substantially – all while reducing healthcare costs.

#### ReaScan®+ Diagnostic System



ReaScan®  
TBE IgM Rapid Test



ReaScan® Reader



ReaScan®  
Chemokine CXCL13

Source: Reagent

<sup>3</sup> <https://www.frontiersin.org/articles/10.3389/fneur.2018.01048/full>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7025284/>

### **ReaScan®+ Diagnostic System: Simple, Fast, Objective, and User-friendly**

Reagent develops and manufactures its ReaScan® products on-premise, leveraging its domain expertise and state-of-the-art research and development (R&D) and production facilities to support an over 20-year sterling reputation and pioneering leadership.

The company's system components include:

**ReaScan Rapid Tests:** ready-to-use immunoglobulin M (IgM)-based tests reactive to viral proteins (Dobrava-Hantaan, Puumala, and TBE) and elevated chemokines (CXCL13) in small human serum, plasma, fingertip blood, or CSF samples. After a couple of simple liquid handling techniques, i.e., dilute, mix, and pipette, clinicians load the barcoded test cassettes into the ReaScan®+ reader. Factory calibrated, the tests provide batch-to-batch consistency, ensuring continued superior, robust, and reliable performance.

**ReaScan® Reader:** a compact, lightweight (200 grams), hand-held immunochromatographic refractometer. It is compatible with lateral flow membrane technologies - recognized worldwide as the most common methods behind low-cost, simple, rapid, and portable detection devices in all settings, from patient bedside to rural and remote environments. Battery operated, the device bypasses system maintenance service requirements.

ReaScan® + reader: A 1D/2D barcode scanner automates sample and patient identification (ID) input, storing up to 300 results together with the user, patient ID, and test date, time, and kit batch numbers for traceability. The ReaScan® Reader can connect to existing laboratory information systems and equipment for automatic result transfer and subsequent patient information sharing, a strategic imperative in the increasingly digitized and evolving value-driven healthcare landscape. The reader's touchscreen offers a user-friendly interface with multiple language options.

### **Win-Win Market Strategy: Optimistic Growth Outlook**

Indeed, Reagent's flagship product line, ReaScan® reader-based rapid diagnostic tests, provides superior performance, establishing validity, and clinical utility, addressing unmet diagnostic needs in infectious diseases, thus transforming zoonotic treatment practices. The cost-effective IVD CE-marked device facilitates non-trained clinical personnel to perform the testing, expanding access to novel diagnostics. The company's high-need niche focus further strengthens its pioneering leadership, carving its path as a serial first-mover company.

*"We do not seek partnerships just for the sake of partnering. We concentrate on high-quality complementary products that do not compete with each other, to fulfilling our customer needs and market trends."*

*-Anu Mickels*

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Reagen’s growth roadmap allows it to collaborate with leading life science solution providers. The company leverages its world-recognized reputation, decades-long innovative leadership, R&D and production infrastructure, and stellar sales network to capitalize on various market opportunities.

Whether developing rapid EIA tests compatible with ReaScan or for clinical diagnostic reference laboratories or serving as a contract development and services manufacturer or distribution partner, Reagen reports double-digit year-over-year growth, underpinned by the ReaScan® product line,

despite unforeseen mega-events impacting the global industry, e.g., COVID-19. Frost & Sullivan analysts firmly believe that Reagen’s multi-pronged growth strategy and unwavering commitment to quality and service excellence support long-term sustained leadership.

## Conclusion

Infectious diseases pose a heavy burden on public health with far-reaching socio-economic disruptions. The global coronavirus pandemic highlighted the need for affordable, rapid, accurate, and easy-to-use point-of-care testing (POCT) for practical infectious diseases clinical management and control, whether tending to an individual patient or responding to a worldwide pandemic.

Frost & Sullivan applauds the way that Reagen’s flagship ReaScan®+ Diagnostic System properly addresses unmet diagnostic needs in infectious diseases. With superior performance and established clinical utility, the company’s ReaScan® reader-based rapid diagnostic tests, i.e., Dobrava-Hantaan, Puumala, and tick-borne encephalitis (TBE) viruses and chemokine CXCL13 for neurological Lyme disease diagnosis, transform zoonotic treatment practices in high-need niche segments, paving its continued pioneering leadership in zoonotic POCT.

Frost & Sullivan previously recognized Reagen’s efforts in Hantavirus and TBE rapid POCT to enhance customer value and enable effective clinical management. Now, its pioneering leadership in further advancing rapid diagnostics and its strong overall performance earn Reagen the 2020 Frost & Sullivan European Company of the Year Award in the zoonotic point-of-care diagnostics market.

## What You Need to Know about the Company of the Year Recognition

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Frost & Sullivan's Company of the Year Award is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

### Best Practices Award Analysis

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

#### *Visionary Innovation & Performance*

**Addressing Unmet Needs:** Customers' unmet or under-served needs are unearthed and addressed by a robust solution development process

**Visionary Scenarios Through Mega Trends:** Long-range, macro-level scenarios are incorporated into the innovation strategy through the use of Mega Trends, thereby enabling first to market solutions and new growth opportunities

**Leadership Focus:** Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

**Best Practices Implementation:** Best-in-class implementation is characterized by processes, tools, or activities that generate a consistent and repeatable level of success

**Financial Performance:** Strong overall business performance is achieved in terms of revenue, revenue growth, operating margin, and other key financial metrics

#### *Customer Impact*

**Price/Performance Value:** Products or services provide the best value for the price compared to similar market offerings

**Customer Purchase Experience:** Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

**Customer Ownership Experience:** Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

**Customer Service Experience:** Customer service is accessible, fast, stress-free, and high quality

**Brand Equity:** Customers perceive the brand positively and exhibit high brand loyalty

## About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at <http://www.frost.com>.

## The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™. [Learn more.](#)

### Key Impacts:

- **Growth Pipeline:** Continuous flow of Growth opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



## The Innovation Generator™

Our six analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

### Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

