

quantitation and analysis of extremely large numbers of these particles give flow cytometry flexibility and sensitivity. With the addition of multiple antibodies and fluorescent dyes, flow also answers the need for multiplexed testing.

Kalorama estimates the world market for flow cytometry was \$XX xxxx in 2006, and with XX% annual growth will reach \$XX by 2011. Two companies dominate the clinical flow cytometry industry, though the growth potential of this technology is attracting a number of innovators. XXXXXXXX and XXXXXXXX XXXXXX together hold XX% of the flow market in 2006. The remaining market share (excluding bead-based flow tests and urinalysis by flow cytometry) is held by several flow system companies and vendors of labeled antibodies and probes used in clinical in-lab developed tests and research laboratories.

Table 5-3

**Revenue History of Leading Companies in Flow Cytometry
2001-2006**

Company	Revenues (in millions)					
	2001	2002	2003	2004	2005	2006

Source: Company Reports

This market evaluation is deceiving. As shown in Tables 5-4 and 5-5, many more companies are active in this sector, including those that supply flow reagents including: antibodies, probes, microspheres, dyes, etc. The majority of these products are used for in-lab developed tests, medical research, or industrial product analysis. This flow market segment is not included in the market assessment presented. It is beyond the scope of this market to give a precise evaluation, but Kalorama anticipates the market for non-clinical flow products to be \$XX—\$XX xxxx in 2006, made up mainly of reagent products.

Flow cytometry has become so pervasive in research that several companies now market flow specific software solutions. Applied Cytometry Systems, Sacramento, CA markets cytometry analysis software; BD Diagnostics, Franklin

number of technological advancements also contribute to the growth. Automated sample preparation systems and digital analysis instrumentation have replaced lower cost manual methodologies. The result has allowed for same day same-day biopsy results and better patient care.

The new automation has also allowed some movement of histology from hospital and reference laboratories to large physician practices in the U.S. These new systems allow less experienced pathology technologists to process some samples, which are then read by digital imaging systems. Since 2004, or so, there is an increasing trend toward the establishment of histology laboratories in physician offices, particularly gastroenterology, urology, and dermatology practices. In-office pathology labs generally process samples such as prostate biopsies, urines for cancer and small tumors on fingers, genitalia and the skin.

Histology and cytology testing are a phenomenon of the developed world, therefore at least XX% of the world market for histology/cytology products is held by North America, Japan, Western Europe and Latin America. The world market for the diagnostic reagents, stains and instruments used in histology and cytology has been estimated at \$XX xxxx in 2006. Emphasis on XXXXX diagnostics will make for XX% annual growth in this segment to reach \$XX in 2011.

Traditional stains used on all types of formalin fixed, paraffin embedded tissues and fluids make up the most mature area in this market. The most widely used stain is the hematoxylin & eosin (H&E) stain used to provide a general overview of tissue structures and cells. A number of other stains are also widely used including: congo red, elastin, feulgin, giemsa, Gomori, iron, Masson, PAS (periodic acid schiff) and reticulín. This segment of histology is estimated at \$XX xxxx in 2006 and is growing steadily at XX% annually to reach \$XX xxxx in 2011. The major players are listed below. XXXX is the leader with XX-XX% of the market.