cytiva

Accelerating diagnostic test development

66% of clinical decisions are based on a diagnostic test,[1] highlighting their importance in developing therapies and improving patient outcomes. There are many elements to consider when designing a diagnostic test, assay or kit, how to move from prototype to commercialization time efficiently may be one of the most important.

This infographic highlights the key considerations to optimize diagnostic test development.

Trends impacting the development of diagnostic tests

In 2020 Cytiva conducted a survey to discover the impacts of development of diagnostic tests. More than half of respondents were focused on viruses, likely to be a direct result of the COVID-19 pandemic.[2]

International initiatives have focused on developing testing and treatment programs for infectious diseases—TB, HIV, malaria, and sexually transmissible diseases, creating a market for test devices to diagnose and monitor treatment efficacy of these diseases and other infectious diseases.[1]

Market growth in 2020 came from pandemic related testing for COVID-19, estimated at **$ 9040 million.**[1] Nearly **200 products** for COVID-19 (not including lab developed tests) have been authorized by the FDA.[1]

Global *in vitro* diagnostic sales by product market, 2020–2025 ($ million)[1]

Top 5 by CAGR

Top 5 by 2025 Market Share

HPV = human papillomavirus. POC = point-of-care. OTC = over the counter.

Factors to consider when selecting diagnostic component suppliers[2]

As part of our research project, molecular and immunodiagnostic kit developers were asked to vote for the factors considered when selecting a manufacturer to supply components/raw materials for diagnostic kits/assays. The top performing factors are shown below, with the percentage of respondents who voted for each.

General factors

54% Operational efficiency

50% Regulatory compliance

50% Balancing scientific needs with commercial goals

Sales and support related factors

59% ISO accreditation

38% Availability of test/trial data

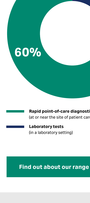
37% Intellectual property protection

Choosing point-of-care or lab-based tests[2]

To get a better understanding of what our customers are focused on, we asked about what test types they spend their time on and what components or raw materials they use. We also asked about their organizations use of kits/assays and how many of those are being manufactured—or in development phase.

Working time spent on test type

% respondents



Using components/raw materials

% respondents

Find out about our range of magnetic beads

Find out about our range of Whatman™ membranes

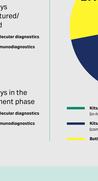
From diagnostic test idea to commercialization

Number of kits/assays manufactured/development phase[2]

Mean

Organization of *in-vitro* diagnostics[2]

% respondents



How can Cytiva help?

Cytiva Diagnostic Services helps you accelerate diagnostic assay development, from early-stage concept and prototype to manufacturing and commercialization. Our laboratory infrastructure, technical expertise and consultation services can help you get to market faster.

- Proof of principle trials
- Early questions and feasibility
- Proof of principle trials
- Planning
- Validation and verification
- Product lockdown
- Customized product release
- Handover to manufacturing

Find out about Cytiva Diagnostic Services

References

1. Kalorama (2020) The Worldwide Market for In Vitro Diagnostic Tests, 13th Edition
2. Cetas Healthcare (2021) Diagnostic Market Awareness Study on behalf of Cytiva N=200, unless otherwise stated.

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