POINT-OF-NEED 2020 - INCLUDING PCR-BASED TESTING

Market & Technology Report - April 2020

Covid-19 is shaking up the diagnostics industry and will have both short- and long-term impact.

WHAT'S NEW

- In addition to the usual segmentation by application/ settings, this year we introduce the expected segmentation and market data/forecasts per type of test, spanning immunoassay, molecular diagnostics, clinical chemistry and more
- Detailed data for over 50 players, presented through charts: Installed base of instruments, instruments placed per year, tests per instrument per year, test ASP per type of test, consumable pullthrough per instrument
- More depth on market shares, per segment, and detailed list of players per segment
- Examples of success stories and failures, companies to watch in the coming years, and key considerations for commercial success
- New detailed sub-segmentation for the veterinary market and for the emergency testing market

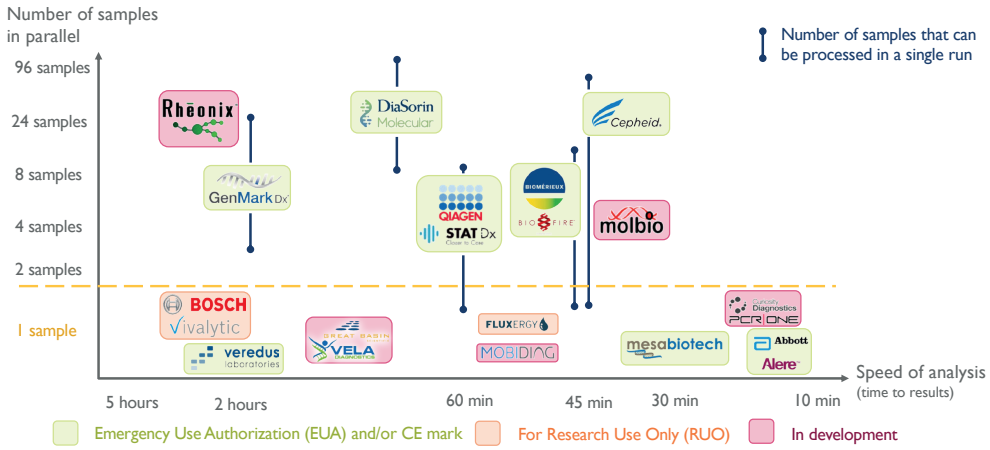
KEY FEATURES

- Overview of what microfluidic technology offers to point-of-need (PoN) testing
- New major trends and evolution at the market level and at the technology level including a focus on the high-plex molecular diagnostics space, and a focus on multi-modal platforms
- Updated market data and forecast 2018-2025, in value and units for microfluidic devices and tests, per segment and per type of test
- Supply chain description and analysis
- Market segmentation with technical and economical requirements per segment, product examples, key players, market share, and market and technology trends

THE COVID-19 PANDEMIC HIGHLIGHTS THE IMPORTANCE OF RAPID, ACTIONABLE POINT-OF-CARE DIAGNOSTICS

The past few months have seen a new biological threat, the COVID-19 infection, also called new coronavirus, and caused by the SARS-CoV-2 virus, which has reshaped the entire diagnostics ecosystem. As the epidemic has slowed down in China, it is Europe's and the USA's turn to be suffering. As a direct consequence, there is a strong demand for diagnostics tests to rapidly identify infected people and numerous companies started developing such tests, including companies relying on microfluidic technologies. In a few weeks, tens of tests were ready. However, everything that has to deal with human health has to face very slow regulatory processes. In front of the sanitary emergency, the FDA and other regulatory bodies finally lowered their standards, granting "Emergency Use Authorizations" for some of these tests. Since mid-march, companies like Cepheid, GenMark, BioFire/bioMérieux, and Mesa Biotech got approval for microfluidic-based rapid molecular testing for SARS-CoV-2. Even more companies have released such tests for Research Use Only (RUO), waiting for approval. The mid-term goal for some of these companies will be to add SARS-CoV-2 to their syndromic respiratory panels. There is a race towards diminution of the time to result, from days to hours to minutes, but also towards increasing the throughput. Abbott announced a 13-minute test at the end of March, but its IDNOW platform deals with only one sample at the time. Other platforms take longer to deliver results but some of them can process multiple samples per run. The opportunity looks huge for diagnostics companies, but is the supply chain ready for mass-production of these tests in addition to their usual business or will it impact the production of other types of tests? The pandemic poses interesting questions regarding the length of development, approval and manufacturing of tests when we have no time to waste but that reliability cannot be compromised. It will be interesting to see how these issues will be addressed once the pandemic will be behind us.

SARS-CoV-2 point-of-care molecular diagnostic tests*



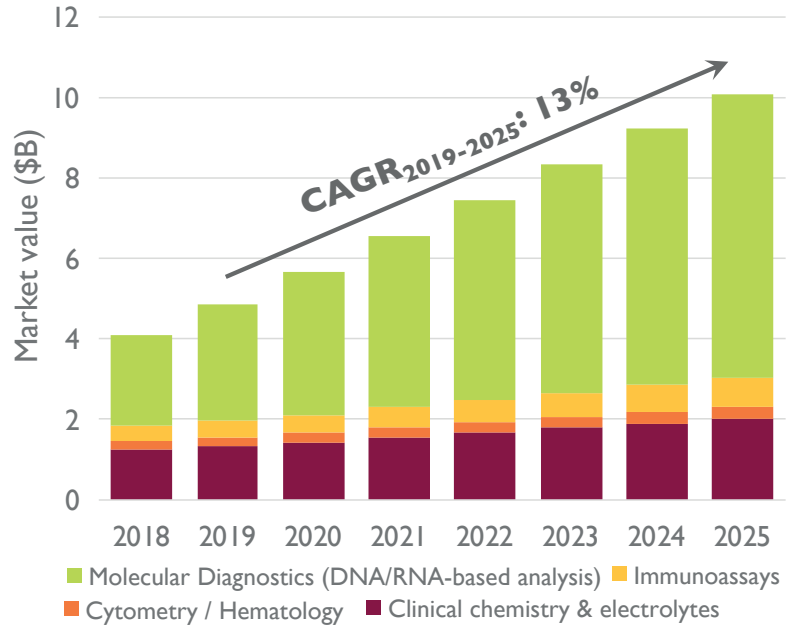
(Yole Développement, April 2020)

DIFFERENT MARKET SEGMENTS ENJOY DIFFERENT DYNAMICS, BUT OVERALL MOLECULAR TESTING IS BOOMING LIKE NEVER BEFORE

The COVID-19 pandemic highlights the need for rapid and actionable results at the point-of-care, which is true for various, increasingly complex and comprehensive test panels. To achieve that, molecular diagnostics are key. This category of test is now making it to the next step, thanks to ever more complex integration and automation on-chip. For the first time in this report, Yole Développement (Yole) proposes market data and forecasts for 2018-2025 per type of test spanning clinical chemistry, immunoassays, molecular diagnostics, cytometry, and more.

Molecular diagnostic tests represented more than half of the market value in 2019 and will represent about 70% by 2025. The overall microfluidic-based point-of-need testing market will grow at a compound annual growth rate (CAGR) from 2019-2025 of 13%, from $4.1B in 2019 to $10.1B in 2025, driven by human diagnostics segments. In the report, market data and forecasts are also split per market segment, spanning emergency testing, remote area testing, doctor's office and pharmacies, veterinary, agro-food, industrial, and more. Though most non-human testing areas are lagging behind, veterinary testing sees plenty of tests now reaching commercialization. New opportunities are emerging in industrial testing, for the quality control of pharmaceutical products. For each segment, market and technology trends are described in the report, along with main players, products and market shares. Companies are racing towards ever-higher-plex panels, meaning they want to enable detection of ever more pathogens in a single test. They also aim to reduce time-to-result below 20 minutes to enable use of their technologies at the point-of-care, for example during classic medical appointments. Both are difficult to achieve at the same time, therefore companies have to make some choices. However, some companies are on track to deliver the promise of high-plex, rapid molecular diagnostics at the point-of-care in the coming years and are introduced in the report. In addition, for the first time Yole provides detailed data on about 50 point-of-need companies, presented through charts. The data includes the installed base of instruments, number of instruments placed per year, and number of tests per instrument per year. It also provides average selling price (ASP) per type of test, and consumable pullthrough per instrument.

Microfluidic-based point-of-need testing market

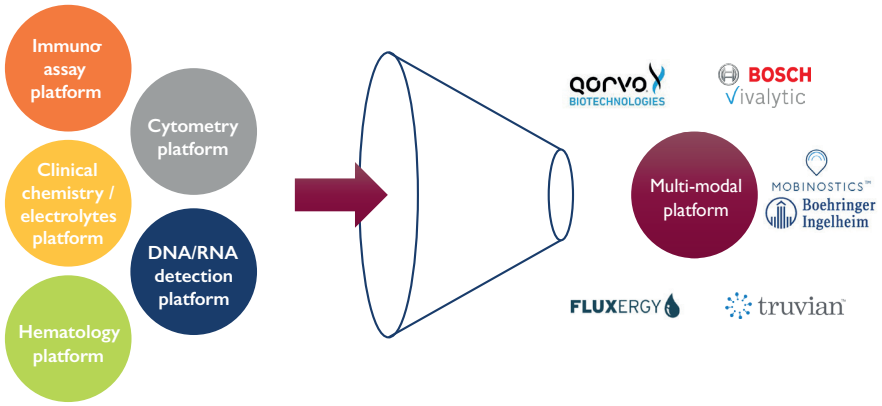


(Yole Développement, April 2020)

THE ADVENT OF MULTI-MODAL PLATFORMS COULD INDUCE PROFOUND CHANGES IN MEDICAL PRACTICE, BUT ARE TECHNOLOGY DEVELOPERS READY TO OVERCOME THIS CHALLENGE?

The holy grail of diagnostics would be a small box able to perform any kind of test in minutes. Platforms that combine clinical chemistry and immunoassays have existed for a long time, but now some companies are addressing a much bigger challenge: combining clinical chemistry, immunoassays, cytometry and molecular diagnostics with the same instrument, at the point-of-care. By doing so, in theory a diagnostics facility could purchase only one instrument and run hundreds of different tests on that platform instead of having to purchase many different instruments, which is costly and requires lab space, and train personnel to use all these instruments. The difficulty is to be able to integrate all these different detection methods in a single, low-footprint and affordable instrument, while being able to design a cost-effective microfluidic cartridge able to run various types of tests on the same footprint. It is difficult to say who will succeed in that area, but first-comers include companies like Bosch Healthcare with the Vivalytic platform, Qorvo Biotechnologies, Fluxergy and Truvian Sciences. Such multi-modal platforms are extremely promising but require a much heavier R&D effort than usual point-of-care platforms, which are already difficult to bring to the market and to scale-up in a cost effective manner. More than ever, this poses the question of companies' manufacturing strategy: is it better to manufacture chips and instruments in-house or to outsource to an experienced microfluidic device contract manufacturer? What are the advantages and the associated risks for both options? Which players have adopted which strategy for which products? In the report, Yole's analysts provide in-depth insights on this topic.

The advent of multi-modal point-of-care testing platforms



(Yole Développement, April 2020)

COMPANIES CITED IN THE REPORT (non exhaustive list)

Abaxis (Zoetis), Abbott, Abionic, Accelix (LeukoDx), Accriva Diagnostics (Instrumentation Laboratory, Werfen), Achira Labs, AgPlus Diagnostics, Akonni Biosystems, Alere (Abbott, Quidel, Siemens), ALine, ANDE, Aprimeo Diagnostics (R-Biopharm), Applied Microarrays, Ativa Medical, Atonomics, Avalun, Axxicon, Balda AG (Stevanato Group), BD (Becton Dickinson), binx health (formerly Atlas Genetics), Biocartis, Biodetection Instruments, BioFire Diagnostics (bioMérieux), BioMensio, bioMérieux, BioSensia, Biosurfit, Blusense Diagnostics, Boehringer Ingelheim Mobinostics, Bosch Healthcare, Caliper Life Sciences (PerkinElmer), Carbo Analytics, Cepheid (Danaher), Charles River Laboratories, Click Diagnostics, Coris Bioconcept, Cubed Laboratories (formerly FCubed), Cue Health, Curetis, Curiosity Diagnostics (Scope Fluidics), Daktari Diagnostics, Denz BIO-Medical, DiaSorin Molecular, DNAe (DNA Electronics), DxNA, Enigma Diagnostics, ENPLAS, Etta Healthcare (Ovagene Oncology), ExcitePCR (PositiveID Corporation), Flow Alliance, Fluid-Screen, FluimediX, Fluxergy, Focus Diagnostics (DiaSorin Molecular), Genalyte, GeneFluidics, GenePOC (Meridian Bioscience), GenMark Diagnostics, GenSpeed Biotech, Great Basin Scientific (Vela Diagnostics), Hahn-Schickard, Helvoet, HemoCue (Radiometer, Danaher), IDEX Health&Science, IQuum (Roche), iLine Microsystems, imec, Inflammatix, InSilixa, Instant Labs (Luminultra), IntegenX (Thermo Fisher Scientific), Klearia, LacriScience, LeukoDx, LexaGene, Luminex Corporation, LumiraDx, Maccura, MBio Diagnostics, Medimate (CE-Mate), MeMed, Menarini, Meridian Bioscience, Mesa Biotech, Microfluidic ChipShop, MicroLiquid, Micronics (Sony), Micronit, Minicare (Siemens), MiniFAB (Schott), Mobidiag, and more.

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Sébastien Clerc is a Technology & Market Analyst in Microfluidics, Sensing & Actuating at Yole Développement (Yole). As part of the Photonics & Sensing team, Sébastien has authored a collection of market and technology reports dedicated to microfluidics and other micro-devices for both market segments: medical, including diagnostics, pharmaceutical, biotechnology, drug delivery, medical devices, and industrial, including environment and agro-food. At the same time, he is involved in custom projects such as strategic marketing, technology scouting and technology evaluation to help academic and industrial players in their innovation processes. Thanks to his technology and market expertise, Sébastien has spoken in more than 20 industry conferences worldwide over the last four years. Sébastien Clerc graduated from Grenoble Institute of Technology (Grenoble INP) in France with a Master's degree in Biomedical Technologies. He then completed his academic studies with a Master's degree in Innovation and Technology Management in the same institute.

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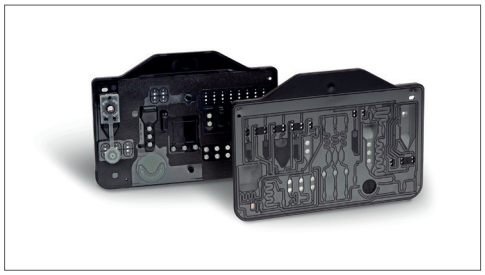

- Status of the Microfluidics Industry 2019
- Organs-On-Chips Market and Technology Landscape 2019
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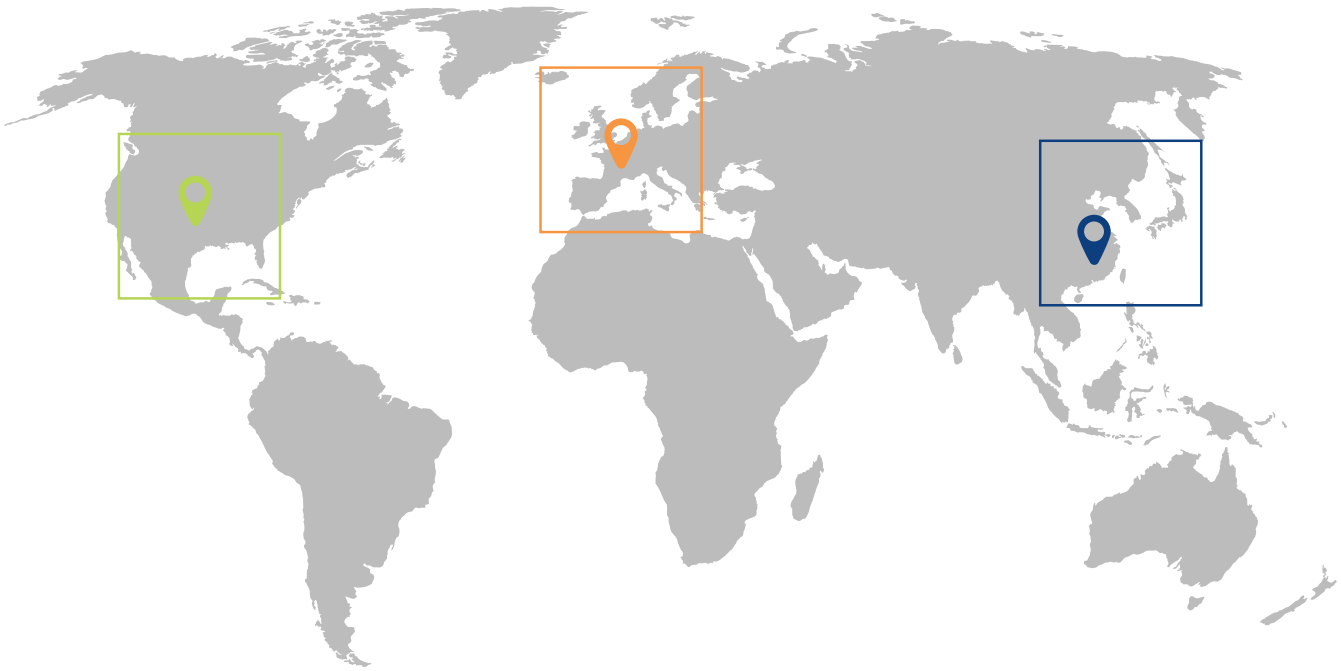

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ABOUT YOLE DEVELOPPEMENT

Founded in 1998, Yole Développement (Yole) has grown to become a group of companies providing marketing, technology and strategy consulting, media and corporate finance services, reverse engineering and reverse costing services. With a strong focus on emerging applications using silicon and/or micro manufacturing, the Yole group of companies has expanded to include more than 120 collaborators worldwide covering MEMS and Image Sensors, Compound Semiconductors, RF Electronics, Solid-state Lighting, Displays, Software, Optoelectronics, Microfluidics & Medical, Advanced Packaging, Manufacturing, Power Electronics, Batteries & Energy Management and Memory.
The "More than Moore" market research, technology and strategy consulting company Yole Développement, along with its partners System Plus Consulting, PISEO and Blumorpho, supports industrial companies, investors and R&D organizations worldwide to help them understand markets and follow technology trends to grow their business.

CONSULTING AND ANALYSIS
- Market data & research, marketing analysis
- Technology analysis
- Strategy consulting
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- Design and characterization of innovative optical systems
- Financial services (due diligence, M&A)

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- Public Relations: Sandrine Leroy (sandrine.leroy@yole.fr)

General Terms and Conditions of Sale

Definitions: **"Acceptance":** Action by which the Buyer accepts these General Terms and Conditions of Sale in their entirety. It is done by signing the purchase order which states "I hereby accept Yole Développement's General Terms and Conditions of Sale".

"Buyer": Any business user (i.e. any person acting in the course of its business activities for its business needs) placing an order pursuant to these General Terms and Conditions of Sale, with the exclusion of any individual consumer acting for his/her sole personal interest.

"Seller": Headquartered in Villeurbanne (France), Yole Développement provides marketing, technology and strategy consulting, media and corporate finance services, reverse engineering/costing services as well as IP and patent analysis. With dedicated teams of technology & market analysts, Yole Développement operates worldwide with the key industrial companies, R&D institutes and investors to help them understand the market and technology trends.

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1. SCOPE

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1.2 These General Terms and Conditions of Sale shall be deemed valid and enforceable between the Contracting Parties after acceptance of an order from the Buyer by the Seller pursuant to Article 1.3 below. For such purpose, the Buyer, when signing the purchase order which mentions "I hereby accept Yole Développement's Terms and Conditions of Sale" is deemed to have fully and unequivocally accepted these Terms and Conditions of Sale.

1.3 Orders are deemed to be accepted only upon written acceptance and confirmation by the Seller, within [7 days] from the date of order, to be sent either by email. In the absence of any confirmation in writing, no order shall be deemed to have been accepted.

2. MAILING OF THE PRODUCTS

2.1 Products are sent by email to the Buyer after Seller's confirmation:
- Within a few days from the Seller's confirmation of the order for Products already released and paid; or
- Within a reasonable time for Products ordered prior to their effective release. In this case, the Seller shall use its best endeavours to inform the Buyer of an indicative release date and the evolution of the work in progress.

2.2 The Seller shall by no means be responsible for any delay pursuant to Article 2.1 above, in particular in cases where a new event or access to new contradictory information would require the Seller analyst to dedicate extra time to compute or compare the data in order to enable the Seller to deliver a high quality Product.

2.3 The mailing of the Product will occur only upon payment by the Buyer, in accordance with the conditions contained in Article 3 above.

2.4. The mailing is operated through electronic means either by email via the sales department or automatically online via an email/password. The Buyer is responsible for ensuring that the Buyers platform has the required capacities and authorisations to receive the Product(s) emailed by the Seller. If the Product's electronic delivery format is defective, the Seller undertakes to replace it at no charge to the Buyer provided that the Seller is informed of the defective formatting within 90 days from the date of the original download or receipt of the Product.

2.5 The person receiving the Products on behalf of the Buyer shall immediately verify the quality of the Products and their conformity with the order. Any claim for apparent defects or for non-conformity shall be sent in writing to the Seller within 8 days of receipt of the Products. For this purpose, the Buyer agrees to produce sufficient evidence of such defects.

2.6 No return of Products shall be accepted without prior written notification from the Buyer to the Seller, even in case of delayed delivery. Any Product returned to the Seller without the Buyer providing prior notification to the Seller as required under Article 2.5 above shall remain at the Buyer's risk. In no event shall the Seller incur any liability for Products erroneously ordered by the Buyer, or for any request from the Buyer to replace a Product previously ordered by a different Product.

3. PRICE, INVOICING AND PAYMENT

3.1 Prices are given in the orders corresponding to each Product sold on a unit basis or corresponding to annual subscriptions. They are deemed to be inclusive of all taxes applicable in the country where the Seller is based (except for France where VAT will be added). The prices are re-evaluated from time to time by the Seller. The effective price is deemed to be the one applicable at the time of the order.

3.2 Payments due by the Buyer shall be sent by cheque payable to Yole Développement, or made by credit card or by electronic transfer to the following account:
HSBC, 1 place de la Bourse 69002 Lyon France
Bank code: 30056
Branch code: 00170
Account n°: 0170 200 1565 87
BIC or SWIFT code: CCFRFRPP
IBAN: FR76 3005 6001 7001 7020 0156 587
To secure the payments due to the Seller, the Seller reserves the right to request down payments from the Buyer. In such case, the need for a down payment will be mentioned on the corresponding order.

3.3 Payment is due by the Buyer to the Seller within 30 days from invoice date, except as otherwise specifically agreed in writing by the Buyer and the Seller. If the Buyer fails to pay at the due date and fails to request and obtain from the Seller a payment extension, the latter shall be entitled to invoice interest in arrears based on the annual rate Refi of the "BCE" + 7 points, in accordance with article L.441-6 of the French Commercial Code.

3.4 The Seller publications (reports, monitors, tracks...) are due for delivery only after receipt by the Seller of any payment due by the Buyer prior to delivery.

3.5 In the event of termination of the contract by the Seller attributable to Buyer misconduct during the contract, the Seller will have the right to invoice all work performed at the time of termination, and to take legal action for damages.

4. LIABILITIES

4.1 The Buyer or any other individual or legal person acting on its behalf, being a business user buying the Products for its business activities, shall be solely responsible for the choice of the Products purchased as well as for the use and interpretations the Buyer makes of the documents it purchases, of the results the Buyer obtains, and of the advice and acts the Buyer bases thereon .

4.2 In no event shall the Seller be liable for:
a) Damages of any kind, including without limitation, incidental or consequential damages (including, but not limited to, damages for loss of profits, business interruption and loss of programs or information) arising out of the use of a Product or the use of or the inability by the Buyer to use the Seller's website, or any information provided on the website, or contained in a Product;
b) Any claim attributable to errors, omissions or other inaccuracies in a Product or interpretations thereof.

4.3 All the information contained in the Products has been obtained from sources believed to be reliable. The Seller does not warrant the accuracy, completeness adequacy or reliability of such information, which cannot be guaranteed to be free from errors.

4.4 Any Product that the Seller sells may, upon prior notice to the Buyer from time to time be modified by Seller or substituted with a similar Product meeting the needs of the Buyer. Such modification shall not lead to any liability of the Seller, provided that the Seller ensures the substituted Product is similar to the Product initially ordered.

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4.7 The Seller does not make any warranties, express or implied, including, without limitation, those of sale ability and fitness for a particular purpose, with respect to any Products. Although the Seller shall take reasonable steps to screen Products for infection of viruses, worms, Trojan horses or other codes containing contaminating or destructive properties before making Products available, the Seller cannot guarantee that any Product will be free from infection.

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- Use in any timesharing, service bureau, bulletin board or similar arrangement or public display;
- Posting any Product to any other online service (including bulletin boards or the Internet);
- Licensing, leasing, selling, offering for sale or assigning a Product or any derivative thereof.

6.3 If the Buyer would like to use data coming from a Product for presentations, press announcements and any other projects, the Buyer needs to contact Yole Développement's Public Relations Director (info@yole.fr) to get an official authorization and confirm that the data are up to date. In return the Seller will make sure to provide up-to-date data under a suitable public format.

6.4 The Buyer shall be solely responsible towards the Seller for any infringement of the obligation described in Article 6.3 above, whether such infringement originates from the Buyer's employees or any person to whom the Buyer has sent the Products. Furthermore, the Buyer shall initiate and personally take care of any related proceedings in coordination with the Seller, and the Buyer shall bear the related financial consequences in their entirety.

6.5 The Buyer shall define within its Company an identified user who shall serve as a contact person for the License purchased by the Buyer. This person will be the recipient of each new report. This person shall also be responsible on behalf of the Buyer, for compliance with all copyrights and other obligations relating to the protection of the Seller's IP rights and general compliance with the terms of the License purchased by the Company. In the context of Bundle and Annual Subscriptions, the contact person shall decide within the Buyer which person(s) shall be entitled to receive the protected link that will allow the Buyer to access the Products.

6.6 It is acknowledged and accepted by the Buyer that whether purchased in the form of Bundles or Annual Subscription, all unselected reports will be deemed cancelled and lost after a period of 12 month following acceptance of the corresponding order by the Seller in accordance with provisions of Article 1.3 above .

6.7 It is further acknowledged and agreed by the Buyer that any investor in the Buyer Company, any external consultant of the Buyer Company or any joint venture done with a third party in which the Buyer Company is involved , is not entitled to use a Product, without paying to the Seller the full price for a license to the required Product..

7. TERMINATION

If the Buyer cancels the order in whole or in part or postpones the date of mailing, the Buyer shall indemnify the Seller for the entire costs that have been incurred as at the date of notification by the Buyer of such delay or cancellation. This may also apply for any other direct or indirect consequential loss that may be incurred by the Seller, pursuant to such cancellation or postponement.

8. MISCELLANEOUS

8.1 All the provisions of these General Terms and Conditions of Sale are for the benefit of the Seller, but also for that of its licensors, resellers and agents. Each of them is entitled to assert and enforce these provisions against the Buyer.
Any notices under these Terms and Conditions shall be given in writing and shall be effective upon receipt by the other Party.

8.2 The Seller may, from time to time, update these General Terms and Conditions of Sale, and the Buyer, shall be deemed to have accepted the latest version of such General Terms and Conditions of Sale, once they have been duly communicated to the Buyer by the Seller.

9. GOVERNING LAW AND JURISDICTION

9.1 Any dispute arising out or linked to these General Terms and Conditions of Sale or to any Licenses or Products purchased in application thereof shall be submitted to the French Commercial Court of Lyon, which shall have exclusive jurisdiction upon such issues.

9.2 French law (without reference to any applicable conflict of law provisions) shall apply to these General Terms and Conditions of sale and any agreement between the Buyer and the Seller made pursuant thereto.