Analysis of the Global In Vitro Diagnostics and Point-of-Care Testing Market

Technology Unlocking the Potential of Blood Transfusion, POCT (Influenza and Cancer) Market

A Frost & Sullivan White Paper

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I. EXECUTIVE SUMMARY

Despite economic and industry challenges, the global in vitro diagnostics (IVD) market continues robust growth. The United States and Europe are mature regions that collectively contribute almost 60% of the worldwide revenue. That stated, Asia-Pacific is being widely recognised as a fast-rising market with immense potential, holding 17% of global sales in 2015.

Key trends in the global market include regulatory changes, a shift to data-driven healthcare, unifying technology investments, lab consolidation combined with automation, and internal and external convergence. The blood transfusion diagnostics market is a prominent segment of the IVD segment, with the majority of revenue derived from blood grouping and typing, followed by disease screening. The US contributes the largest revenue share; while demand is increasing in Japan, China, and India.

Point-of-care testing (POCT) is becoming popular due to the growing need for rapid tests in emergency rooms, operating theatres, recovery rooms, cath labs, and intensive care units. Physician clinics also show keen interest in POCT due to the ease of diagnosis, faster results, and increasing pool of patients who are willing to pay out-of-pocket for the services. Among the in-demand POCT are for influenza and non-communicable diseases, such as cancer. Given the potential of POCT platforms and their ability to transform healthcare delivery, companies are strengthening their research and development focus on POCT instruments to achieve better performance.

The IVD market includes reagents, consumables, and instruments that perform testing outside the body on obtained specimens (e.g., blood or urine) to measure analytes of interest for patient evaluation. Globally, instruments represent the largest market share, followed by reagents due their extensive usage in all diagnostic devices and equipment.

<table>
<thead>
<tr>
<th>KEY FACTS</th>
<th>IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition from centralized laboratory.</td>
<td>Global IVD market forecasted to grow from US$58.10 billion in 2015 to US$76.94 billion in 2019.</td>
</tr>
<tr>
<td>Increasing automation and modernization of laboratories and hospitals likely to increase opportunities in the global POCT market.</td>
<td>Global POCT market revenue in 2015 was US$7.55 billion; it is expected to reach US$10.35 billion by 2019. The POCT market represents 13% of the global IVD market.</td>
</tr>
</tbody>
</table>
II. TRENDS AFFECTING THE GLOBAL IVD MARKET

Six key trends are expected to accelerate quality and demand in the IVD market.

TREND 1: CHANGING REIMBURSEMENT MODELS AND REGULATIONS

Government regulations impact IVD market growth, with most nations developing increasingly structured and stringent policies that influence product launches. China and India are among the IVD market hot spots. Figure 1 examines regional regulatory processes and market trends.

Figure 1: IVD Market Regulatory Analysis, Selected Regions, 2015

<table>
<thead>
<tr>
<th>REGION</th>
<th>REGULATORY PROCESS</th>
<th>UNIQUE IVD MARKET TRENDS</th>
<th>IMPACT ON THE GLOBAL MARKET</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>Moderately lenient</td>
<td>Strong market with increasing adoption rates of POCT and molecular diagnostics tests.</td>
<td>Holds the largest market share based on percentage of sales, at 31%.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The US Food and Drug Administration (FDA) regulations curtail innovation to an extent.</td>
<td>Post the highest growth in the POCT and molecular diagnostics testing segments.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Growing integration of communications technology in IVD devices, denoting progress on mhealth.</td>
<td></td>
</tr>
<tr>
<td>EUROPE</td>
<td>Most lenient</td>
<td>Lenient regulations make it a thriving testing ground.</td>
<td>Has the second largest market share based on percentage of sales; Western Europe at 26%, and Eastern Europe at 2.6%.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The CE mark is known worldwide, with many manufacturers favoring the region for new product launches.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Consolidation of clinical laboratories support cost effectiveness.</td>
<td></td>
</tr>
<tr>
<td>ASIA (JAPAN, INDIA &amp; CHINA)</td>
<td>Less to moderately lenient</td>
<td>Regulatory leniency varies by country.</td>
<td>Asia-Pacific holds 17% of market share based on percentage of sales.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Japan has the least lenient regulations; however, recent changes are motivating manufacturers to invest.</td>
<td>China shows one of the fastest IVD expansions with 7.1% of market share based on percentage of sales globally.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High patient population, increasing number of hospitals, and diagnostics laboratory are driving the development</td>
<td></td>
</tr>
</tbody>
</table>
TREND 2: INVESTING IN UNIFYING TECHNOLOGY

In the past, physician preference determined the tests and devices used in each market. The current market, however, is strongly influenced by changes in reimbursement and regulatory policies that pressure hospitals to contain costs and optimize patient outcomes. This is resulting in the restructuring of hospital business models, affecting the way IVD companies add value to their product portfolios. There is a clear shift from volume to value-based healthcare inspiring IVD company business models as per Figure 2. While Figure 3 provides a competitive analysis of selected companies’ business models.

Figure 2: Top 5 Factors that Influence IVD Companies’ Business Models, Global, 2015

<table>
<thead>
<tr>
<th>REGION</th>
<th>REGULATORY PROCESS</th>
<th>UNIQUE IVD MARKET TRENDS</th>
<th>IMPACT ON THE GLOBAL MARKET</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>of India’s IVD market. In July 2015, the Revised Pre-Screening Checklist for acceptability of application of In vitro Diagnostic was released. Emerging trends are leasing or rental POCT models in private hospitals and partnerships with third-party diagnostics companies to address growing IVD needs. China has moderately lenient regulations favoring domestic companies. As a result, Tier 1 companies are using partnership approach with local vendors and distributors to expand their market share. Government efforts to regulate laboratory testing given the growing number of hospitals for rural populations spurring market growth.</td>
<td></td>
</tr>
</tbody>
</table>

| INCREASE IN MERGERS AND ACQUISITIONS | The number of entrants in the IVD field is increasing. Larger participants such as Roche are rapidly acquiring smaller companies. |
| RESTRICTURING OF PRODUCT PORTFOLIOS | Large and established companies are moving away from certain diagnostic fields, such as diabetes, to widespread diseases such as cancer and personalized solutions. There is also a push to integrate Big Data analysis in diagnostics practices. |
### PARTNERSHIPS WITH PHARMACEUTICAL AND MEDICAL DEVICES COMPANIES

Major pharmaceutical companies are keen on acquiring or partnering with molecular diagnostics technology companies. Pharma companies are looking at companion diagnostics plans in their models.

### GROWING INTEREST IN POCT

Increasing clinical evidence shows not only an improvement in patient outcomes, but also cost effectiveness and greater efficiency in implementing these devices in a clinical setting. IVD companies are investing heavily in this technology for many fields.

### INNOVATION OF PRODUCTS THAT COMPLEMENT THE EXISTING PORTFOLIO

More IVD companies are shifting from creating new products to a more cost-efficient model of developing add-ons that increase the efficacy and accuracy of tests. This is becoming the prevalent model for established companies.

---

**Figure 3: Competitive Analysis of the Global IVD Market, 2015**

<table>
<thead>
<tr>
<th>Part</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Restructuring Portfolio</strong></td>
<td><strong>Investing in Emerging Nations</strong></td>
</tr>
<tr>
<td>ROCHE</td>
<td>Reinvesting in infectious diseases and downsizing on diabetes diagnostics</td>
</tr>
<tr>
<td>SURMODICS</td>
<td>Restructured its IVD segment to focus more on reagents and kits</td>
</tr>
<tr>
<td>SIEMENS</td>
<td>Strong partnership with DASA Diagnostic Laboratory Group in Brazil earned Siemens a 50% revenue increase in its diagnostics business</td>
</tr>
</tbody>
</table>
TREND 3: CONSOLIDATION AND AUTOMATION OF LABS

Five main factors are leading to the consolidation and automation of laboratories:

- **Increasing automation:** Likely to limit or eliminate human error during sample preparation, uploading tests, and analysis enabling laboratories to support the growing demand for IVD testing and produce better test results.
- **Budget cuts:** Reimbursement cuts are forcing hospitals and labs in the private and academic sectors to consolidate.
- **Competition from other technologies:** POCT, which is showing rapid growth, directly competes with conventional labs. The growing adoption and reimbursements for POCT are resulting in stiffer competition.
- **Unifying laboratory systems:** Traditionally, laboratories had fragmented models where instruments were not consolidated in a single unit. Now, there is a pressing need for lab systems to unify their individual systems into a single platform to increase efficiency.
- **Escalating costs:** Higher instrument/reagent prices and maintenance fees are pushing labs to consolidate.

TREND 4: SHIFT TO DATA-DRIVEN HEALTHCARE

Patients are becoming more comfortable with digital devices and services as healthcare stakeholders invest in digital strategies to increase efficiency and improve cost-effectiveness. Integration of technology in labs and hospitals are driving clinicians, data analysts, and corporate leaders, among others, to extract meaningful information from data to deliver higher-quality, more coordinated healthcare services. Accountable care organizations and laboratories emphasise diagnostic testing integrated with hospital systems to harness data while monitoring individual patients. Figure 4 illustrates the evolution of digital healthcare.

*Figure 4: Digital Health Step Process Globally, 2015*
TREND 5: CONSUMER LAB TESTING
Innovations in technology are transforming the role of conventional lab testing, providing more options for consumers and changing the business models of manufacturers and service providers. An emerging trend in the US is how testing is moving from labs to retailers such as Walgreens. Consumers can look forward to ordering tests directly without having to visit a physician or hospital. Independent companies offer prices that are 50% to 90% less than Medicare costs by removing physicians from the equation, which is in direct competition with many larger lab service organizations. The evolving consumer lab testing trend is leading to more efficient, accurate, and time-saving tests that are cost-effective and offer immediate access for diagnosis and transparency in results. Lab test manufacturers need to market to a new consumer base, away from traditional physicians and clinicians. Figure 5 illustrates the shift in lab testing in the US.

Figure 5: IVD Market Lab Testing Changes, US, 2015

CURRENT SCENARIO
- Patients must go through a physician to get tested.
- Limited transparency among physicians-laboratories-patients regarding test results.
- No insurance coverage; consumers have to pay out-of-pocket.
- Patient service centers such as those maintained by Quest Diagnostics and LabCorp prevalent for lab testing.
- Testing is centralized.

REGULATORY SCENARIO
- The Arizona House Bill 2645 passed in April 2015, allow state residents to purchase a limited number of tests without a physician’s prescription.
- Greater consumer purchasing power could result in disruptions for:
  - IVD equipment manufacturers
  - Major national reference labs

CHANGING SCENARIO
- There is a shift toward decentralized testing.
TREND 6: HEALTHCARE CONVERGENCE
The healthy convergence within and among the pharmaceutical, medical devices, and diagnostics industries are likely to benefit the IVD market, better addressing patient needs. For example, the union of pathology and genomic disciplines are anticipated to result in better clinical data and diagnostics. In fact, the historically-distinct components of the healthcare industry are evolving towards greater integration addressing unmet patient needs and cost pressures, and eventually, changing fundamental business models.

IVD companies tend to share technologies rather than compete against one another to produce bundled tests, improving the patient care continuum. Technological convergence is bound to increase volume as more patients opt for bundled packages. Hologic is among the companies adopting a convergence strategy to address the growing IVD market demand. Previously, the global diagnostics company had primarily focused on imaging for breast cancer competing with other biopsy testing manufacturers. Hologic repositioned its strategy by acquiring Suros, a leading innovator in the field of devices for minimally-invasive biopsy and tissue excision, and now offers a comprehensive breast health platform including imaging equipment, breast biopsy devices, and guidance systems. Figure 6 illustrates an internal convergence model.

Figure 6: Internal Convergence Model

Industry convergence helps manufacturers integrate digital platforms such as handheld devices into IVD and emerge as market leaders. The integrative approach to diagnose and monitor chronic illnesses such as diabetes elevates patient-physician interaction, resulting in much better care, as shown in Figure 7.
**Figure 7: Digital Health and IVD Convergence Model—Diabetes**

<table>
<thead>
<tr>
<th>TEST</th>
<th>DIAGNOSIS</th>
<th>TREATMENT</th>
<th>SELF-MANAGEMENT</th>
<th>MANAGEMENT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-monitoring blood glucose systems</td>
<td>Lab-based tests</td>
<td>Prescription, treatment, and monitoring options</td>
<td>Follow-through with patients</td>
<td></td>
</tr>
</tbody>
</table>

**Digital platform:** EHRs at hospitals harness this data.

**Companies:** TelCare BGM, HealthPAL, Biomedtrics

**Digital platform:** Applications that allow users to track their glucose and nutritional levels of the food they eat, and provide real-time motivational, behavioral, dietary, and educational coaching for diabetes management.

**Companies:** TelCare BGM, HealthPAL, Biomedtrics

**Digital platform:** Teleconferencing to give healthcare providers immediate access to patients’ medical information in relation to glucose levels, diet, exercise, weight, fitness goals, and trends.

**Companies:** CellNovo, Biomedtrics
III. GLOBAL IVD MARKET OVERVIEW

IVD is a group of tests that can detect diseases, conditions, and/or infections mostly by using body fluids such as blood, tissue, plasma, and urine. The largest segment of the global IVD market is immunochemistry, accounting for almost 40% of market revenue. Immunochemistry is expected to demonstrate stable growth because of its cost efficiency and adoption in less medically advanced countries. The molecular diagnostics and POCT segments are also rapidly growing due to healthcare models becoming more patient-centric and efficient. IVD applications include infectious diseases, sexually-transmitted diseases, drug testing, nephrology, diabetes, cancer/oncology, cardiology, and autoimmune diseases. Infectious disease testing is expected to be the highest revenue generator due to increasing incidences globally. Figure 8 illustrates the market breakdown.

*Figure 8: IVD Market Segmentation, Global, 2015*

**MARKET DEFINITION**

The IVD market includes reagents, consumables, and analyzers that are used to perform testing outside the body on obtained specimens to measure analytes of interest for patient evaluation. The tests are performed in central laboratories, reference laboratories, professional test sites near patients (i.e., POCT), or by patients themselves. Globally, instruments hold the largest market share, followed by reagents, that are growing rapidly because they are being used for all diagnostics devices and equipment.
MARKET SIZE

Despite economic and industry challenges, the IVD market is growing robustly and at double the rate of the global pharmaceutical industry. The global IVD market generated revenue of US$58.10 billion in 2015; and is forecasted to reach US$76.94 billion by 2019 at a CAGR of 7.3%. The transition from traditional to more advanced diagnostics devices is poised to make the market more lucrative. Figure 9 illustrates the global annual revenue from 2012 to 2019.

Figure 9: Total IVD* Market Revenue Forecast, Global, 2012–2019

*Does not include tissue diagnostics segment.

Note: All figures are rounded. The base year is 2015. Source: Frost & Sullivan
IV. BLOOD TRANSFUSION DIAGNOSTICS MARKET

Blood transfusion diagnostics refers to tests performed on blood and blood products before blood is transfused to patients. Each unit of blood must be tested for blood grouping and disease screening when mandated to prevent complications that may appear after a few days or even months later. Adverse reactions could include fever, skin rash, nausea and back pain. Blood transfusion diagnostics is becoming a crucial component of the healthcare process to provide essential information to physicians and patients. Figure 10 shows the blood transfusion diagnostics market segmentation.

Figure 10: Blood Transfusion Diagnostics Market Segmentation, Global, 2015

North America US accounting for a major market share dominates the blood transfusion diagnostics market, followed by Europe. Japan, China, and India, along with Latin America, Middle East and Asia are emerging markets.

BLOOD GROUPING AND TYPING
Antigen typing (ABO, Rh, and extended blood antigen phenotyping)
Antibody detection and identification that could cause reactions in the recipient, such as during pregnancy

DISEASE SCREENING
Antibody-based detection for screening infectious blood performed only at donor centers; not approved to diagnose a patient’s condition
Diseases that can be tested using antibody screening or testing genetic material using immunoassay or nucleic acid testing are Hepatitis B/C, Human Immunodeficiency Virus (HIV) Types 1 and 2, Human T-Lymphotropic Virus (HTLV) Types I and II, Syphilis, Chagas, and West Nile virus

BLOOD GROUPING AND TYPING
In most regions, blood grouping and typing remain dominant over disease screening due to the transition from manual to automated methods. Automated blood bank analyzers from the top vendors are categorized into 3 different technologies: column agglutination technology (CAT), solid phase red cell adherence (SPRCA), and erythro-magnetic technology (EMT). Automated solutions have significantly reduced analysis times and
rapidly increased laboratory efficiency while offering better sensitivity than conventional test tube (CTT) methods. Many immunohematologists believe that CTT is the gold standard while several publications have shown that the CTT method has fewer false positives, inhibiting the switch to automated platforms. Perceived as a cheaper solution, the CTT method is not likely to become obsolete. Figure 11 compares the sensitivity, specificity, and test time by technology.

*Figure 11: Blood Transfusion Diagnostics Market - Comparison of Immunohematology Methods¹, US, 2014*

<table>
<thead>
<tr>
<th>TECHNOLOGY</th>
<th>CAT</th>
<th>SPRCA</th>
<th>EMT</th>
<th>CTT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity for conventional serology antibodies</td>
<td>90–94%</td>
<td>97%</td>
<td>83–94%</td>
<td>43% (low ionic strength solution and IAT)</td>
</tr>
<tr>
<td>Specificity</td>
<td>94.4%</td>
<td>94.3%</td>
<td>98%</td>
<td>98.6%</td>
</tr>
<tr>
<td>Antibody screening sensitivity</td>
<td>Better than CTT</td>
<td>Better than CTT</td>
<td>Better than CTT</td>
<td>Less sensitive than other methods</td>
</tr>
<tr>
<td>Time taken for Abo grouping</td>
<td>~ 20 min</td>
<td>N/A</td>
<td>&gt; 30 min</td>
<td>Less than 20 min</td>
</tr>
<tr>
<td>Readability</td>
<td>Very clear</td>
<td>Very clear</td>
<td>Very clear</td>
<td>Variability</td>
</tr>
<tr>
<td>Detection of IgG</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Detection of IgM</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Expression of weaker blood groups</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>May detect</td>
</tr>
<tr>
<td>Washing step</td>
<td>Not required</td>
<td>1 step</td>
<td>Not required</td>
<td>Multiple washing</td>
</tr>
</tbody>
</table>

**DISEASE SCREENING**

Similar to blood grouping and typing, revenue growth for the disease screening segment is being fueled by automated molecular platforms. Most market revenue still comes from serological tests to screen for pathogens. Infectious agents are screened through the enzyme-linked immunosorbent assay (ELISA) technique, enzyme immunoassays (EIAs), chemiluminescent immunoassays (CLIAs), indirect fluorescent antibody (IFA), Western blot, and nucleic acid testing (NAT).

¹ Automation in Immunohematology; Asian J Transfus Sciv 6(2); Jul-Dec 2012
MARKET SIZE
The global blood transfusion diagnostics market generated revenue of US$2.82 billion in 2015, expecting to reach US$3.31 billion by 2019 with a growth rate of 4.0%. Blood typing and grouping, along with product innovation, are expected to drive market growth.

Figure 12: Total Blood Transfusion Diagnostics Market Revenue Forecast, Global, 2012–2019

Note: All figures are rounded. The base year is 2015. Source: Frost & Sullivan

COMPETITIVE LANDSCAPE
The global transfusion diagnostics market is fragmented with the 3 largest manufacturers—Immucor, Johnson & Johnson/Ortho-Clinical Diagnostics, and Beckman/Olympus—controlling 10% to 12% of the total market. Johnson & Johnson’s wholly-owned subsidiary, Ortho-Clinical Diagnostics, is the largest transfusion diagnostic equipment and solution provider and holds the highest market share. Beckman/Olympus is in second place.

Other notable participants are Abbott Laboratories, BioMerieux SA, Bio-Rad Laboratories Inc, Chiron Corporation, DiaMed Inc, Fujirebio Diagnostics Inc, and Roche Diagnostics Corporation.
V. POCT

DEFINITION
Globally, manufacturers are focusing on POCT that can profoundly change therapy decisions, improve outcomes, and lower costs. POCT uses portable diagnostics devices for accurate monitoring within a few minutes at a patient’s bedside. It also is used in ICUs and emergency rooms. The devices typically require minimal operator interaction, are non-invasive, and have efficient data management and connectivity tools.

While most of Western Europe and the US are well-versed with automated POCT, it is still in the growth stages in Asia-Pacific, where automation and modernization of laboratories and hospitals are expected to increase market opportunities. Figure 13 shows POCT market segmentation.

* Most commonly performed POCT for infectious diseases are for influenza A and B, group A streptococcus (strep A), clostridium difficile (C. diff.), streptococcus pneumoniae (strep pneumoniae), respiratory syncytial virus (RSV), chlamydia, and helicobacter pylori (H. pylori)

** Fecal occult blood tests (FOBT) detect blood in the stool and are performed as part of routine examinations to screen primarily for colorectal cancer.
MARKET SIZE
Globally, the POCT market revenue in 2015 achieved US$7.55 billion, expecting to grow at a CAGR of 8.2% to US$10.35 billion by 2019. The market is driven by technological advancements and transition from central laboratories to rapid testing. Figure 14 shows the annual revenue of the global POCT market.

*Figure 14: Total POCT Market Revenue Forecast Global, 2012–2019*

Note: All figures are rounded. The base year is 2015. Source: Frost & Sullivan
OVERVIEW OF POCT-INFLUENZA

Influenza testing, a part of the infectious disease POCT, is the largest segment in terms of revenue. Rapid influenza diagnostic tests (RIDTs) are in high demand to support early diagnosis and disease management and are suitable to determine the cause of respiratory disease outbreaks. They can be used in remote settings and physician’s offices or clinics without laboratory services. The test typically does not require sophisticated laboratory equipment and can be interpreted by a healthcare practitioner in 5 to 15 minutes. Manufacturers are continuously trying to improve test sensitivity and specificity to compete with laboratory methods.

The influenza virus is divided into three types: A, B, and C. The predominant seasonal viruses are influenza A/H1N1, A/H3N2, and B. Globally, influenza A and B are among the leading causes of respiratory infections every year, affecting 5% to 10% of adults and 20% to 30% of children. Figure 16 shows diagnostic assays available in different laboratory settings.

Leading participants in the infectious disease segment are Alere, Quidel, Meridian BioScience

2 WHO-Biological-Vaccines: Influenza
Figure 16: Diagnostic Assays Available in Different Laboratory Settings, Global, 2015³

³ Use of Influenza Rapid Diagnostic Tests by WHO, 2010
Figure 17: Influenza Virus Testing Methods

<table>
<thead>
<tr>
<th>METHOD¹</th>
<th>TYPES DETECTED</th>
<th>ACCEPTABLE SPECIMENS²</th>
<th>TEST TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral tissue cell culture (conventional; yields live virus)</td>
<td>A and B</td>
<td>NP³ swab, throat swab, NP² or bronchial wash, nasal or endotracheal aspirate, sputum</td>
<td>3 to 10 days</td>
</tr>
<tr>
<td>Rapid cell culture (shell vials; cell mixtures; yields live virus)</td>
<td>A and B</td>
<td>As above</td>
<td>1 to 3 days</td>
</tr>
<tr>
<td>Immunofluorescence, direct or indirect (IFA) fluorescent antibody (DFA or IFA) staining (antigen detection)</td>
<td>A and B</td>
<td>NP³ swab or wash, bronchial wash, nasal or endotracheal aspirate</td>
<td>1 to 4 hours</td>
</tr>
<tr>
<td>RT-PCR⁵ (singleplex and multiplex; real-time and other RNA-based) and other molecular assays (influenza viral RNA or nucleic acid detection)</td>
<td>A and B</td>
<td>NP³ swab, throat swab, NP³ or bronchial wash, nasal or endotracheal aspirate, sputum</td>
<td>Varies (from 60 minutes to 8 hours)</td>
</tr>
<tr>
<td>Rapid molecular assay (influenza viral RNA or nucleic acid detection)</td>
<td>A and B</td>
<td>NP³ swab, nasal aspirate, wash, swab</td>
<td>&lt;30 minutes⁷</td>
</tr>
<tr>
<td>RIDTs⁶ (antigen detection)</td>
<td>A and B</td>
<td>NP⁴ swab, (throat swab), nasal wash, nasal aspirate</td>
<td>&lt;30 minutes</td>
</tr>
</tbody>
</table>

¹ Serologic (antibody detection) testing is not recommended for routine patient diagnosis
³ NP = nasopharyngeal
⁴ Reverse transcription polymerase chain reaction, including FDA-approved test systems, reference laboratory testing using ASR or lab-developed reagents
⁵ Chromatographic- and/or fluorescence-based lateral flow and membrane-based immunoassays
⁶ Alere i Influenza A&B was FDA cleared for use with both nasal swabs (direct) and NP or nasal swabs in VTM. It was CLIA-waived for use with nasal swabs (direct) only. Roche Cobas Influenza A/B was cleared and CLIA-waived by FDA for use with nasopharyngeal swabs only.

**COMPETITIVE LANDSCAPE**

Alere, Quidel, and Meridian Bioscience are active market participants in the infectious disease POCT including influenza. Other notable players are BD Diagnostics, Fisher Scientific, and SA Scientific. At the end of 2014, Roche Diagnostics launched a PCR molecular diagnostic system: the cobas® Influenza A/B test used for differential diagnosis of influenza A virus and influenza B virus RNA in 20 minutes or less. Figure 18 exhibits the list of selected commercially available RIDTs approved by the US FDA.

*Figure 18: List of Selected Commercially Available RIDTs Approved by the US FDA*

<table>
<thead>
<tr>
<th>PROCEDURE¹ (MANUFACTURER/ DISTRIBUTOR)</th>
<th>INFLUENZA VIRUS TYPES DETECTED</th>
<th>APPROVED SPECIMENS²</th>
<th>USES ANALYZER READER DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Directigen EZ Flu A+B³ (Becton-Dickinson &amp; Co.)</td>
<td>A and B</td>
<td>NP wash/aspirate/swab throat swab</td>
<td>No</td>
</tr>
<tr>
<td>BD Veritor System for Rapid Detection of Flu A+B³ (CLIA-waived), (Becton Dickinson &amp; Co.)</td>
<td>A and B</td>
<td>NP swab/ nasal swab</td>
<td>Yes</td>
</tr>
<tr>
<td>BD Veritor System for Rapid Detection of Flu A+B³ (Moderately Complex), (Becton Dickinson &amp; Co.)</td>
<td>A and B</td>
<td>NP wash/aspirate</td>
<td>No</td>
</tr>
<tr>
<td>Binax NOW® Influenza A&amp;B³ Test (Alere Scarborough Inc.)</td>
<td>A and B</td>
<td>NP swab, nasal wash/aspirate/swab</td>
<td>No</td>
</tr>
<tr>
<td>BioSign® Flu A+B³ or OraSure QuickFlu Rapid A+B Test or Polymedco Poly stat Flu A&amp;B Test or LifeSign LLC Status Flu A&amp;B (Princeton BioMedtech Corp.)</td>
<td>A and B</td>
<td>NP swab/aspirate/wash, nasal swab</td>
<td>No</td>
</tr>
</tbody>
</table>

Note:

1 List may not include all FDA-approved test kits. Discontinued tests not included.

2 Approved respiratory specimens according to manufacturer’s package insert. Note that test performance may vary if other respiratory specimens are used.

3 Distinguishes between influenza A and B virus infections

4 Does not distinguish between influenza A and B virus infections when used alone
## PROCEDURE\(^\text{1}\) (MANUFACTURER/DISTRIBUTOR)

<table>
<thead>
<tr>
<th>INFLUENZA VIRUS TYPES DETECTED</th>
<th>APPROVED SPECIMENS(^\text{2})</th>
<th>USES ANALYZER READER DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ClearView Exact II Influenza A &amp; B Test or Alere Influenza A &amp; B Test (Alere Scarborough Inc)</td>
<td>A and B</td>
<td>Nasal swab</td>
</tr>
<tr>
<td>OSOM® Influenza A&amp;B(^\text{3}) Test (Sekisui Diagnostics)</td>
<td>A and B</td>
<td>Nasal swab</td>
</tr>
<tr>
<td>QuickVue® Influenza A/B Test(^\text{4}) (Quidel Corp.)</td>
<td>A and B</td>
<td>Nasal wash/aspirate/swab</td>
</tr>
<tr>
<td>QuickVue® Influenza A+B Test(^\text{5}) (Quidel Corp.)</td>
<td>A and B</td>
<td>NP swab, nasal wash/aspirate/swab</td>
</tr>
<tr>
<td>RAMP Influenza A/B Assay or 3M™ Rapid Detection Flu A+B Test(^\text{3}) (Response Biomedical Corp.)</td>
<td>A and B</td>
<td>NP swab/aspirate, nasal wash/aspirate</td>
</tr>
<tr>
<td>SAS™ FluAlert A&amp;B Test(^\text{3}) (SA Scientific Inc.)</td>
<td>A and B</td>
<td>Nasal wash/aspirate</td>
</tr>
<tr>
<td>SAS™ Influenza A Test(^\text{3}) (SA Scientific Inc.)</td>
<td>A only</td>
<td>Nasal wash/aspirate</td>
</tr>
<tr>
<td>SAS™ Influenza B Test(^\text{3,4}) (SA Scientific Inc.)</td>
<td>B only</td>
<td>Nasal wash/aspirate</td>
</tr>
<tr>
<td>Sofia® Analyzer and Influenza A+B FIA(^\text{3}) (CLIA-waived) (Quidel Corp.)</td>
<td>A and B</td>
<td>NP swab, Nasal swab</td>
</tr>
</tbody>
</table>

Note:
\(^1\) List may not include all FDA-approved test kits. Discontinued tests not included.
\(^2\) Approved respiratory specimens according to manufacturer’s package insert. Note that test performance may vary if other respiratory specimens are used.
\(^3\) Distinguishes between influenza A and B virus infections
\(^4\) Does not distinguish between influenza A and B virus infections when used alone
### OVERVIEW OF POCT-CANCER

Globally, non-communicable diseases including cancer are growing rapidly, but instant and accurate methods of cancer diagnosis are limited. In 2015, the global cancer/tumour profiling technologies market was valued at US$38.17 billion; expecting to reach US$61.80 billion by 2019. The market is skewed towards diagnostic POCT. Immunoassays are commonly used for cancer detection; most cancer POCT uses body fluids such as blood, urine, or sputum within 50ul to 200ul or fecal solids. Reliance of POCT for cancer diagnosis remains low; technology for the detection of various cancer biomarkers is being used for early detection prior to detailed diagnosis procedures.

The fecal occult blood test (FOBT) is the prominent POCT for cancer at the patient’s bedside. FOBT detects blood in the stool and is performed as part of routine examinations to screen primarily for colorectal cancer. There are a growing number of private rapid-test manufacturers providing FOBTs; market leaders include Beckman Coulter, Alere, Enterix, Quidel, Aerscher Diagnostics, Hemosure, and Stanbio.

POCT for early diagnosis of bladder cancer, breast cancer and prostrate is becoming popular. The NMP22 BladderChek Test by Alere is fast and non-invasive and provides a result within 30 minutes. The test mainly supports in early diagnosis and monitoring of bladder cancer, while the patient is receiving treatment.

Another emerging type of POCT is for prostate cancer. Imego and Fujirebio (formerly known as CanAg Diagnostics AB) developed a new POCT technology platform for prostate specific antigen (PSA) in blood serum. The instrument is based on fluorescent sandwich immunoassay performed on serum samples. The generic platform can be modified for detection of other serum-carried disease markers.

Despite limited commercially available POCT devices, advancements in molecular diagnostics and microfluidics technology are expected to expand rapidly in the oncology market. POCT is expanding to detect oral, gastrointestinal, cervical, and skin cancers.
### VI. UNIQUE ASPECTS OF THE SG CAP™ TECHNOLOGY

Multiplexing is a recent technology that is able to detect or measure multiple analytes simultaneously on the same platform. SG Cap™ technology offers this innovative, molecule-capturing, multiplex diagnostics system in a point of care setting. The technology, developed by South Korea-based PCL Inc, studies molecular interactions, including drug-target pairs and protein-protein relationships. PCL successfully developed its highly-sensitive microarray-based multiplexing platform to aid in the biomarker detection of HIV, HCV, HBV infectious diseases, multiple respiratory virus detection, and multiple cancer diagnosis. Figure 19 shows the application of SG Cap™.

SG Cap™ technology employs the properties of PCL’s proprietary SolB™ reagent, that captures compounds in their natural 3D form to significantly minimise diffusion distances and increase load capacity. SolB™ captures most types of molecules including:

- Small molecules and chemicals
- Nucleotides
- Peptides and small proteins
- Antibodies and large proteins
- Nucleic acids and aptamers
- Tissue, cell, and bacterial lysates

**Figure 19: Application of SG Cap™**

<table>
<thead>
<tr>
<th>IMMOBILIZED MATERIAL</th>
<th>TEST MATERIAL</th>
<th>APPLICATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>Protein, DNA, aptamer, chemical compound</td>
<td>o Disease diagnosis&lt;br&gt; o Binding test&lt;br&gt; o Binding partner ID</td>
<td></td>
</tr>
<tr>
<td>Chemical compound</td>
<td>Aptamer, protein</td>
<td>o SELEX process&lt;br&gt; o Binding test&lt;br&gt; o Drug target ID&lt;br&gt; o Drug repositioning</td>
<td></td>
</tr>
<tr>
<td>Aptamer</td>
<td>Protein, chemical compound, small molecules</td>
<td>o Disease diagnosis and molecular detection&lt;br&gt; o Binding test</td>
<td></td>
</tr>
<tr>
<td>Cell lysate</td>
<td>Protein</td>
<td>o Confirmation of protein expression profile</td>
<td></td>
</tr>
</tbody>
</table>
Figure 20: SG Cap™ Technology in Comparison to 2D Protein Chip and ELISA Kit

<table>
<thead>
<tr>
<th>Feature</th>
<th>2D Protein Chip</th>
<th>SG Cap™</th>
<th>ELISA Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiplex</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Automation</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>High-throughput</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Sample Processing</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

Figure 21: SG Cap™ Microarray Technology Platform

- **Hi3-1, Hi3**: HIV/HCV/HBV multiplex kit
- **Hi4**: HIV/HCV/HBV/HTLV multiplex kit
- **Ai**: Influenza A/B POC kit
- **Cancer 6**: 6-cancer multiple diagnostic platform
VII. CONCLUSION: SG CAP™ TECHNOLOGY UNLOCKING THE POTENTIAL OF DIAGNOSTICS AND POCT INDUSTRIES

Worldwide, the total IVD market is expected to reach US$71.9 billion by 2019. The blood transfusion diagnostics market is divided by disease screening and blood grouping, with the latter dominating the industry in most regions. POCT is another segment of the IVD market fast-gaining popularity globally. POCT (Influenza) is among the largest segment from a revenue perspective. However, reliance on POCT for diagnosis of cancer remains low. Growing awareness and ongoing R&D is anticipated to enhance this segment in years. The SG Cap™ platform is helping to revolutionize the global IVD and POCT market.

PCL developed the cutting-edge SG Cap™ platform for the global IVD and POCT markets. The patented SG Cap™ material screening technology can detect small molecules, proteins, peptides, and antibodies.

Figure 22: Sol-Gel Microarray Technology ⁵

⁵ PCL Official Website: Mission- Sol-Gel Diagnostic Technology
SG CAP MICROARRAY TECHNOLOGY

- The multiplex analysis system enables diagnosis of multiple diseases and disease markers in one well (single 96-well plate).
- The innovative system also is compatible with the ELISA 96-well platform and automated system.
- SG Cap™ Platform – Hi3, Ai and Cancer 6 used for multiple disease diagnostics.

The Sol-Gel diagnostic technology facilitates blood transfusion diagnostics and POCT for influenza and cancer. Unlike other blood transfusion diagnostic kits, SG Cap™ technology is able to diagnose HIV, HBV, HCV, and HTLV simultaneously.

Figure 23: Technology Comparison for IVD and POCT, Global, 2015

Globally, the IVD and POCT market is highly fragmented with various solution providers based on the type of technology innovation. SG Cap™ technology appears to be superior due to its high sensitivity and specificity compared to other commercially available technology platforms.

In coming years the SG Cap™’s Cancer6 technology is expected to be in demand in the global POCT market, mainly due to the limited availability of cancer POCT. As a result, most manufacturers are working to address the growing need for non-communicable diseases POCT.
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