



Global Hematology Analyzer Market: Industry Analysis and Forecast, 2016-2024

By-

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Submitting to:- IIHMR University

Working Organization:- Future Market Insights

Introduction

- Hematology analyzer is quantitative, clinical laboratory instrument which provides a complete blood count, leukocyte differential count and reticulocyte analysis for in vitro diagnostic use.
- The simplest analyzer can perform multiple parameter analysis. The most basic analyzer perform 17 parameter analysis (even less that in few cases). By contrast, the advanced analyzers can measure up to 50 parameters or even more than that.
- Current hematology analyzers use a different combination of techniques like electrical impedance, light absorption, fluorescence, light scatter, and electrical conductivity methods to produce complete red blood cell, platelet, and leukocyte analyses. Presently used hematology analyzers are incorporated with flow cytometry which gives cell size, cell granularity and cell composition.
- Analyzers increases sensitivity and specificity by reducing the manually verification of abnormal or flagged patient results by combining different techniques (like combining the impedance, light transmission, cytochemistry, and fluoro-flow cytometry). This has improved the accuracy in counting, low-incidence cell and various immature cells.
- Hematology analyzer also provide information about bone marrow, which is the blood forming-tissue (Used to diagnosis). Conditions like anemia, acute and chronic illness, bleeding tendencies and white blood cell disorders can be diagnosed by Complete blood count and cell morphology.
- The Complete Blood Count and Differential Blood Count are used to diagnose during the last quarter century, blood cell analysis is progressed from the use of labor-intensive manual procedures to the use of highly automated instruments.

Working Principle

- The basic techniques used in hematology analyzers are: flow cytometry, fluorescent flow cytometry, and electrical impedance
- For example, electrical impedance is used to differentiate red blood cells (RBCs) from WBCs, and platelets by volume.
- Flow cytometry is more expensive than electrical impedance analysis technique, but it gives more detailed information about the blood cell morphology. It is used for determining five-part differentials of WBC along with CBC.
- Specific cell population of blood can be determined by adding fluorescent reagent to the sample along with the flow cytometry. The ratio of nucleus-plasma in each stained cell can be revealed by fluorescent dyes. It is also useful for the platelets analysis, nucleated RBC and reticulocyte count.

Product Overview

The 3-part differential analyzer:-

- It is used to measure the volume of white blood cells electrically and classifies the cells, according to their size, into three types: lymphocytes (small WBC group), monocytes, eosinophils, and basophils (a medium-sized WBC group), and neutrophils (a large WBC group).

Product Overview (Cont.)

The 5-part differential analyzer

- The 5-part differential analyzer can differentiate WBC into neutrophils, lymphocytes, monocytes, eosinophil's, and basophils.
- It is used for Multi-dimensional analysis like Cell Complexity, DNA/RNA content, Cellular content, and Cell size but never in isolation.

The 6-part differential analyzer:-

- The 6 part differential analyzer is used for measurement of immature granulocytes (IG) along with 5 varieties of WBC i.e. neutrophils, lymphocytes, monocytes, eosinophil's, and basophils.
- Higher nucleic acid content in comparison with mature granulocytes is used for identification of immature granulocytes by using fluorescence flow cytometry of 6 part Differential Analyzer. Promyelocytes, myelocytes and metamyelocytes are types of Immature Granulocyte but not band cells.

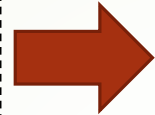
Guidelines –Hematology Analyzers

Hematology Analyzers comes under Class II medical device

FDA Guidelines:-

Special Controls

- Special controls are regulatory requirements for class II devices. FDA classifies into class II devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.



Special controls are usually device-specific and include:

- Performance standards
- Postmarket surveillance
- Patient registries
- Special labeling requirements
- Premarket data requirements
- Guidelines

European Guidelines

Hematology Analyzer are one among the In-Vitro Diagnostics

- Whereas the major part of medical devices are covered by Council Directive 90/385/EEC of 20 June 1990 on the approximation of laws relating to active implantable medical devices (2) and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (3) with the exclusion of in vitro diagnostic medical devices; whereas this Directive seeks to extend the harmonisation to in vitro diagnostic medical devices and whereas, in the interest of uniform Community rules, this Directive is based largely on the provisions of the said two Directives;
- Whereas, in Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (2), the Council laid down harmonised conformity assessment procedures;
- Whereas medical devices should, as a general rule, bear the CE marking indicating their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;

Japan Guidelines

- **Pre-market Certification (*Ninsho*).** To register and market most Class II IVDs, the D-MAH/MAH (Designated Market Authorization Holder) needs to file a Pre-Market Certification application with a Registered Certification Body (RCB), e.g., BSI (British Standard Institution), TUV (Technical Inspection Association), SGS (Société Générale de Surveillance) etc., and obtain their certification. Several European Notified Bodies are also Japanese RCBs.

Rationale

- The study is useful to:
- Understand the market scenario of the Hematology Analyzers.
- Understand drivers and restraints of the market
- Give ideas about market share of the product, modality, end user and region wise segments respectively.

Background

- This Study is designed to understand the market potential of hematology analyzers in five different regions (North America, Latin America, Europe, APAC and MEA) with the help of historical data.

Hematology analyzer market: Segmentation

➤ Segmentation based on product

- 3-part differential hematology analyzer
- 5-part differential hematology analyzer
- 6-part differential hematology analyzer

➤ Segmentation based on modality

- Standalone Analyzers
- Point of care Analyzers

➤ Segmentation based on End users

- Hospitals
- Diagnostic Centers
- Ambulatory Surgical centers
- Blood Banks

➤ Segmentation based on Region

- North America
- Latin America
- Europe
- APAC (Asia & Pacific)
- MEA (Middle East & Africa)

Research Question

- What is the market potential of Global Hematology Analyzers?

Objectives

- To identify market attractiveness of all segments
- To find out the dominant region in the global Hematology Analyzer Market
- To identify the Opportunities and Trends of the Market

Methodology

- **Study Method**

Secondary Research

- **Study type**

Retrospective study

- **Sample size**

41 annual reports and 20 articles

Methodology (Cont.)

Data collection

- Secondary data
 - **Secondary data**- Historical data is collected from various corporate filling like annual report of the companies and U.S. Securities and Exchange Commission (SEC). Other sources include balance sheets, sales figures, Inventory record, and previous marketing research studies.

Research Instrument (tools and techniques)

- The data is collected by historical trend examination and thorough secondary research. M.S Excel is used for statistical analysis and CAGR (Calculated from historical data) used to for forecasting (Forecasting period 2016-2024).

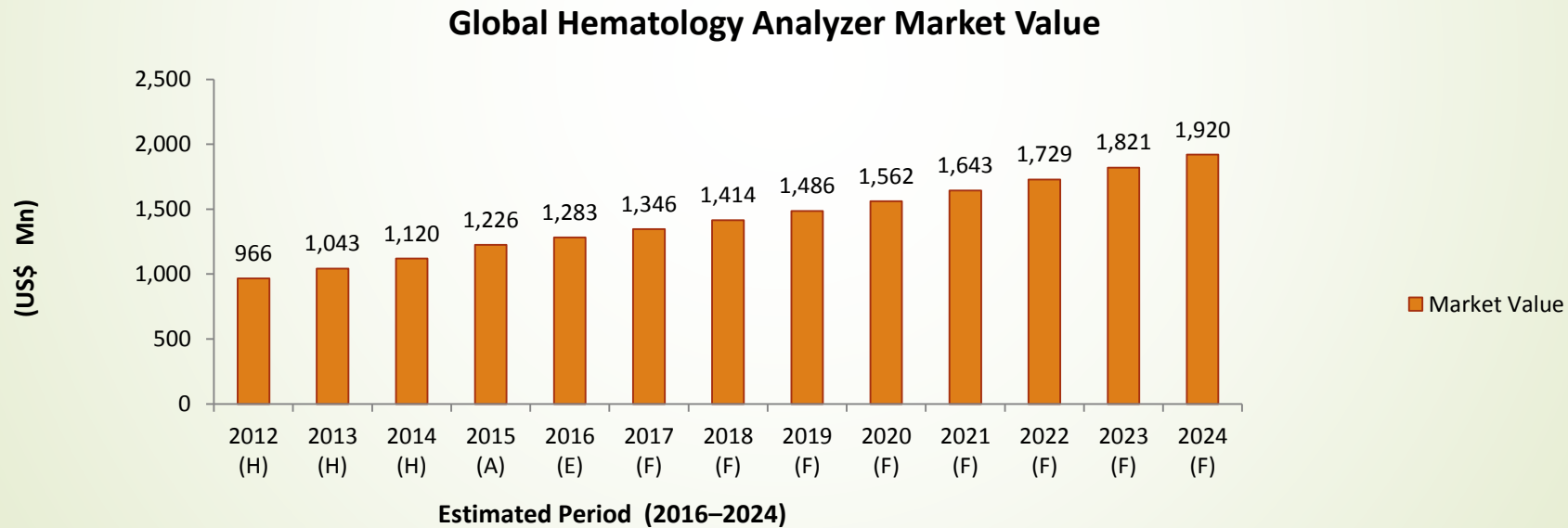
Study duration

- 3 months (6st February to 6th May)

Data Analysis (Findings & Inferences)

1. Estimated & Forecasted global Hematology Analyzer Market Value (US\$ Mn), 2016–2024

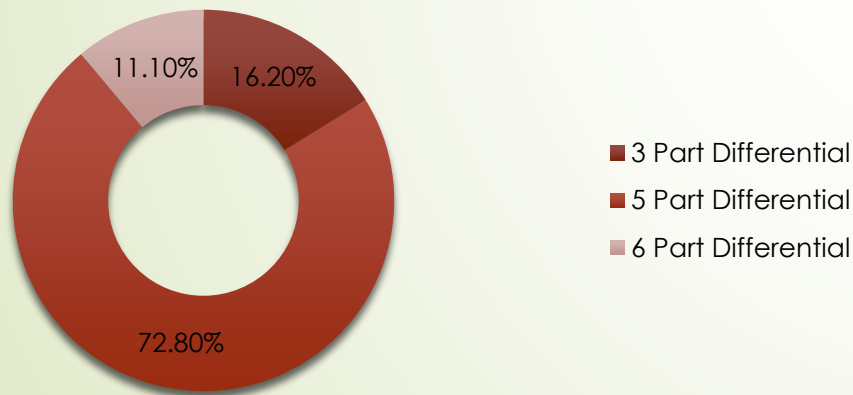
- The global Hematology Analyzer market is anticipated to expand at a CAGR of 5.2% between 2016 and 2024.
- Increasing prevalence of diseases require continuous diagnosis for controlling the diseases, which is expected to boost demand for Hematology Analyzer market over the forecast period.



2. Estimated & forecasted global Product Segment Share, 2016–2024

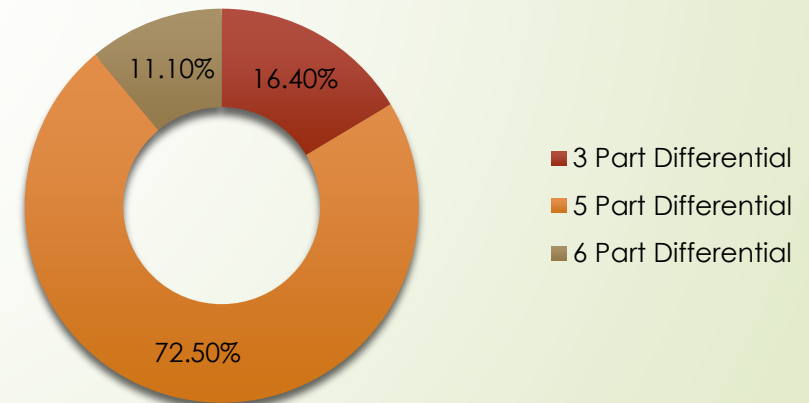
- 3 Part Differential Analyzer segment is owing to the stable growth and expected to grow at 5.3% CAGR during the forecast period.
- 5 Part Differential Analyzer segment is expected to account for major revenue share of the global Hematology Analyzer market.
- 6 Part Differential Analyzer segment is owing to the increased adoption of 6 Part Differential Analyzer during the forecast period.

Product Segment Share



Estimated global hematology analyzer product share 2016

Product Segment Share

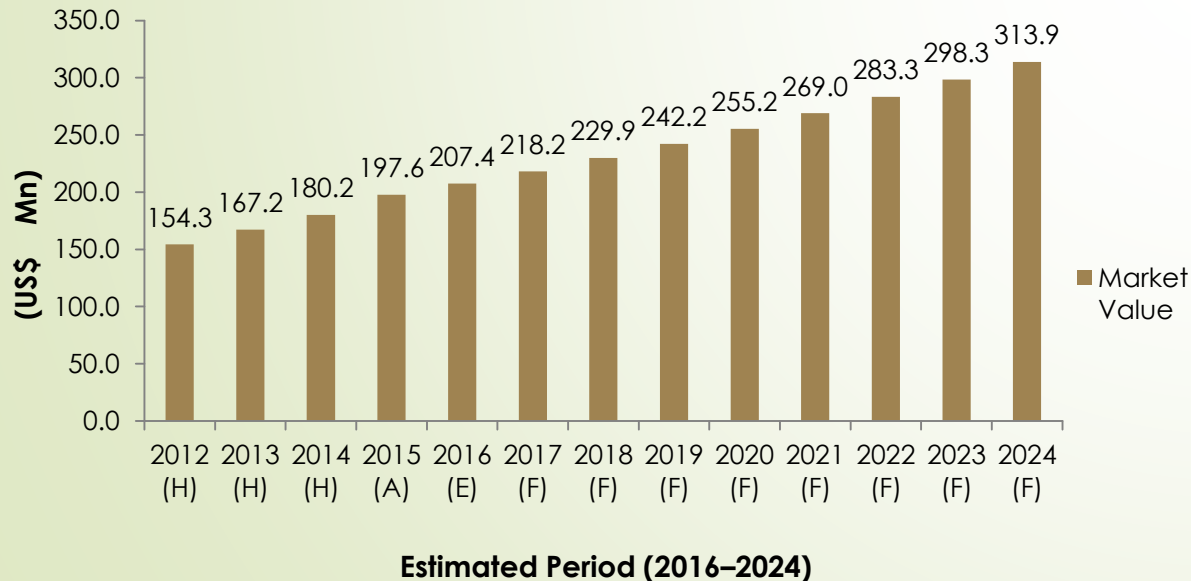


Forecasted Global Product Segment share, 2024

3. Estimated & forecasted Global 3 Part Differential Analyzer Segment Value (US\$ Mn), 2016–2024

- 3 Part Differential Analyzer segment is anticipated to expanding at a 5.5% CAGR over the forecast period.
- The increases in the application rate of 3 part differential analyze due to its low cost is expected to boost the demand over the forecast period.

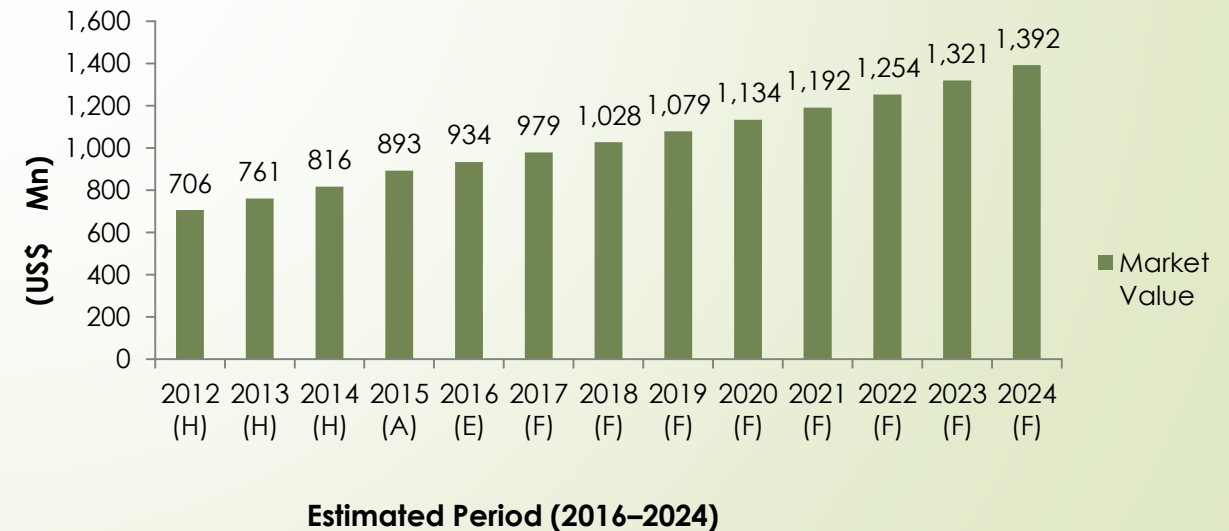
3 Part Differential Analyzer Segment Value



4. Estimated & forecasted Global 5 Part Differential Analyzer Segment Value (US\$ Mn), 2016–2024

- The demand for 5 Part Differential Analyzer is expected to grow at 5.6% over the forecast period owing to increasing acceptance in emerging countries.

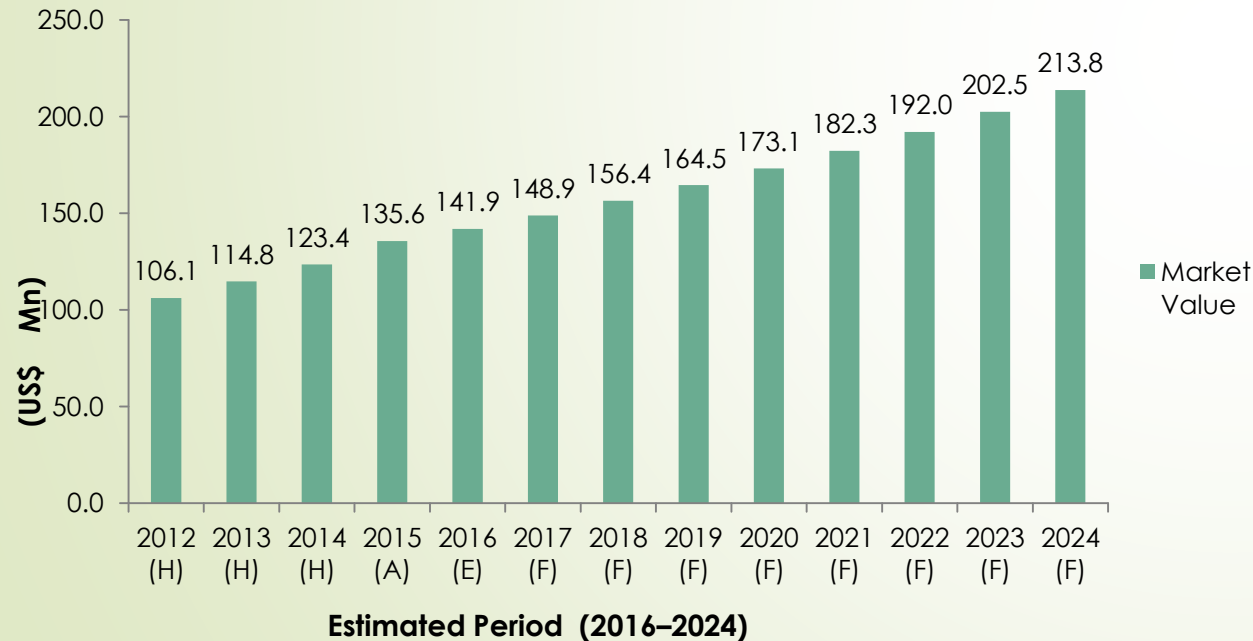
5 Part Differential Analyzer Segment Value



5. Estimated & forecasted Global 6 Part Differential Analyzer Segment Value (US\$ Mn), 2016–2024

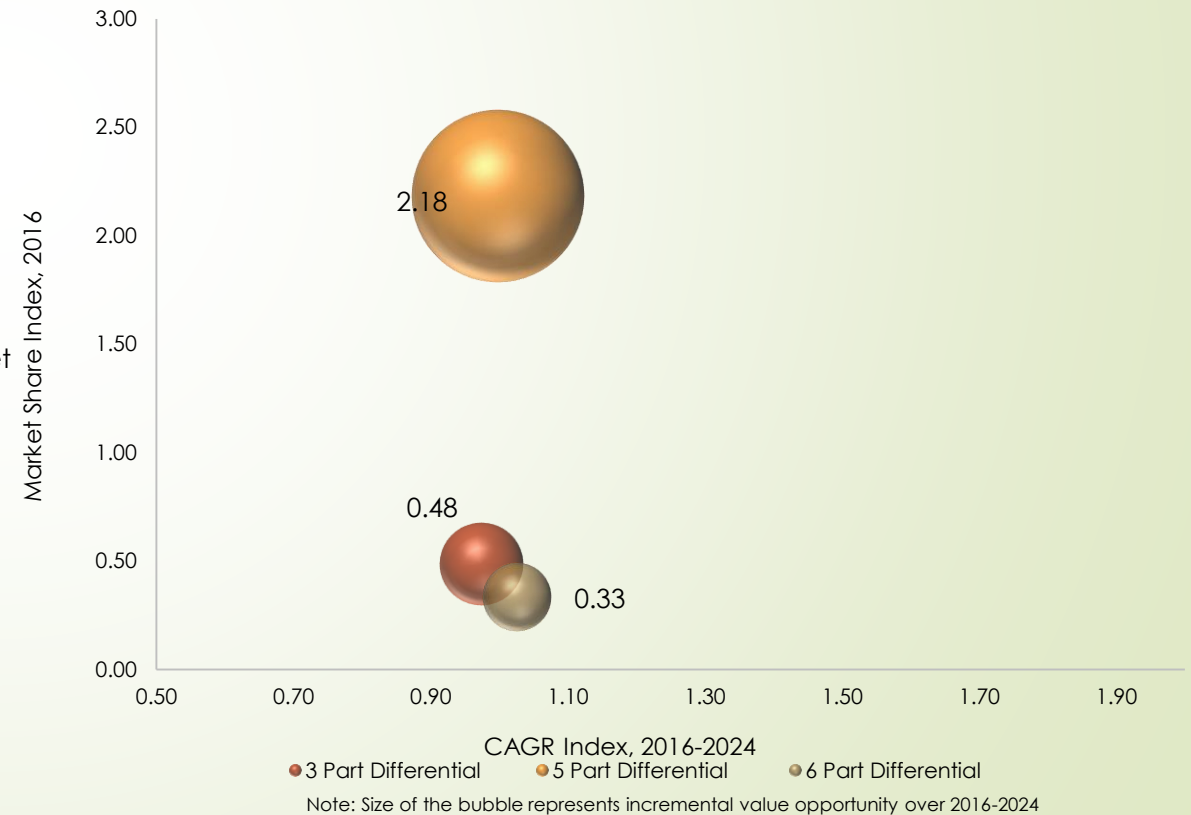
The demand for 6 Part Differential Analyzer is expected to grow at 5.6% CAGR over the forecast period owing to technological advancements of 6 Part Differential over the other two product types.

6 Part Differential Analyzer Segment Value



6. Market attractiveness of global Hematology Analyzer product segment

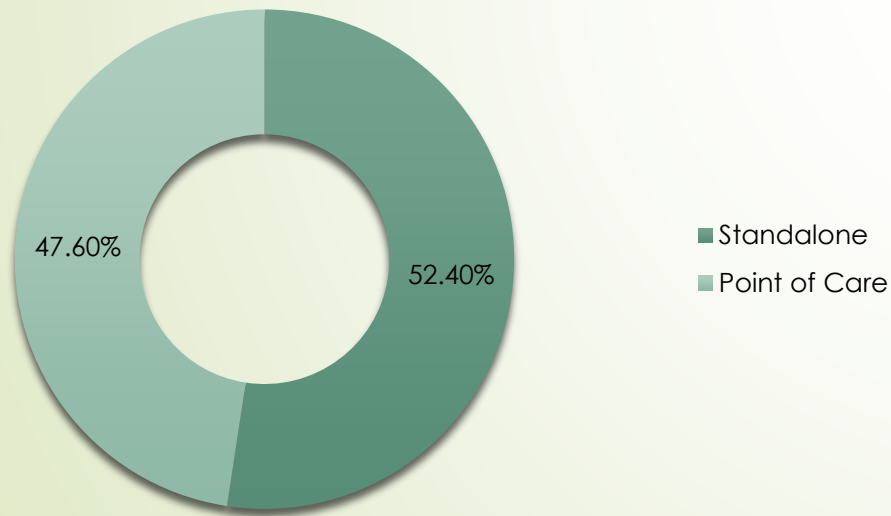
5 Part Differential Analyzer segment dominated the global Hematology Analyzer market in revenue terms in 2015 and is projected to continue to do so throughout the forecast period. 5 Part Differential Analyzer segment is the most attractive segment, over the forecast period.



7. Estimated & forecasted global modality Segment Share, 2016–2024

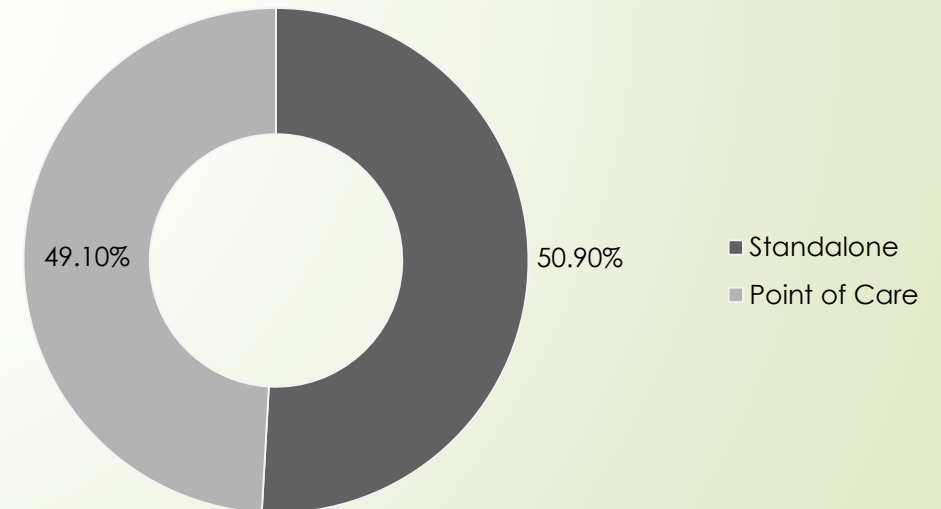
- Standalone is expected to account for major revenue share of the global Hematology Analyzer market by 2016, as the Standalone Analyzers are mostly preferable in the large scale hospitals.
- Point of Care is expected to account for minor revenue share of the global Hematology Analyzer market due to owing presence of large number of small scale hospitals.

2016 Estimated Share of Modality Segment



Estimated global hematology analyzer modality share

2024 Forecasted share of Modality Segment

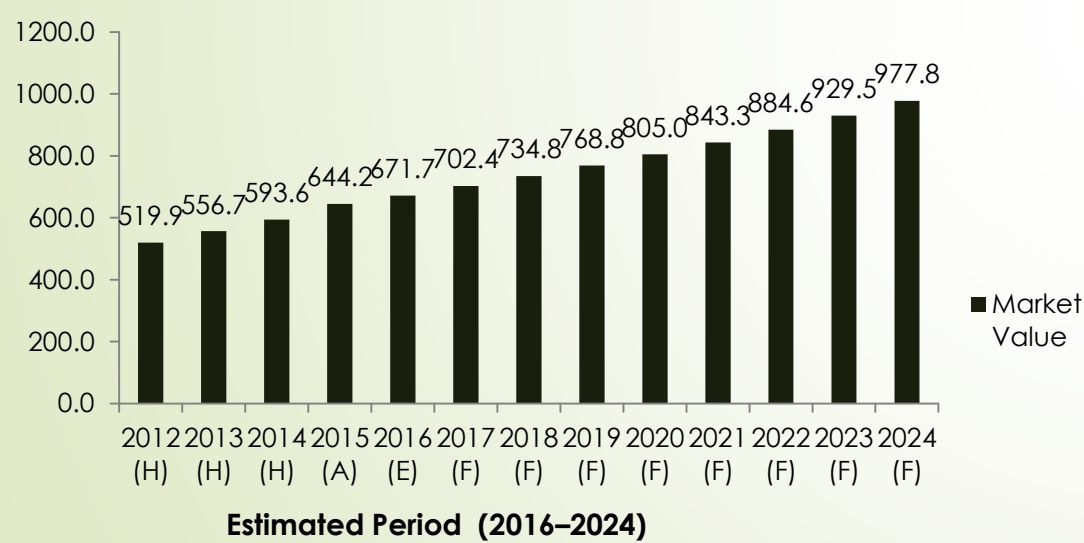


Forecasted global hematology analyzer modality share

8. Estimated & forecasted global standalone Segment Value (US\$ Mn), 2016–2024

- Standalone Analyzer is high Capital based instruments with multiple functions and more advantageous over the small capital based instruments. It is stable growing segment in developed countries and expected to grow at 5.3 %CAGR.

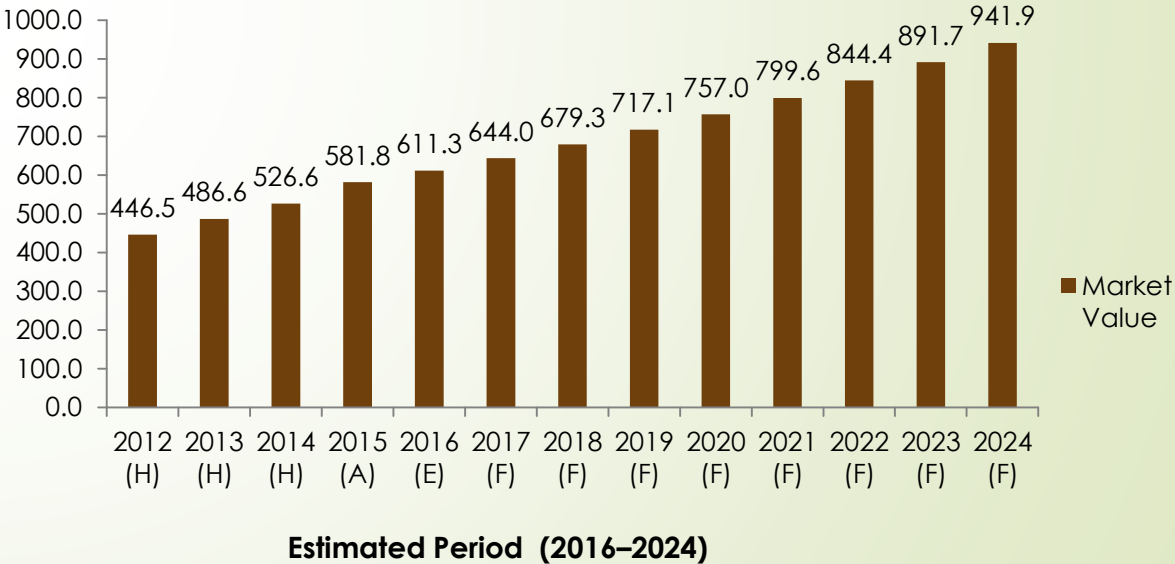
Standalone Segment Value



9. Estimated & forecasted global Point of Care Segment Value (US\$ Mn), 2016–2024

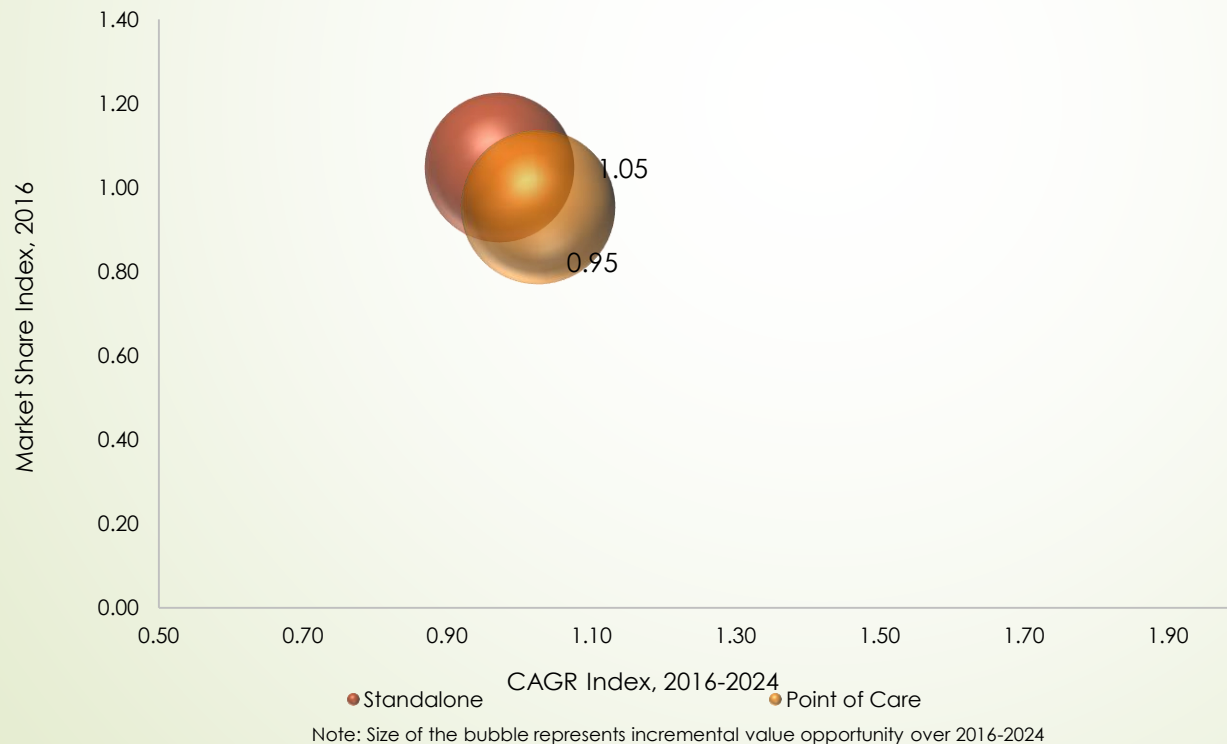
- Point of Care is best suited in small hospitals with less bench space and increases the flexibility of Diagnosis. It is fastest growing segment in the emerging countries with 5.6 % CAGR.

Point of Care Segment Value



10. Market attractiveness of Modality segment

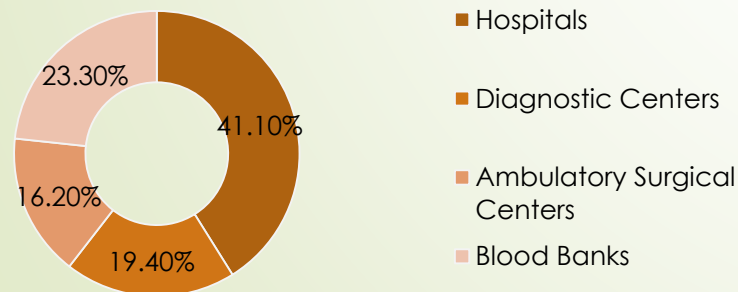
- ▶ Standalone segment dominated the global Hematology Analyzer market in revenue terms in 2015 and is projected to continue to do so throughout the forecast period. Modality segment is the most attractive segment, with during the forecast period
- ▶ Point of Care segment is expected to be the second most lucrative segment in the global Hematology Analyzer market, over the forecast period



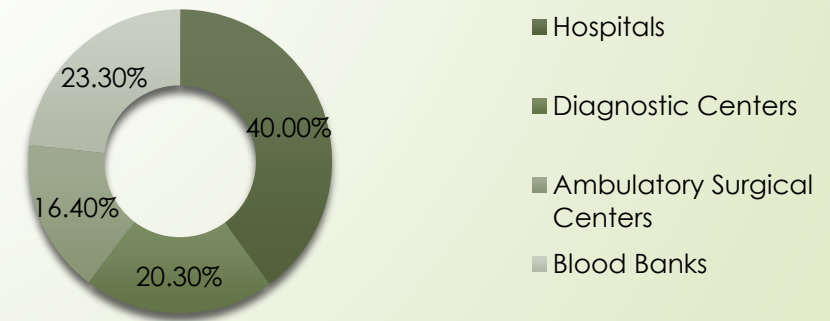
11. Estimated & forecasted global End User Segment Share, 2016–2024

- Hospitals segment is expected to lose in its market share by 2024 over 2016, due to decreasing number of hospital visits for diagnosis purpose.
- Diagnostic Centers segment is expected to gain its market share by 2024 over 2016 due to large number of diagnostic centers worldwide and easy availability of the diagnosis through this segment.
- Ambulatory Surgical Centers segment is expected to gain its market share by 2024 over 2016, due to increasing patient compliances with this segment.
- Blood Banks segment is owing to high stable growth due to high regulatory control.

2016 Estimated Share of End User Segment



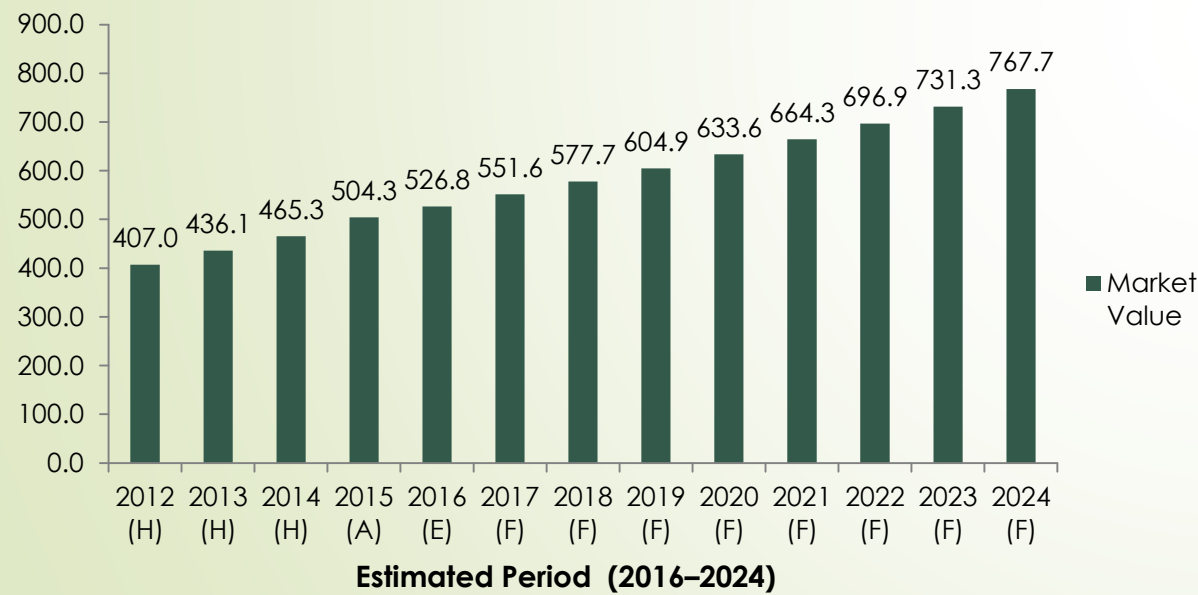
2024 Forecasted share of End User Segment



12. Estimated & forecasted global Hospital Segment Share Value (US\$ Mn), 2016–2024

It has been witnessed that the demand for Hematology Analyzers is remains constant in hospitals. It is expected to grow at 4.9 % CAGR.

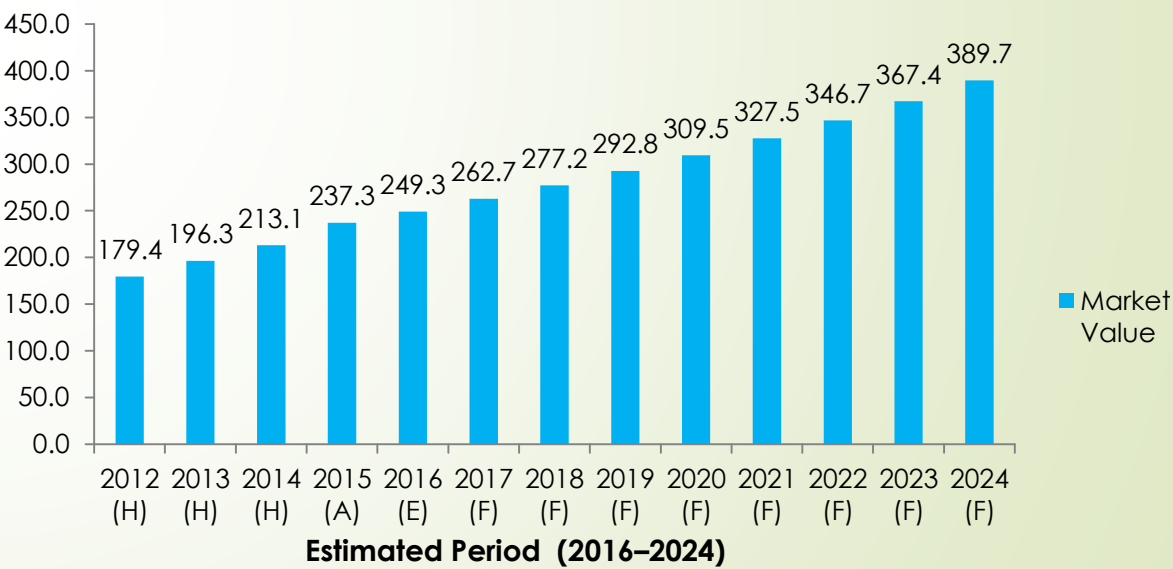
Hospital Segment Value



13. Estimated & forecasted global Diagnostic Center Segment Share Value (US\$ Mn), 2016–2024

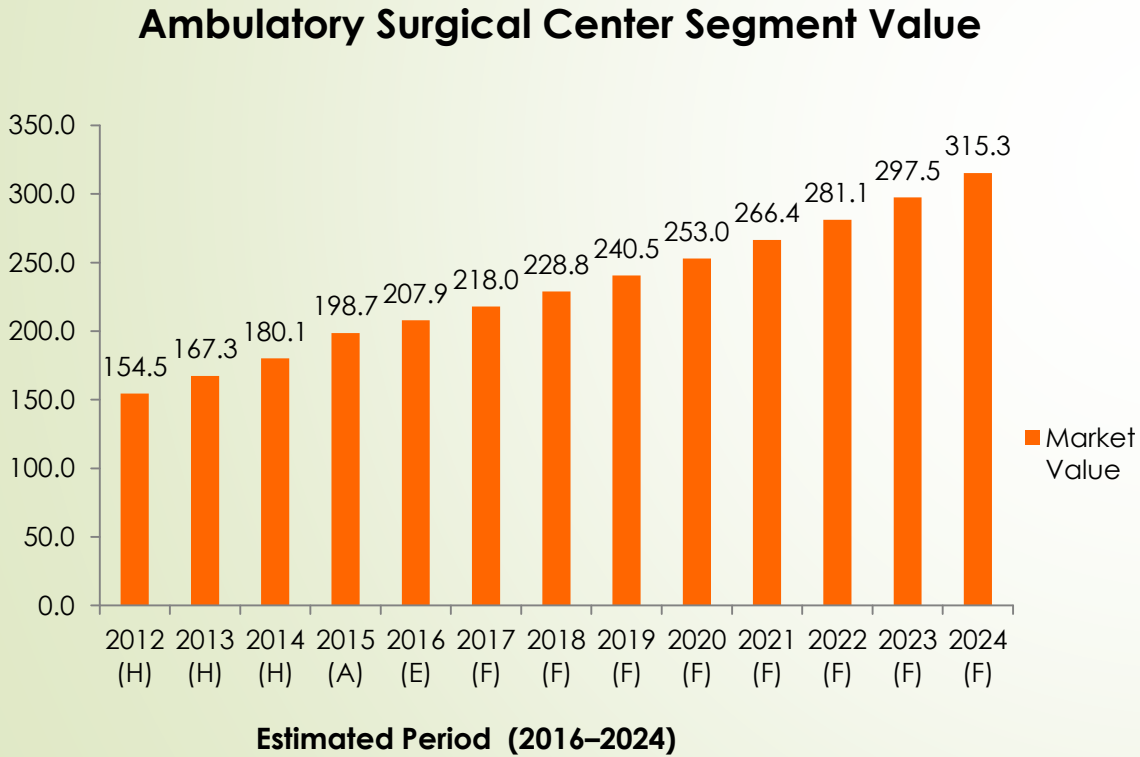
Increasing convenience with diagnostic centers is expected to boost the growth of the End User segment over the forecast period. It is expected to grow at 6.1 % CAGR.

Diagnostic center Segment Value



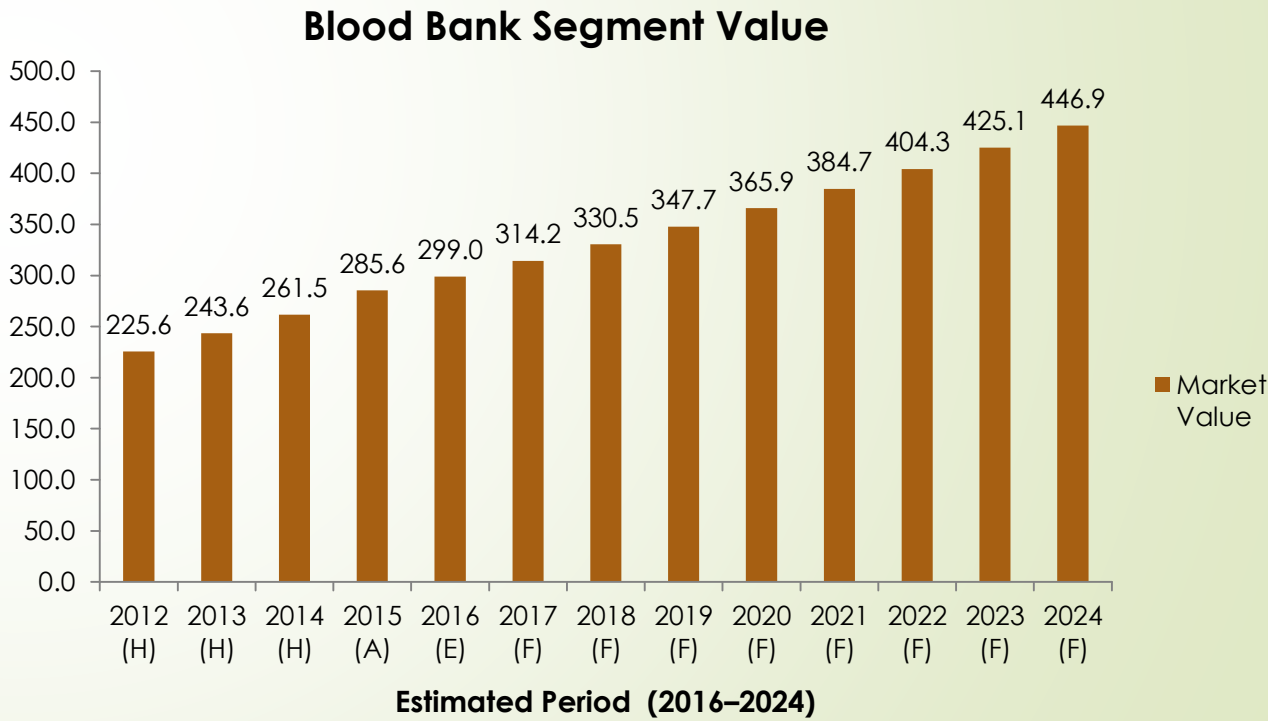
14. Estimated & forecasted global Ambulatory Surgical Center Segment Share Value (US\$ Mn), 2016–2024

Increasing cases in Ambulatory surgical centers for emergency purposes is expected to boost the growth of the Hematology Analyzer Market. It is expected to grow at 6 % CAGR.



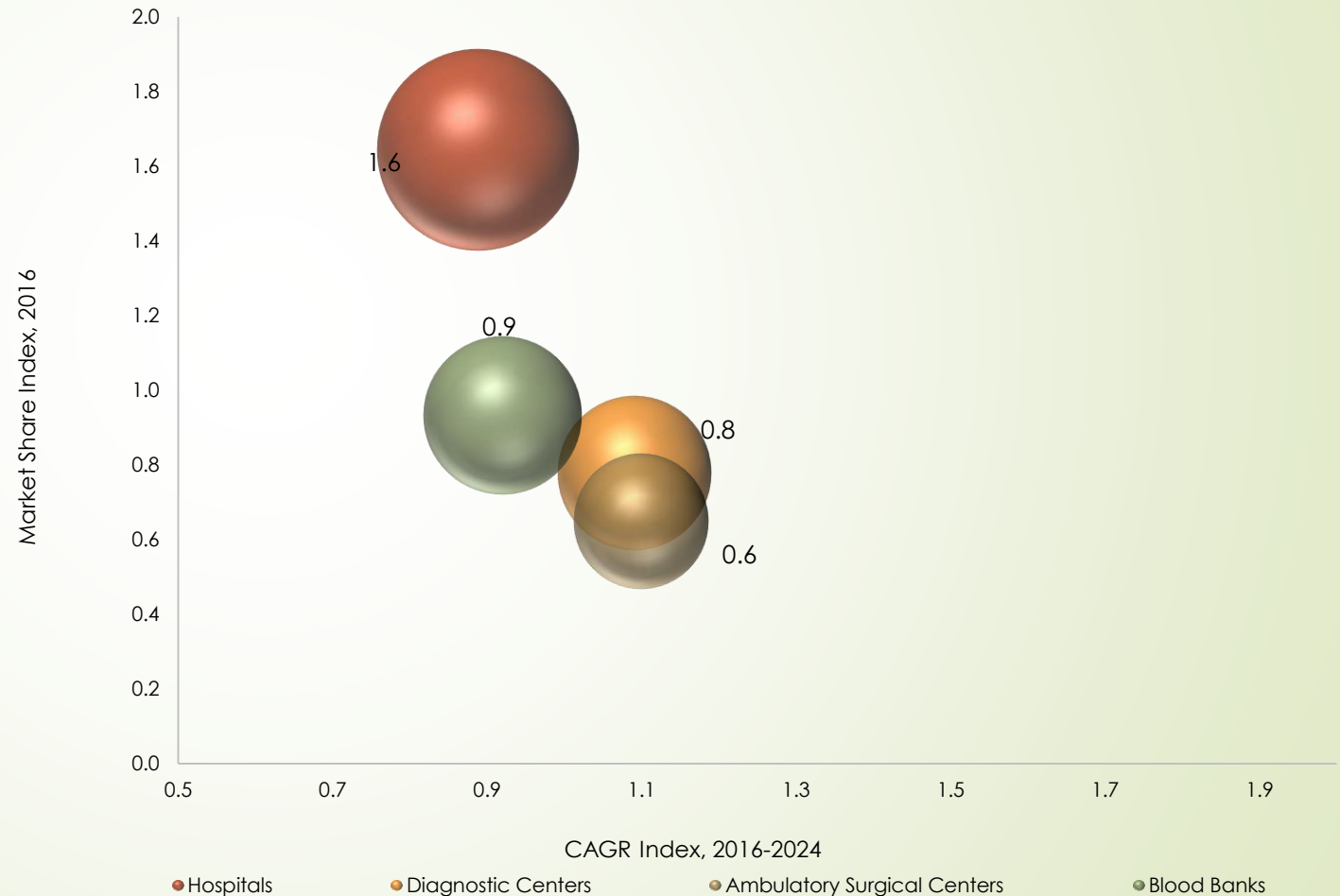
15. Estimated & forecasted global Blood bankSegment Share Value (US\$ Mn), 2016–2024

Owing to increasing blood donations due to rising awareness in the developing countries is expected to boost demand for Hematology Analyzers in Blood Banks segment. It is expected to grow at 5.2% CAGR.



16. Market attractiveness of End User segment

- Hospital segment dominated the global Hematology Analyzer market in revenue terms in 2015 and is projected to continue to do so throughout the forecast period. This segment is the most attractive segment during the forecast period
- Blood bank segment accounted for second major value share in 2015 and is projected to remain same by 2024 end, during the forecast period
- Diagnostic center segment is expected to be the third most lucrative segment in the global Hematology Analyzer market, during the forecast period
- Ambulatory Surgical Centers segment is expected to be the almost same attractive segment like diagnostic center segment in the global Hematology Analyzer market, during the forecast period



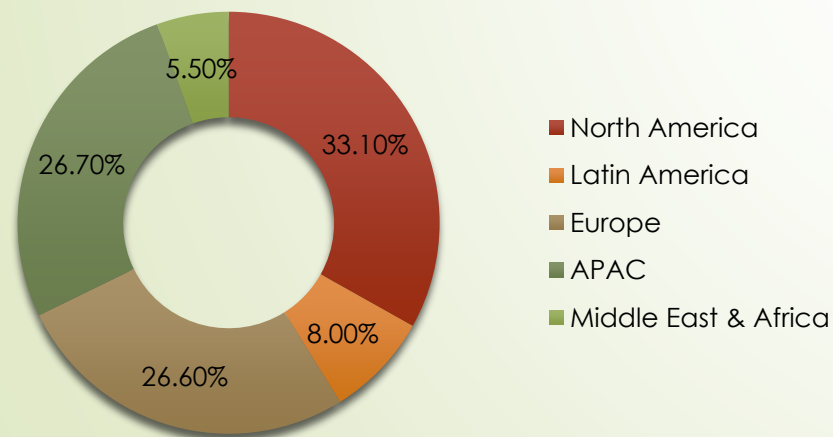
Source: PMR, 2016

Note: Size of the bubble represents incremental value opportunity over 2016-2024

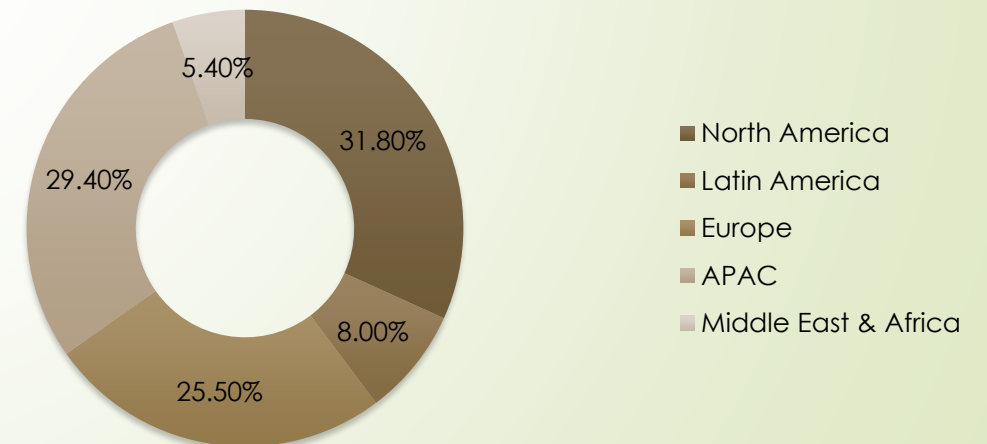
17. Estimated & forecasted region wise Segment Share, 2016–2024

- ▶ North America regional market is expected to account for major revenue share of the global Hematology Analyzer market by 2016 end and owing to stable market and new technology advancements pool, which in turn is expected to boost demand for Hematology Analyzer over the forecast period.
- ▶ Europe Hematology Analyzer market is expected to account for second major revenue share of the global Hematology Analyzer market by 2016 end and owing to increasing adoption of new product line European countries.

2016 Estimated Region Wise Share



2024 (Forecasted share of Region wise)

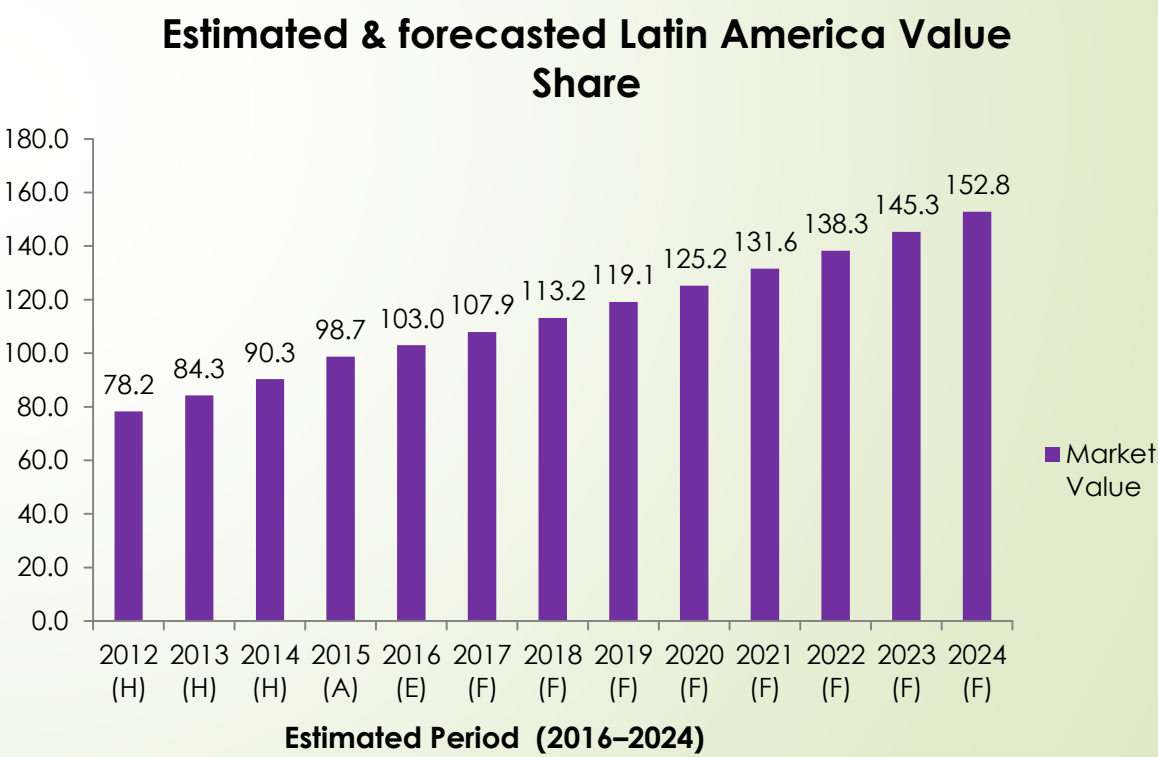
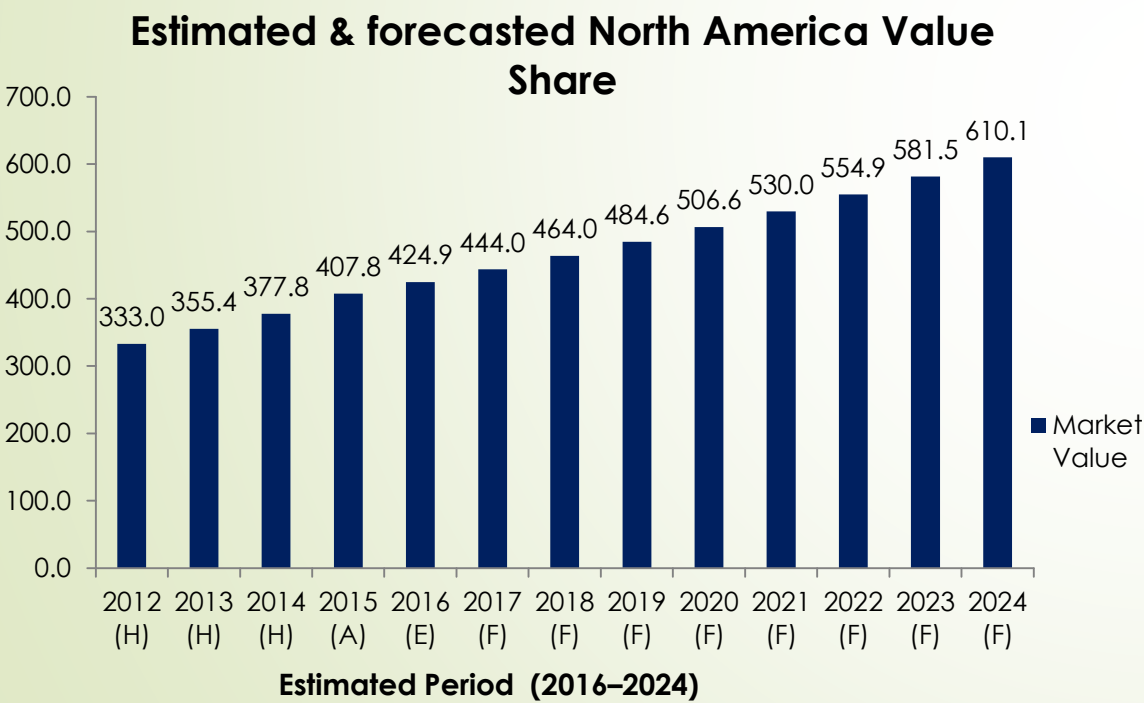


18. Estimated & forecasted North America Value Share, 2016–2024

19. Estimated & forecasted Latin America Value Share, 2016–2024

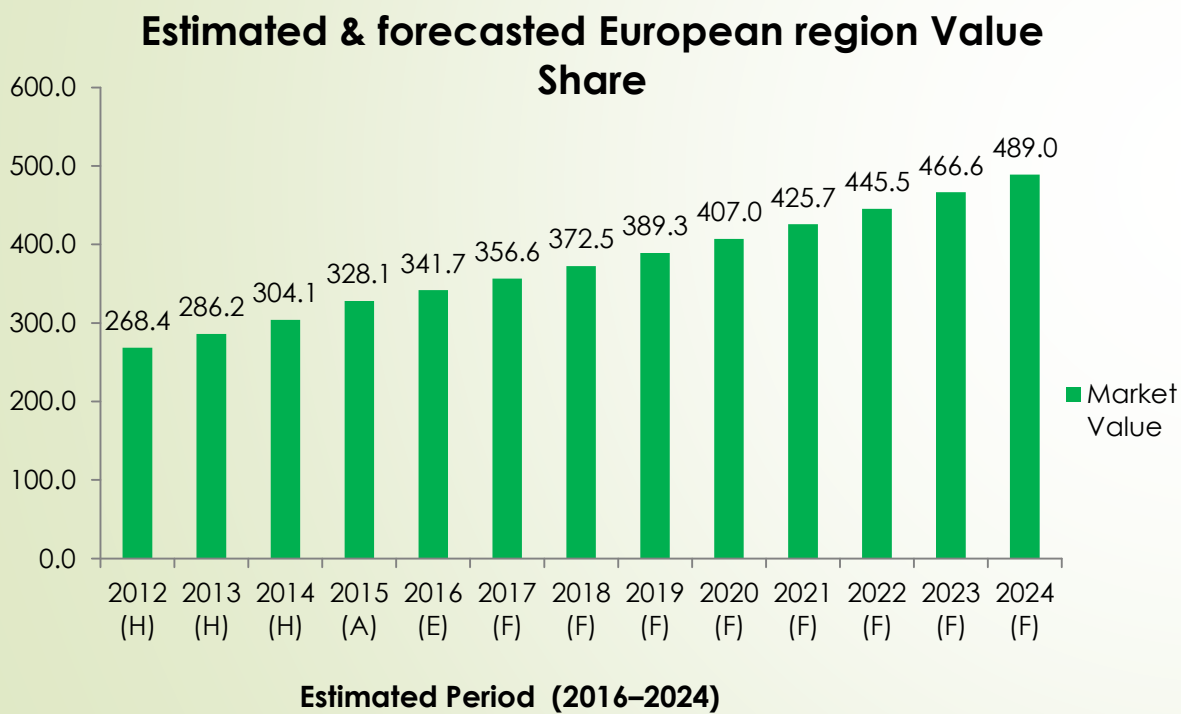
North America Hematology Analyzer market is flooded with variety of Hematology Analyzers for diagnostic purposes, moreover the high awareness of blood related issues in this region is expected to grow 4.9 % CAGR over the forecast period

Changing government policies and globalization of companies boosting the growth of Hematology Analyzers market over the forecasted period. It is expected to grow at 5.3% CAGR.



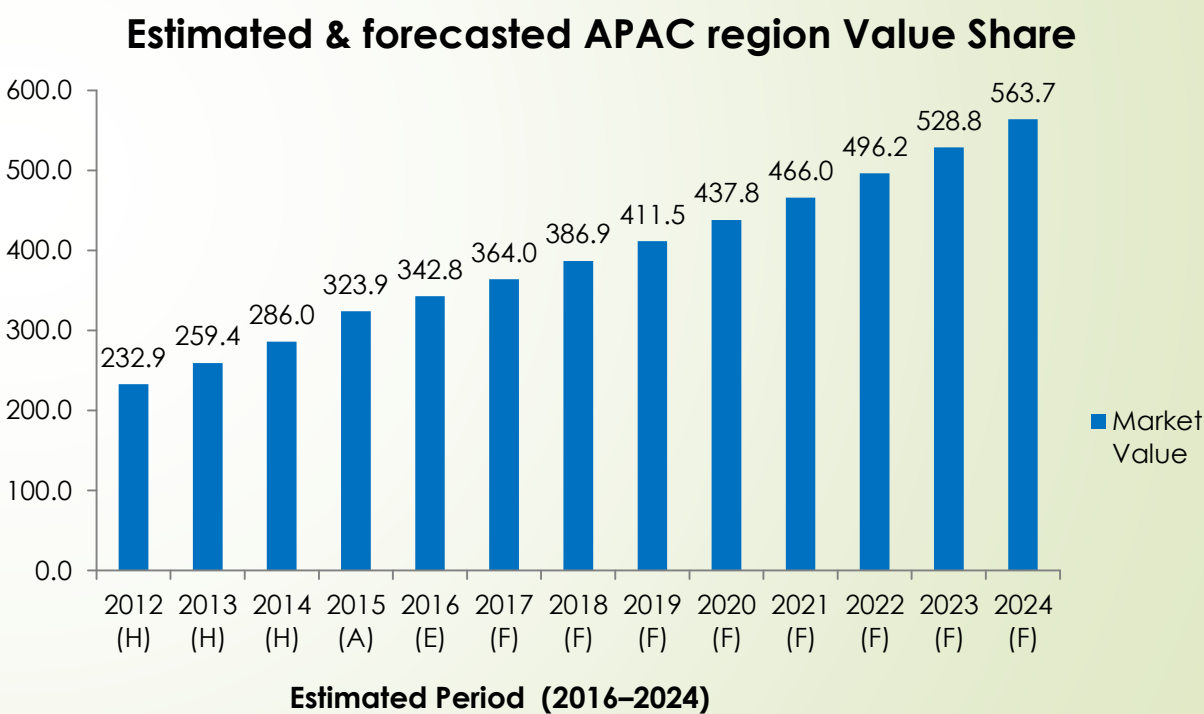
20. Estimated & forecasted European Region Value Share, 2016–2024

- The increasing research activities for development of hematology Analyzers is gaining traction in Europe, which in turn is expected to give at 4.6 % CAGR over the forecast period.



21. Estimated & forecasted APAC Region Value Share, 2016–2024

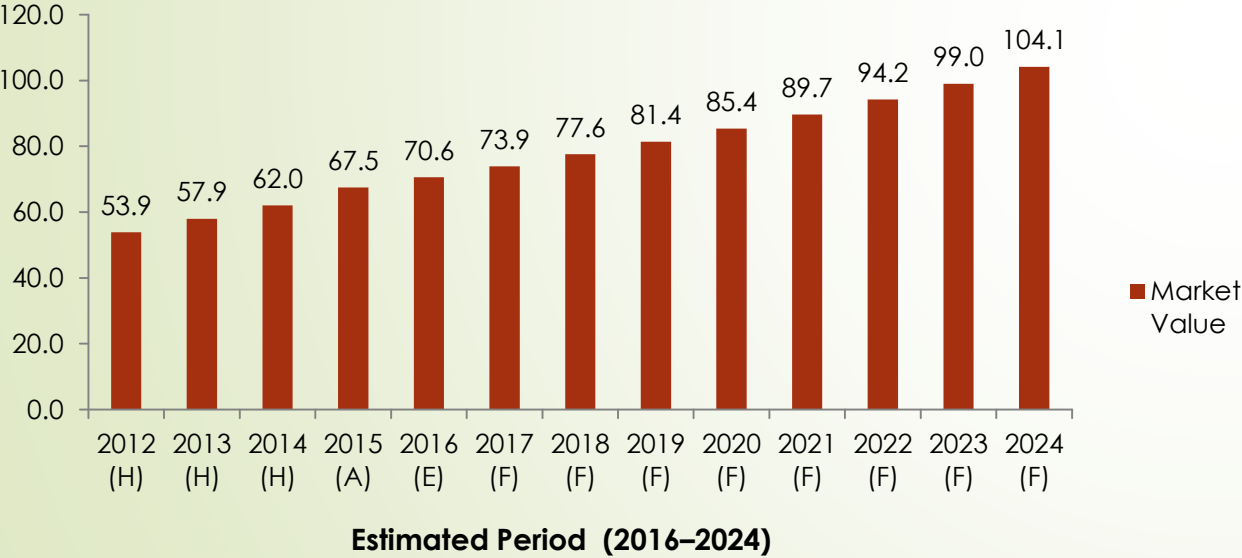
- High penetration and emerging economies of APAC region is expected to boost demand for Hematology Analyzer market over the forecast period. It is expected to grow at 6.5% CAGR.



22. Estimated & forecasted MEA Region Value Share, 2016–2024

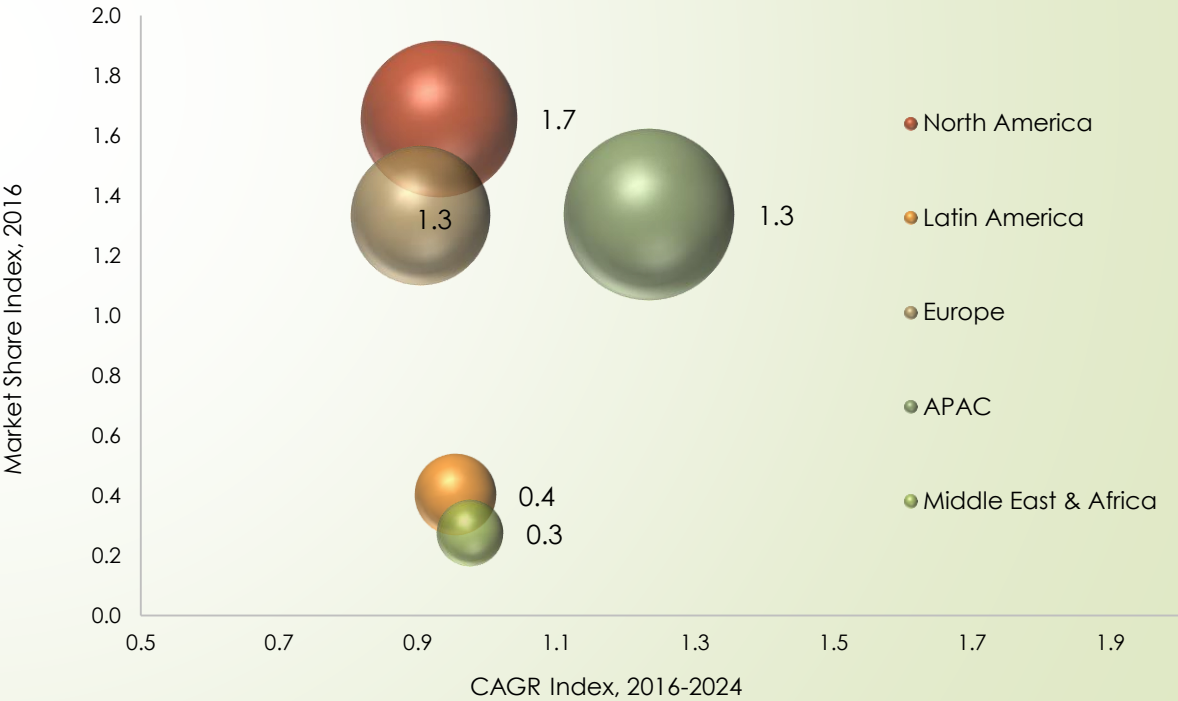
- Poor health system and changing policies is expected to hamper revenue growth however gradually increasing awareness in GCC countries is expected to grow at 3.6% CAGR over the forecast period.

Estimated & forecasted European region Value Share



23. Estimated & forecasted MEA Region Value Share, 2016–2024

- North America Hematology Analyzer market dominated the global Hematology Analyzer market in revenue terms in 2015 and is projected to continue to do so throughout the forecast period.
- Europe Hematology Analyzer market is expected to be the second most lucrative in the global Hematology Analyzer market, during the forecast period.
- APAC Hematology Analyzer market is expected to be the third most lucrative in the global Hematology Analyzer market, during the forecast period.





Market scenario

Drivers:-

- Increase in the quality and efficiency of healthcare system
- Changing government policies
- Product Innovation
- Technology Development

Restraints

- Macro-Economic and Geopolitical Uncertainties
- Liquidity Risk
- Changing Regulatory Environment
- Excess and Obsolete Inventories

Limitations :-

- The study completely based on secondary data and forecasted CAGR is calculated from historical data
- Any change in economical factors might affect the forecasted values
- Demand fluctuation might affect the forecasted value
- Study is limited by present market scenario which might get affected by future trends

Opportunities

- New product innovation
- Geographic diversity

Trends

Focus on Innovation

3D Approach

Automation

Optimization of Technologies



Conclusion

- ❑ Global Hematology Analyzer market revenue is expected to increase at a CAGR of 5.2% during the forecast period (2016–2024).
- ❑ In terms of revenue, 5 Part Differential Analyzer segment was the dominant Product type segment in the global Hematology Analyzer market in 2015. The segment is expected to further gain traction, owing to increasing adoption of 5 Part Differential Analyzer in developing countries.
- ❑ Diagnostic centers segment are fastest growing segment in the end user segment,
- ❑ North America Hematology Analyzer market accounted for largest revenue market share of 33.3% in 2015. Revenue from the market in APAC Region is expected to register the fastest CAGR of 6.5% during the forecast period.



Recommendations

- More innovation towards 3 part differential analyzers might helpful to generate revenues.
- Standalone equipment are more advanced and more costlier than point of care equipment, companies have to reduce the price to attract more no of customers.
- Diagnostics center segment have a potential to dominate the market, if they concentrate more towards the customers.
- APAC region is fastest growing segment which have a high potential to become dominant, if this region is more focused towards new technologies and adoption of new products faster.

References

- Chung T. D., Kim H. C. Recent advances in miniaturized microfluidic flow cytometry for clinical use. Electrophoresis 2017.
- Cadwallader B. Nursing home owes \$6.5 million in patient death. The Columbus Dispatch. http://www.dispatch.com/live/content/local_news/stories/2009/04/29/wrongful.ART_ART_04-29-09_B3_H2DMTHK.html
- Dugdale D. C. CBC: MedlinePlus Medical Encyclopedia. <http://www.nlm.nih.gov/medlineplus/ency/article/003642>.
- O'Neil P., Vital E., Betancourt-Loria N., Montes D. Performance evaluation of the complete blood count and white blood cell differential parameters on the ACT 5diff Hematology Analyzer. Lab. Hematol.
- DeMoranville V. E. Complete blood count In Gale Encyclopedia of Nursing and Allied Health. 2nd ed. Gale; Farmington Hills, MI;
- kurlander R., Schechter G. P. Interpretation of standard hematologic tests In Bethesda Handbook of Clinical Hematology. Rodgers G. P., Young N. S., Eds.; Lippincott Williams & Wilkins: Philadelphia, PA;
- Crosland-Taylor P. J. A device for counting small particles suspended in a fluid through a tube. Nature.
- Morgan H., Holmes D., Green N. G. High speed simultaneous single particle impedance and fluorescence analysis on a chip. Curr. Appl. Phys. 2006, 6(3), 367–370
- Simonnet C., Groisman A. High-throughput and high-resolution flow cytometry in molded microfluidic devices. Anal. Chem.
- Morgan H., Sun T., Holmes D., Gawad S., Green N. G. Single cell dielectric spectroscopy. J. Phy. D Appl. Phys.
- Aulesa C., Pastor I., Naranjo D., Piqueras J., Galimany R. Validation of the Coulter LH 750 in a hospital reference laboratory. Lab. Hematol.
- Boule Medical AB. 510(k) Substantial equivalence determination decision summary K032214. http://www.accessdata.fda.gov/cdrh_docs/reviews/K032214.pdf (accessed September 24, 2009)
- Habbersett R. C., Naivar M. A., Woods T. A., Goddard G. R., Graves S. W. Evaluation of a green laser pointer for flow cytometry. Cytometry
- Ateya D. A., Erickson J. S., Howell P. B., Hilliard L. R., Golden J. P., Ligler F. S. The good, the bad, and the tiny: A review of microflow cytometry. Anal. Bioanal. Chem.
- Chipeta J, Mharakurwa S, Thuma P, Kumar N. A synopsis of current malaria diagnosis trends. Medical Journal of Zambia.

References

- Acharya AR, Magisetty JL, Chandra A, Chaithra BS, Khanum T, Vijayan VA. Trend of malaria incidence in the state of Karnataka, India for 2001 to 2011. Archives of applied science research.
- Bisoffi Z, Sirima SB, Menten J, Pattaro C, Angheben A, Gobbi F, Tinto H, Lodesani C, Neyu B, Gobbo M, Van den Ende J. Accuracy of a rapid diagnostic test on the diagnosis of malaria infection and of malaria-attributable fever during low and high transmission season in Burkina Faso. Malar.
- Inoue H. Overview of Automated Hematology Analyzer XE-2100. Sysmex Journal International.
- Ruzicka K, Veitl M, Thalhammer S, Schwarzingner I. The New Hematology Analyzer Sysmex XE-2100: Performance Evaluation of a Novel White Blood Cell Differential Technology. Arch Pathol Lab Med.
- Bailey JW, Williams J, Bain BJ, William JP, Chiodin PL. Guideline: the laboratory diagnosis of malaria. British Journal of Haematology.
- Yan J, Li N, Wei X, Li P, Zhao Z, Wang L, et al. Performance of two rapid diagnostic tests for malaria diagnosis at the China-Myanmar border area. Malaria Journal.
- Tatsumi, N. , I. Tsuda , A. Furota , T. Takubo , M. Hayashi , and H. Matsumoto . Principle of blood cell counter—development of electric impedance method. Sysmex J Int.
- Ornstein, L. and H. R. Ansley . Spectral matching of classical cytochemistry to automated cytology. J Histochem Cytochem.
- Buttarello, M. , P. Bulian , V. Temporin , and P. Rizotti . Sysmex SE-9000 hematology analyzer: performance evaluation on leukocyte differential counts using an NCCLS H20-A protocol. Am J Clin Pathol 1997.
- Inoue, H. Overview of automated hematology analyzer XE-2100TM. Sysmex J Int
- van Wersch, J. W. J. and C. Bank . A new development in haematological cell counting: the Sysmex NE-8000, automation for cell count and physical five-part leukocyte differentiation. J Clin Chem Clin Biochem
- Besarab, A. , M. Amin , and M. Ahsan . et al. Optimization of epoetin therapy with intravenous iron therapy in hemodialysis patients. J Am Soc Nephrol
- Bhandari, S. , D. Norfolk , A. Brownjohn , and J. Turney . Evaluation of RBC ferritin and reticulocyte measurements in monitoring response to intravenous iron therapy. Am J Kidney Dis
- Korst, L. M. , J. P. Phelan , M. O. Ahn , and G. I. Martin . Nucleated red blood cells: an update on the marker for fetal asphyxia. Am J Obstet Gynecol