

**PLASMA AND IMMUNOGLOBULIN (IgG) PERSPECTIVE  
IN LATIN AMERICA**

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**(presented by Jan M Bult)**

**BIENNIAL MEETING OF THE  
LATIN AMERICAN SOCIETY FOR IMMUNODEFICIENCIES  
(LASID) 2019**

**Cancun, Mexico, October 9-12, 2019**

## METHODOLOGY

The data used to develop the charts and tables shown in this presentation have been compiled from surveys conducted by the Marketing Research Bureau in some fifty countries and published in its syndicated reports.

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- **From Plasma to Immunoglobulin (IgG)**
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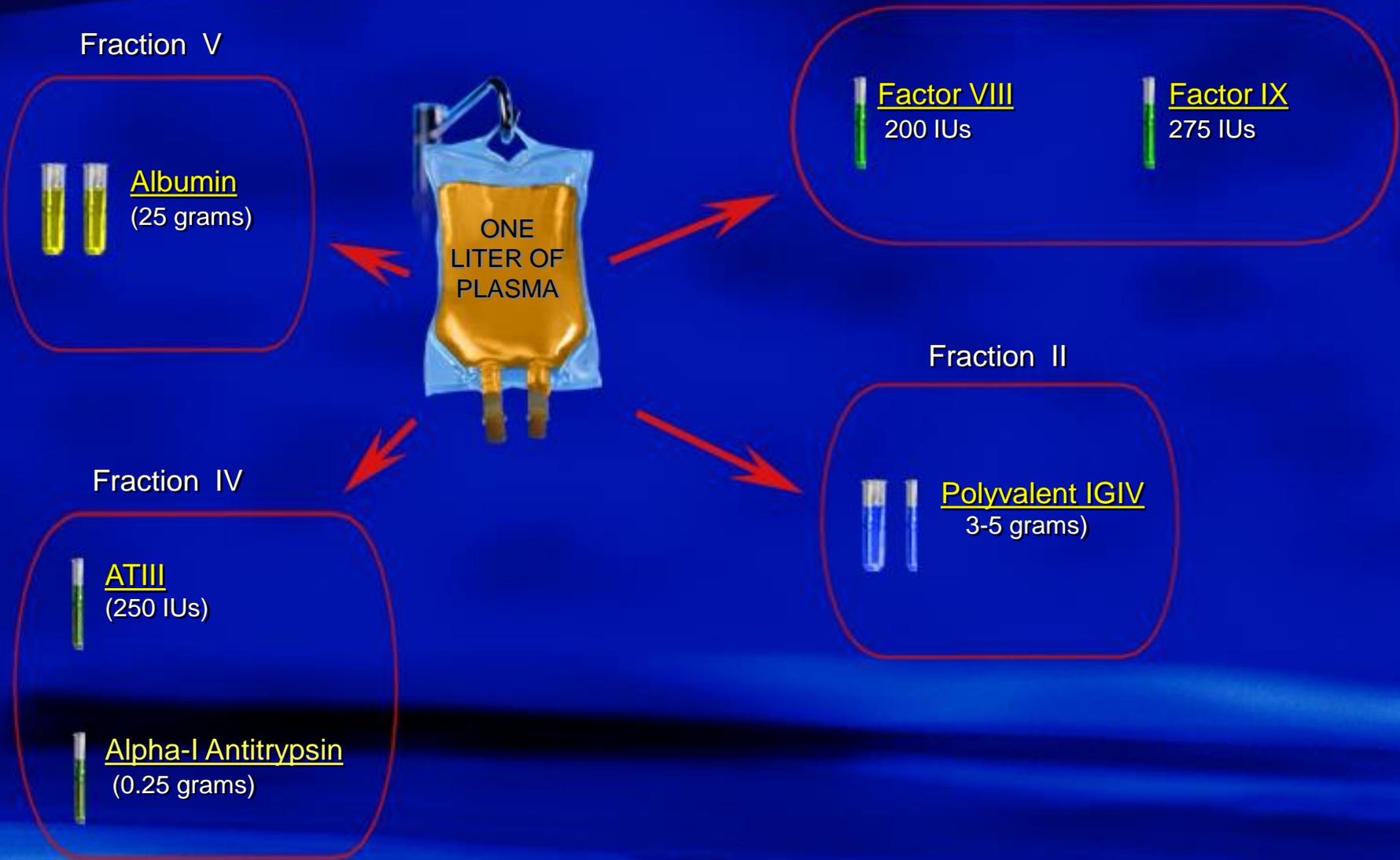


# Plasmapheresis Station

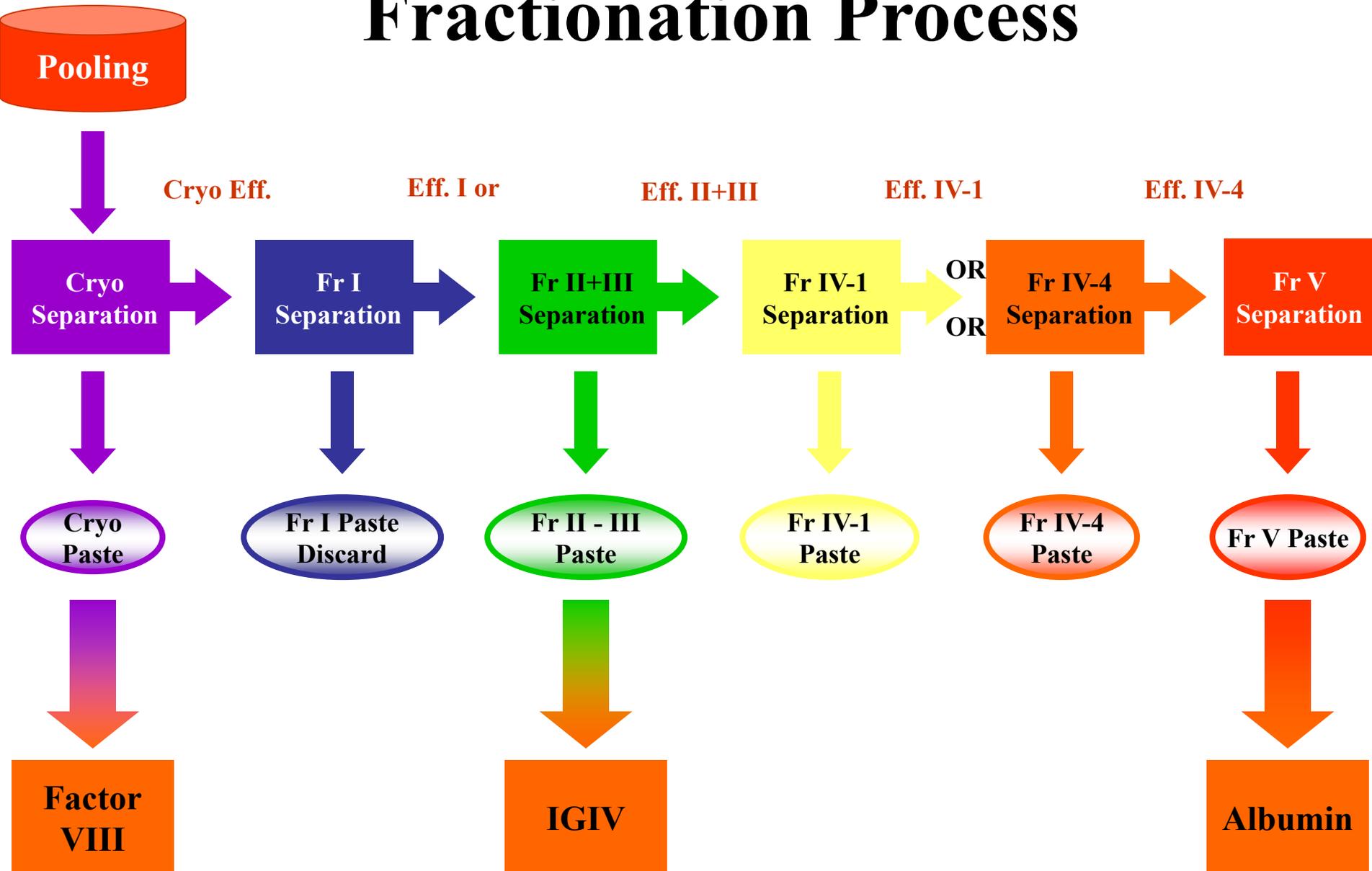




# PLASMA FRACTIONATION



# Fractionation Process







# Plasma Fractionation



# REGIONAL DISTRIBUTION OF FRACTIONATION PLANTS 2017



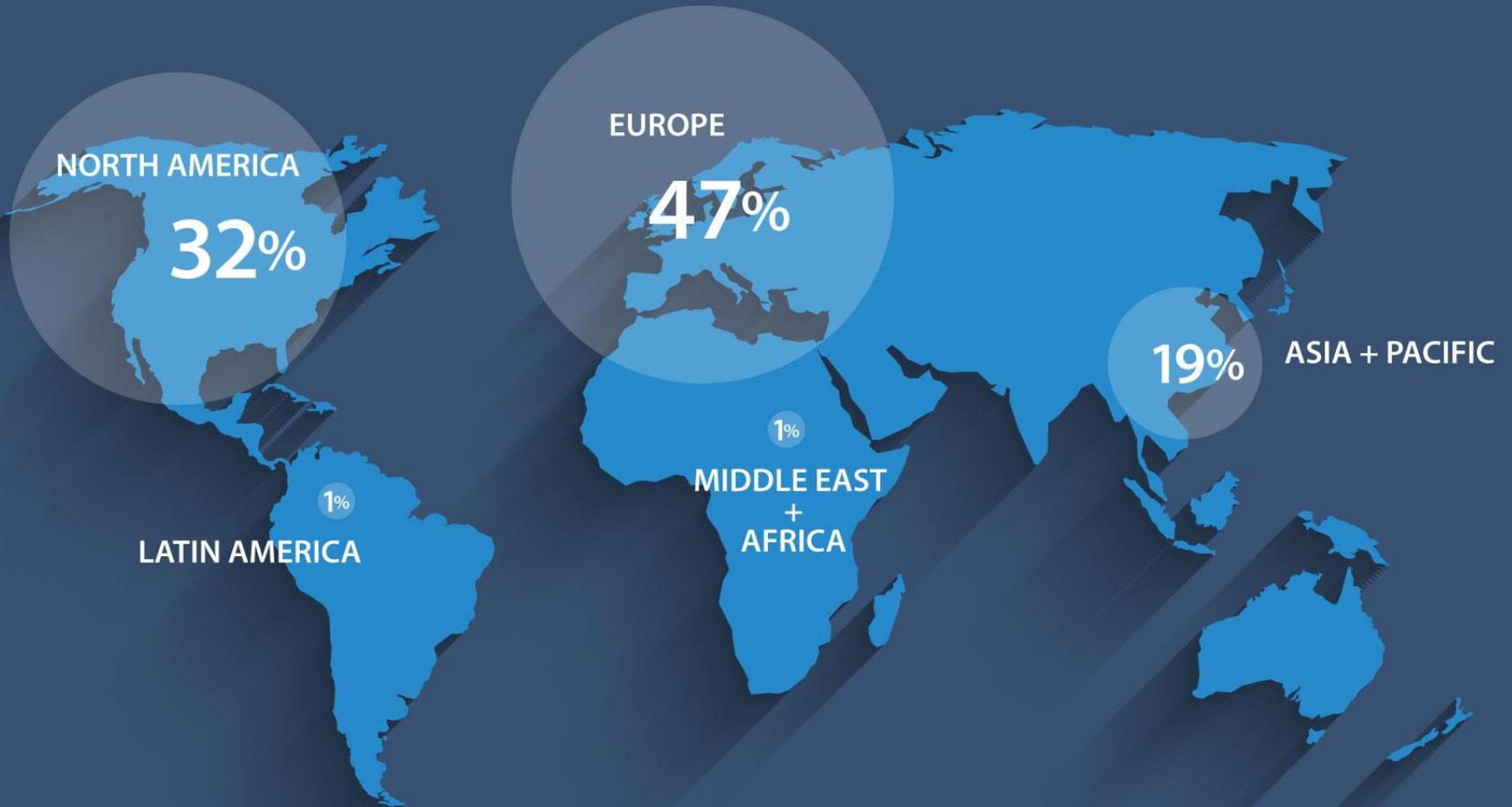
TOTAL NUMBER OF FRACTIONATION PLANTS: 80

NON-PROFIT: 19 COMMERCIAL: 61

NUMBER OF COMPANIES OPERATING FRACTIONATION PLANTS: ca. 45



# REGIONAL DISTRIBUTION OF FRACTIONATION THROUGHPUT 2017



**GLOBAL FRACTIONATION THROUGHPUT 2017:  
54.5 MILLION LITERS**



## **From Recovered and Source Plasma to Plasma-Derived Medicinal Products (PDMP)**

80 plasma fractionation plants are in operation worldwide. They belong to some 45 companies or non-profit organizations.

Asia has the highest number of fractionation plants (38) followed by Europe (26) and North America (8). The largest plants in terms of processing capacity are located in the United States.

Europe has the world's highest fractionation throughput (47%). The multinational companies move intermediate paste and plasma from one manufacturing site to another across continents to maximize their production efficiency.

# The Human Factor

- The plasma industry differs from the traditional pharmaceutical sector in the following ways:
- Technical aspect: the fractionation of plasma is a complex process, due to the biological nature of its raw material: human plasma,
- Socio-economic & ethical aspect: the use of plasma and blood as raw material to make IgG creates social, economic and ethical issues, that do not exist in other industries
- Patient/Industry Relationships: The patients' organizations exercise a strong influence on the industry policies and processes with regard to product safety, supply and access.

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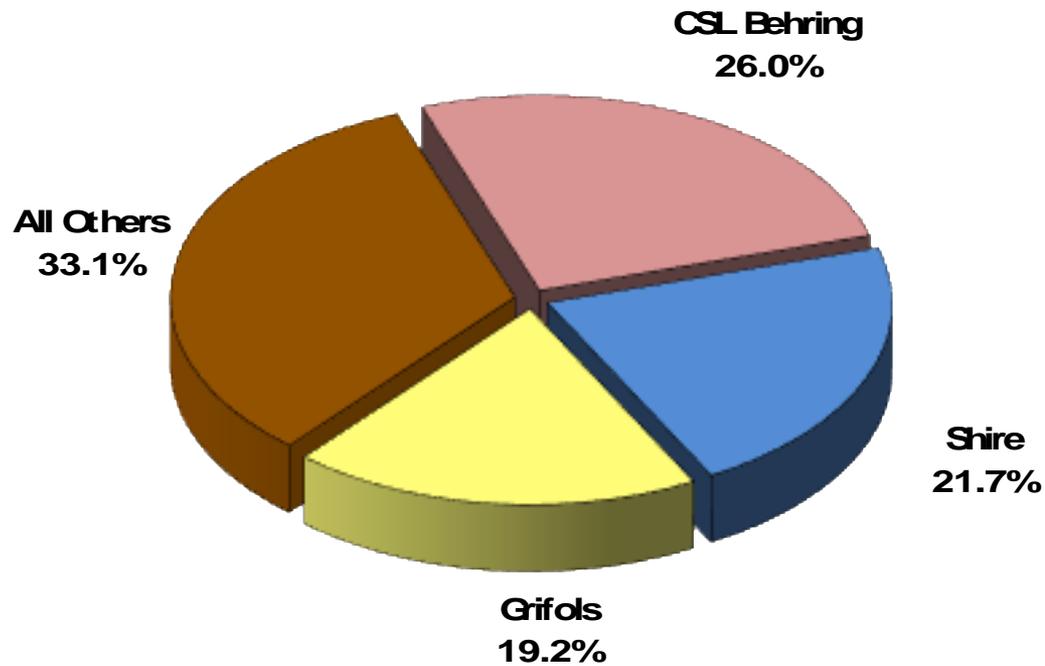
- **From Plasma to Immunoglobulin (IgG)**
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- **More Plasma from Latin America!**



# THE WORLDWIDE PLASMA PROTEINS MARKET BY COMPANY - 2016

WITHOUT RECOMBINANT FACTORS

Total Market 21,174 Million



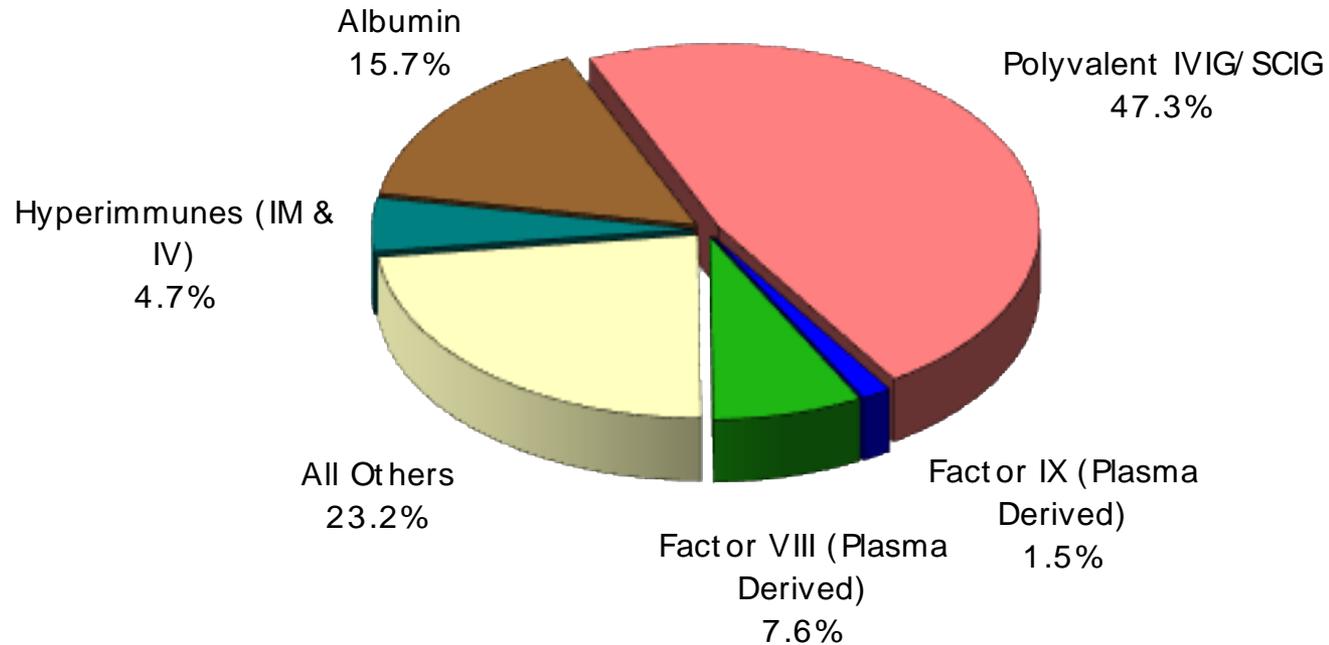
Breakdown by Company



# THE WORLDWIDE PLASMA PROTEINS MARKET BY PRODUCT - 2016

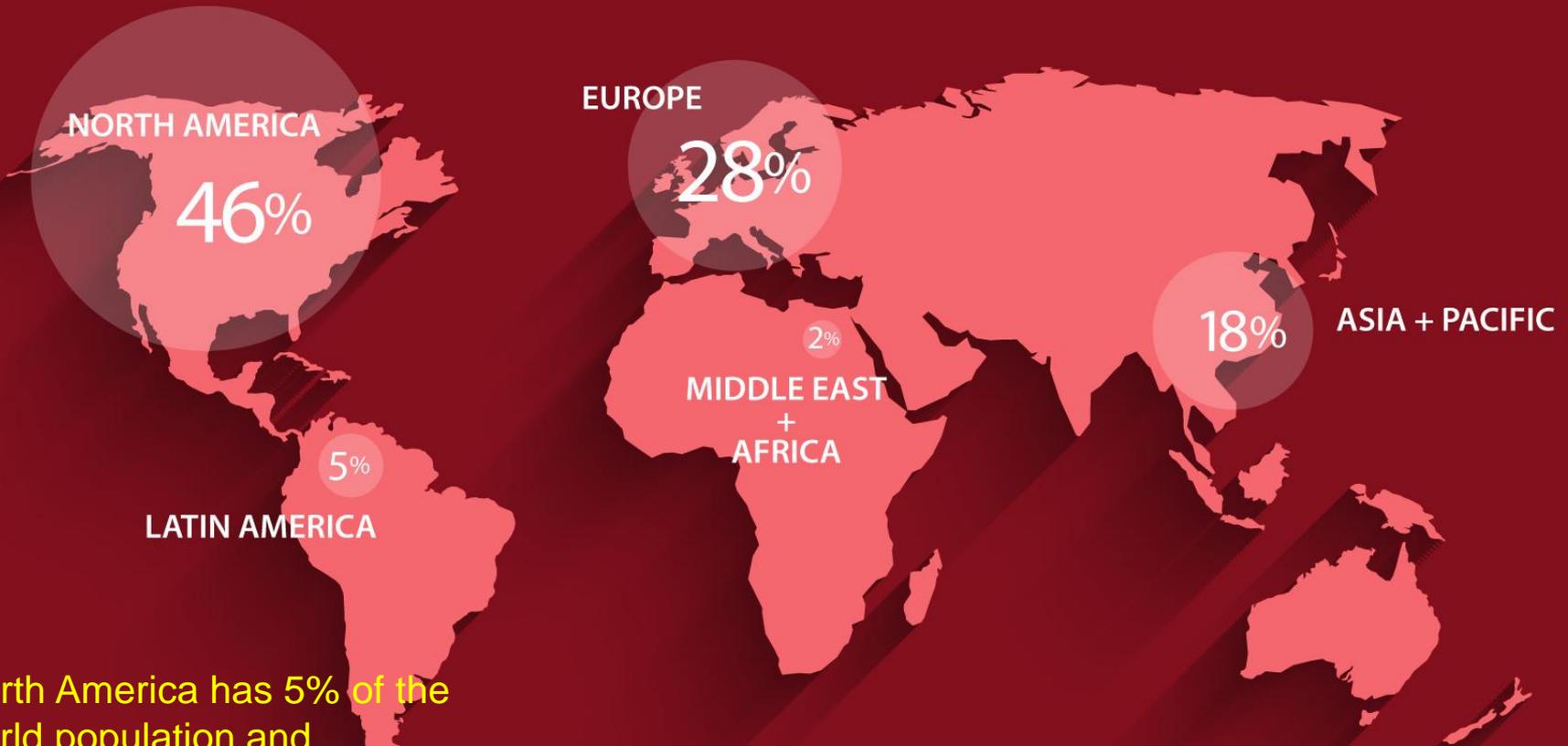
WITHOUT RECOMBINANT FACTORS

Total Market \$21,174 Million



Breakdown by Products: IgG is almost half of the total market

## WORLDWIDE IVIG/SCIG UNIT SALES BY REGION



North America has 5% of the world population and consumes 46% of the global IgG supply; Latin America has almost 9% of the world population and only consumes 5% of the world's IgG supply

The regional discrepancies stem from history, public health priorities, poor diagnosis, and funding

**TOTAL: 152 METRIC TONS**



# THE GLOBAL IVMG & SCIG CONSUMPTION BY REGION 2008 - 2017 (Kilograms)

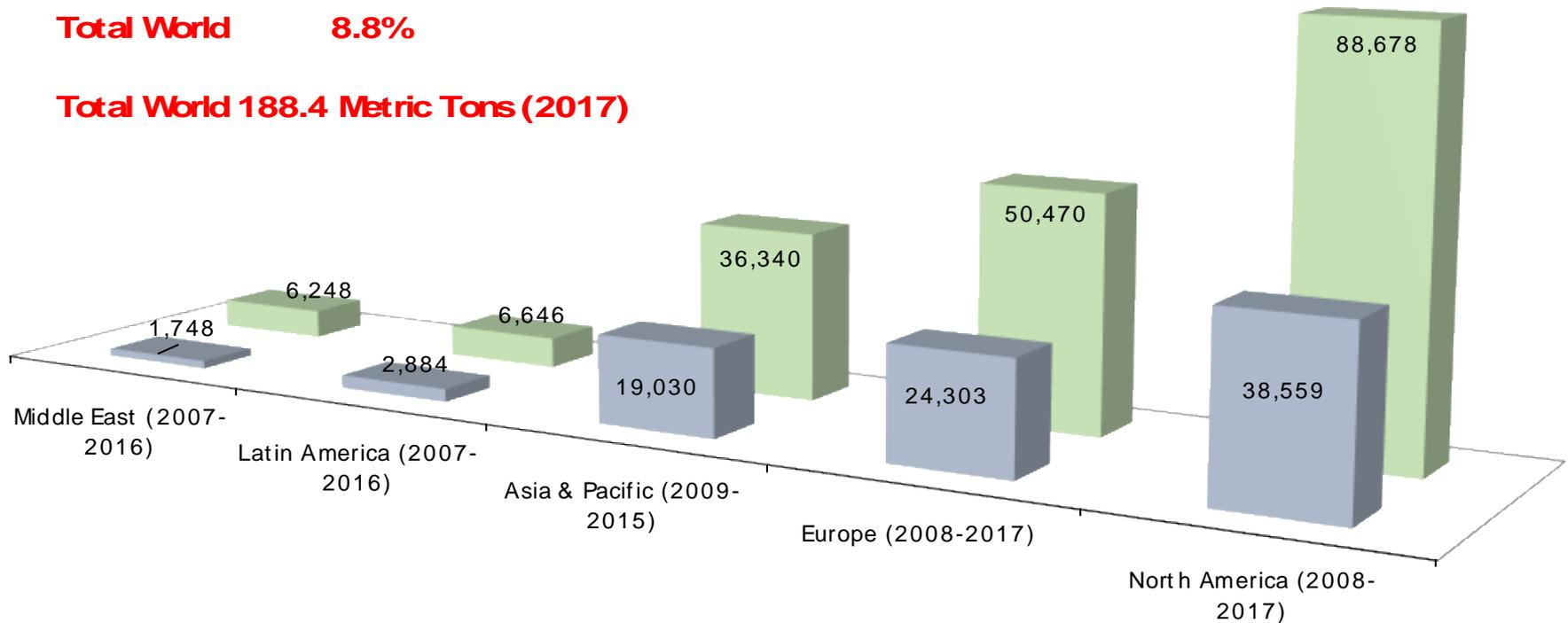
## Compounded Annual Growth Rates

over nine years

<b>North America</b>	<b>9.7%</b>
<b>Europe</b>	<b>8.5%</b>
<b>Asia Pacific</b>	<b>7.5%</b>
<b>Latin America</b>	<b>9.7%</b>
<b>Middle East</b>	<b>15.2%</b>
<b>Total World</b>	<b>8.8%</b>

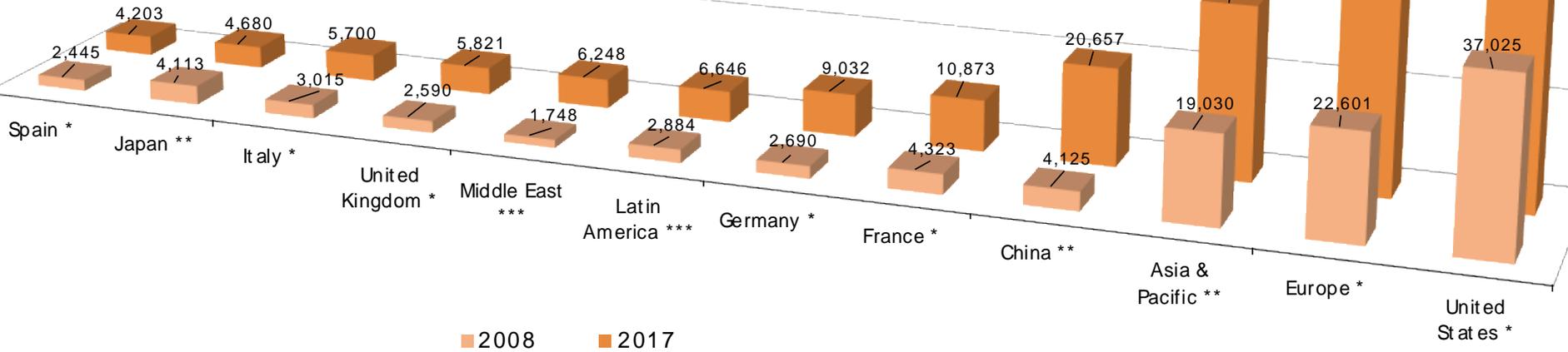
■ 2008  
■ 2017

**Total World 188.4 Metric Tons (2017)**

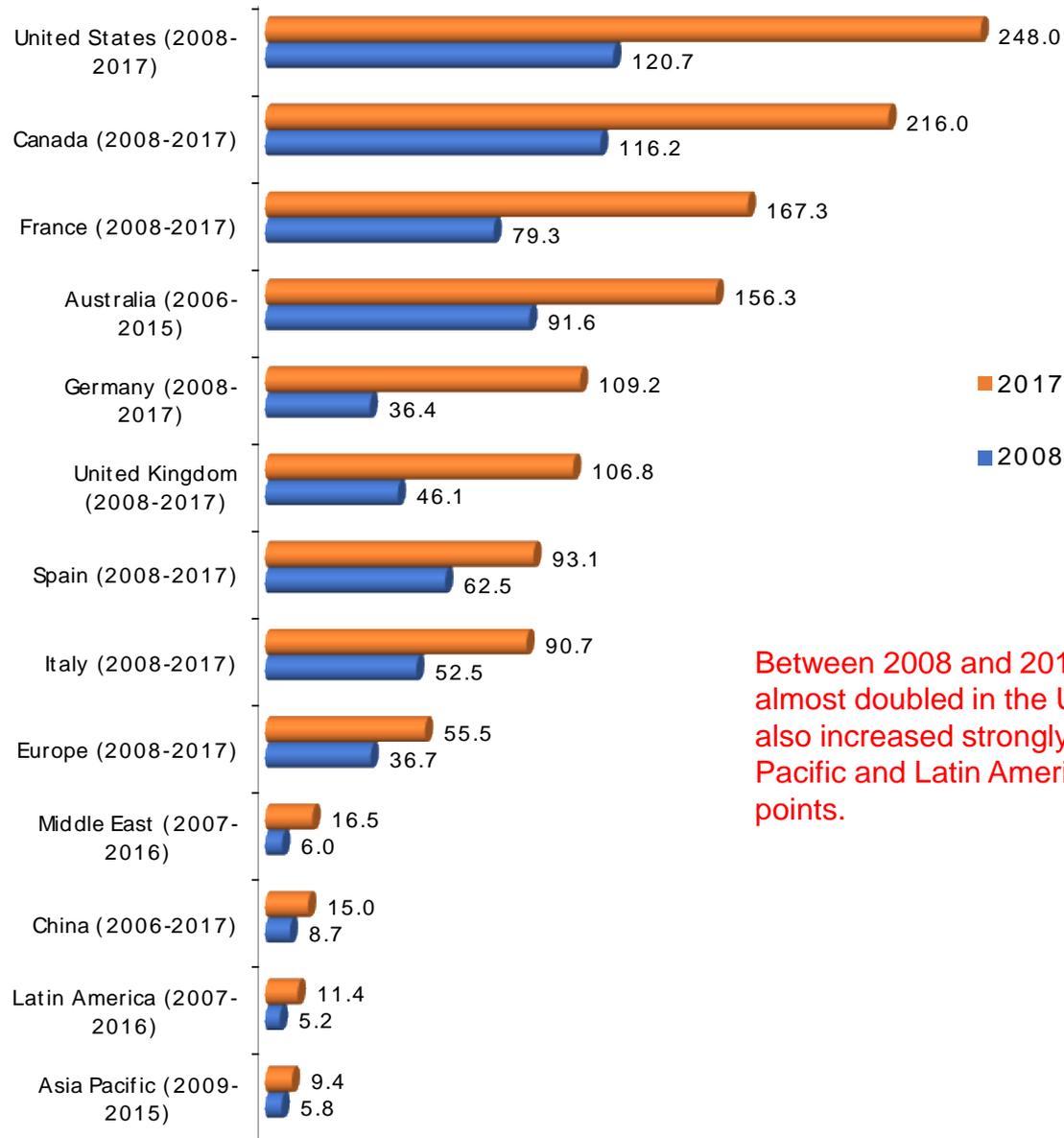


## IMMUNOGLOBULIN CONSUMPTION IN SELECTED REGIONS AND COUNTRIES - 2008 - 2017 (Kilograms)

In 2017, IgG consumption in the U.S. is 60% higher than Europe's. Latin America and the Middle East have comparable consumption levels. The IgG consumption in either Germany's or France's is larger than the consumption in the whole of Latin America and the Middle East, illustrating the extent of unmet needs.



**IMG & SUBCUTANEOUS CONSUMPTION PER CAPITA  
IN SELECTED REGIONS AND COUNTRIES - 2008 & 2017  
(Grams per thousand population)**



Between 2008 and 2017, the consumption per capita almost doubled in the US, Canada, and France. It also increased strongly in the Middle East, Asia & Pacific and Latin America, but from low starting points.

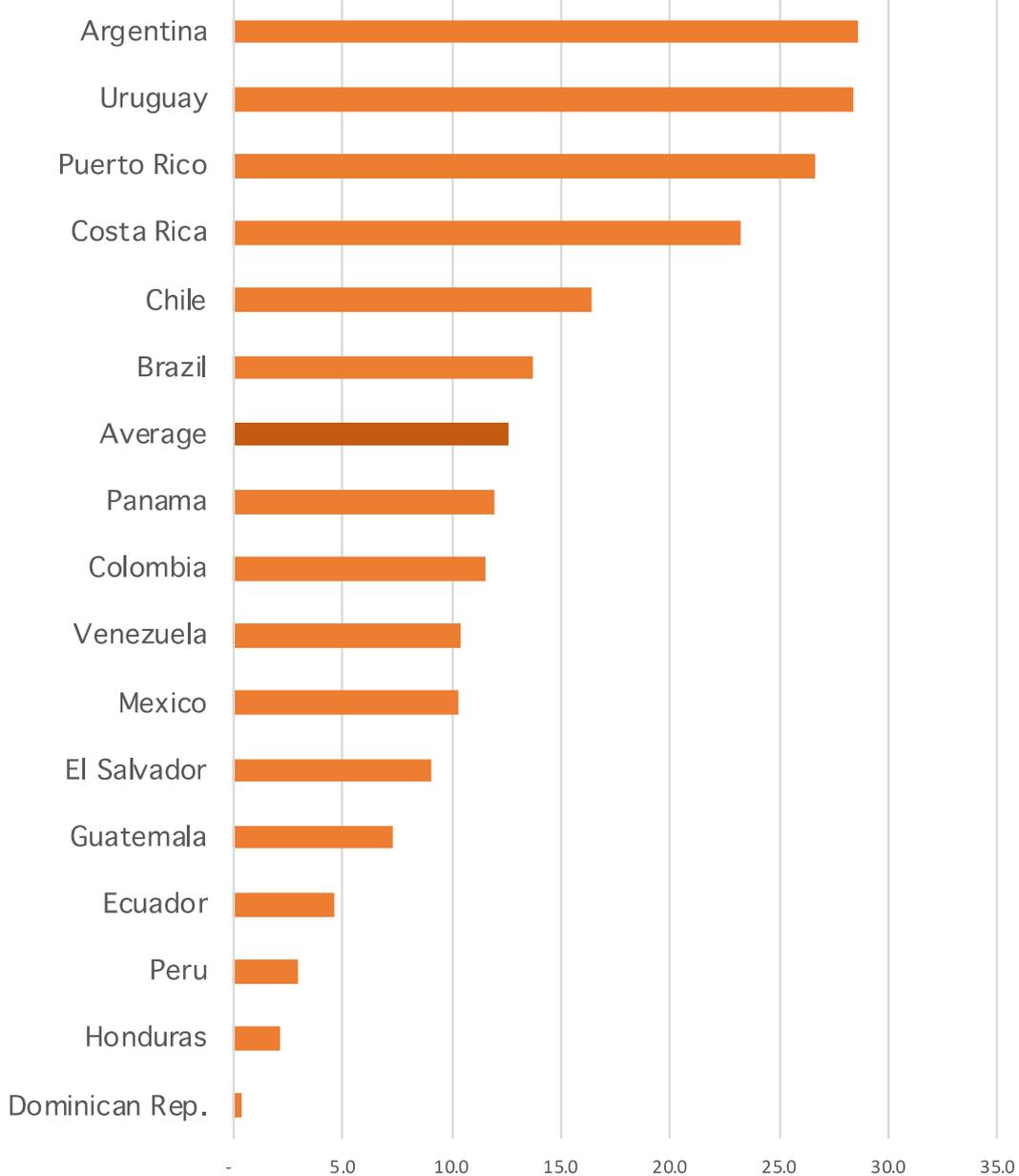


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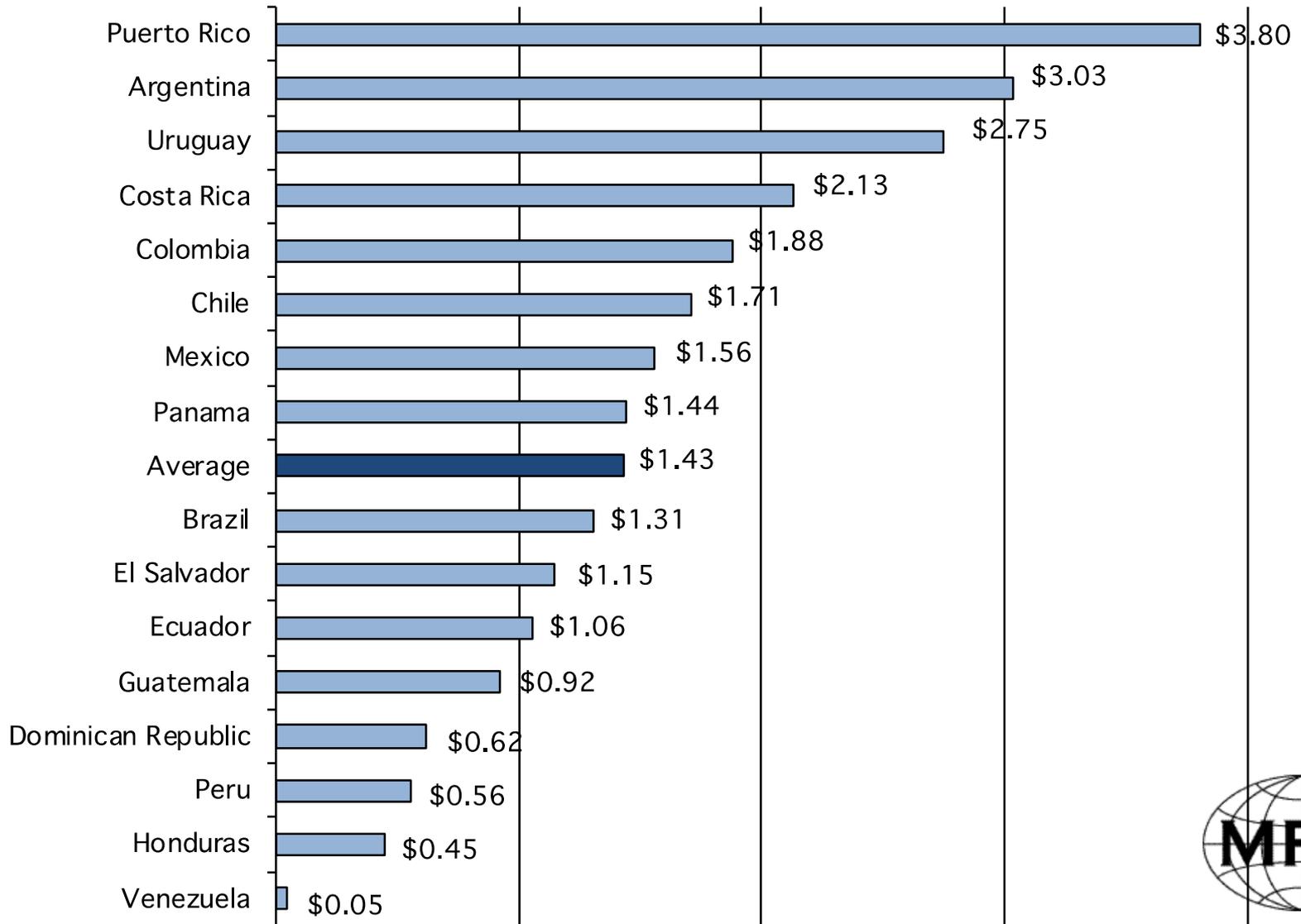
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IMMUNOGLOBULIN CONSUMPTION IN LATIN AMERICA -  
2016  
(Kilograms per Million Population)

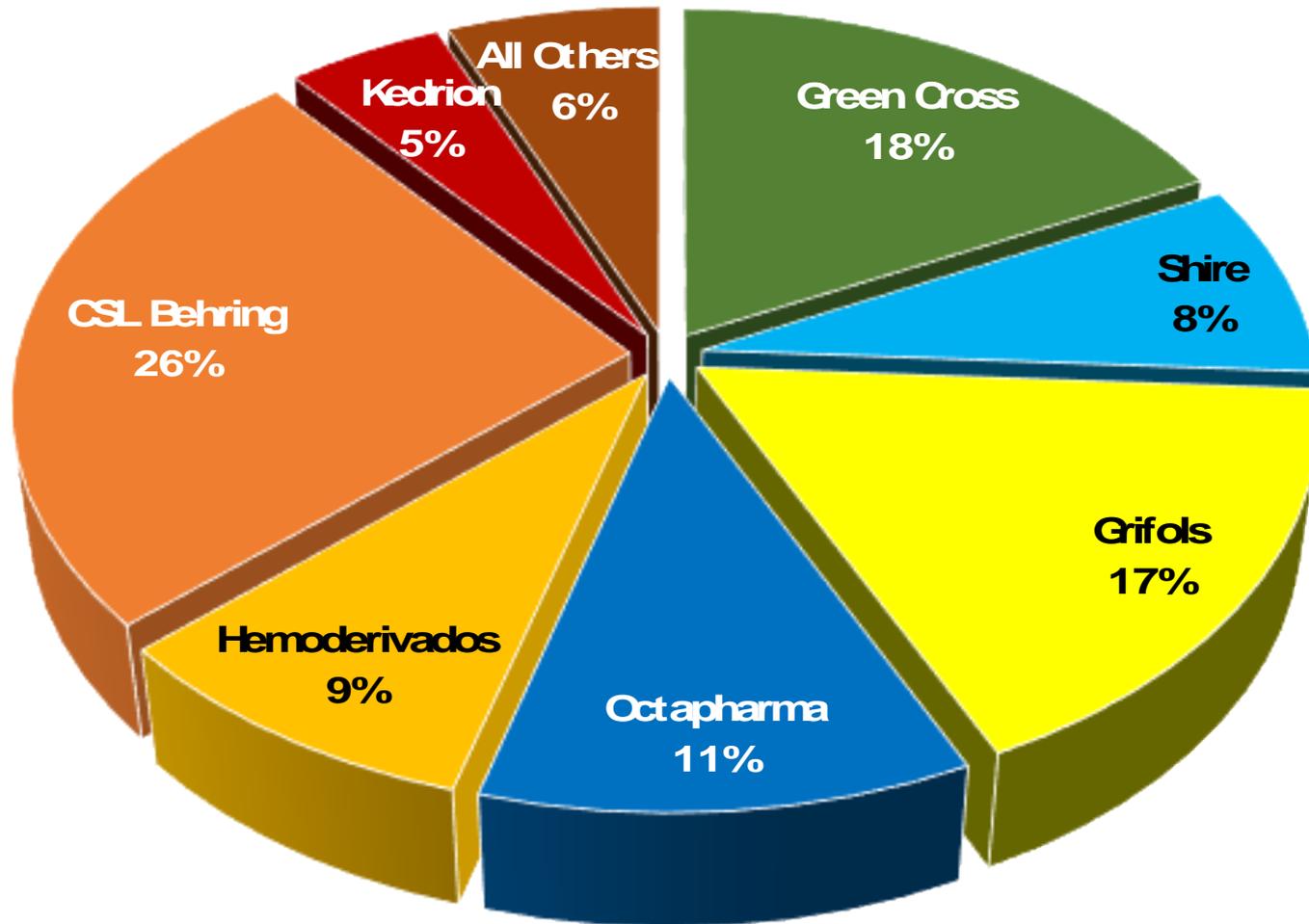


AVERAGE EXPENDITURE ON PLASMA PRODUCTS BY COUNTRY  
IN LATIN AMERICA - 2016  
Plasma-derived Products  
(Dollars per Capita)

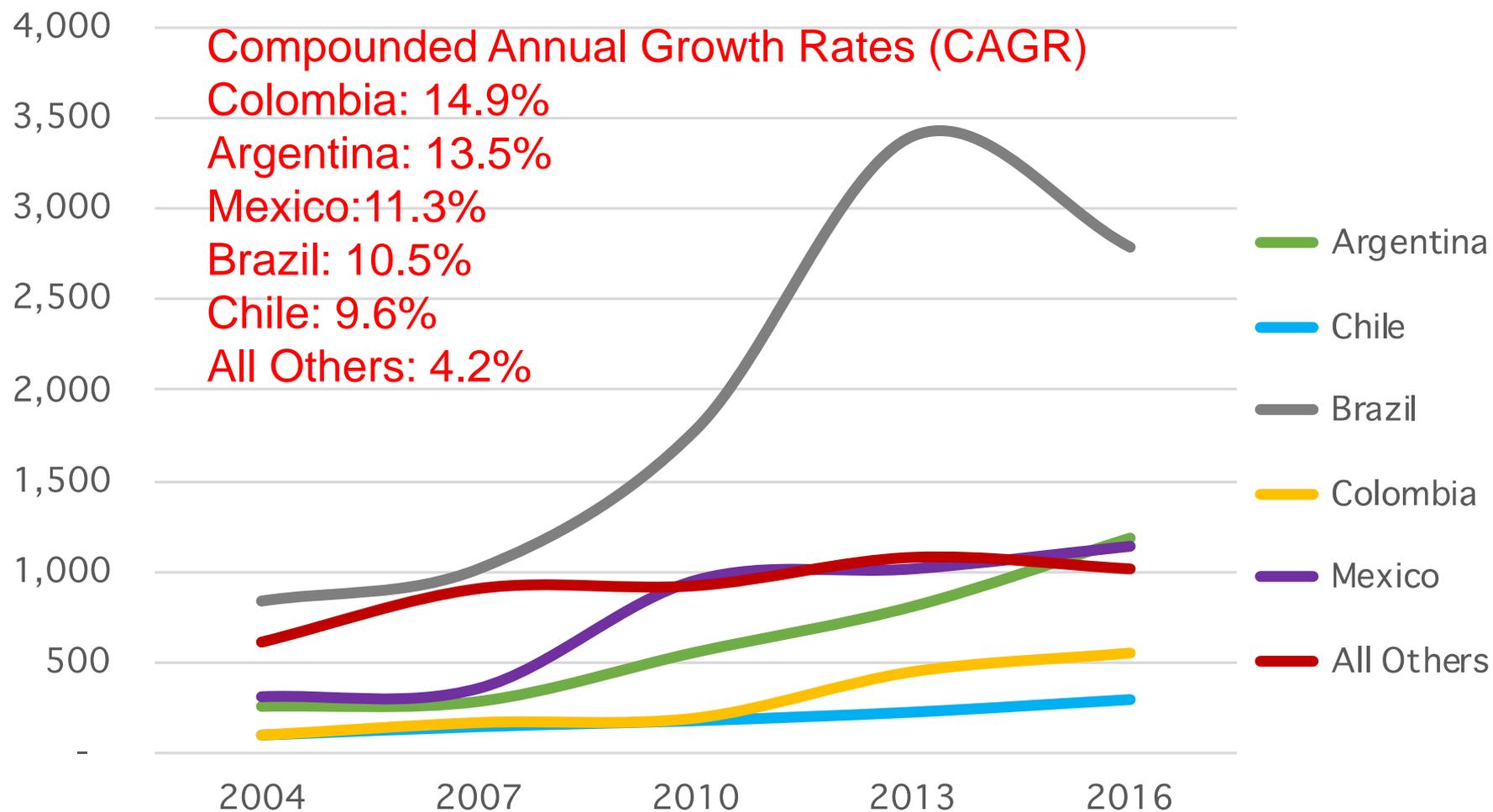


DISTRIBUTION OF THE IMMUNOGLOBULIN MARKET BY  
COMPANY IN VOLUME IN LATIN AMERICA - 2016

Total Quantity: 6,645 kilograms



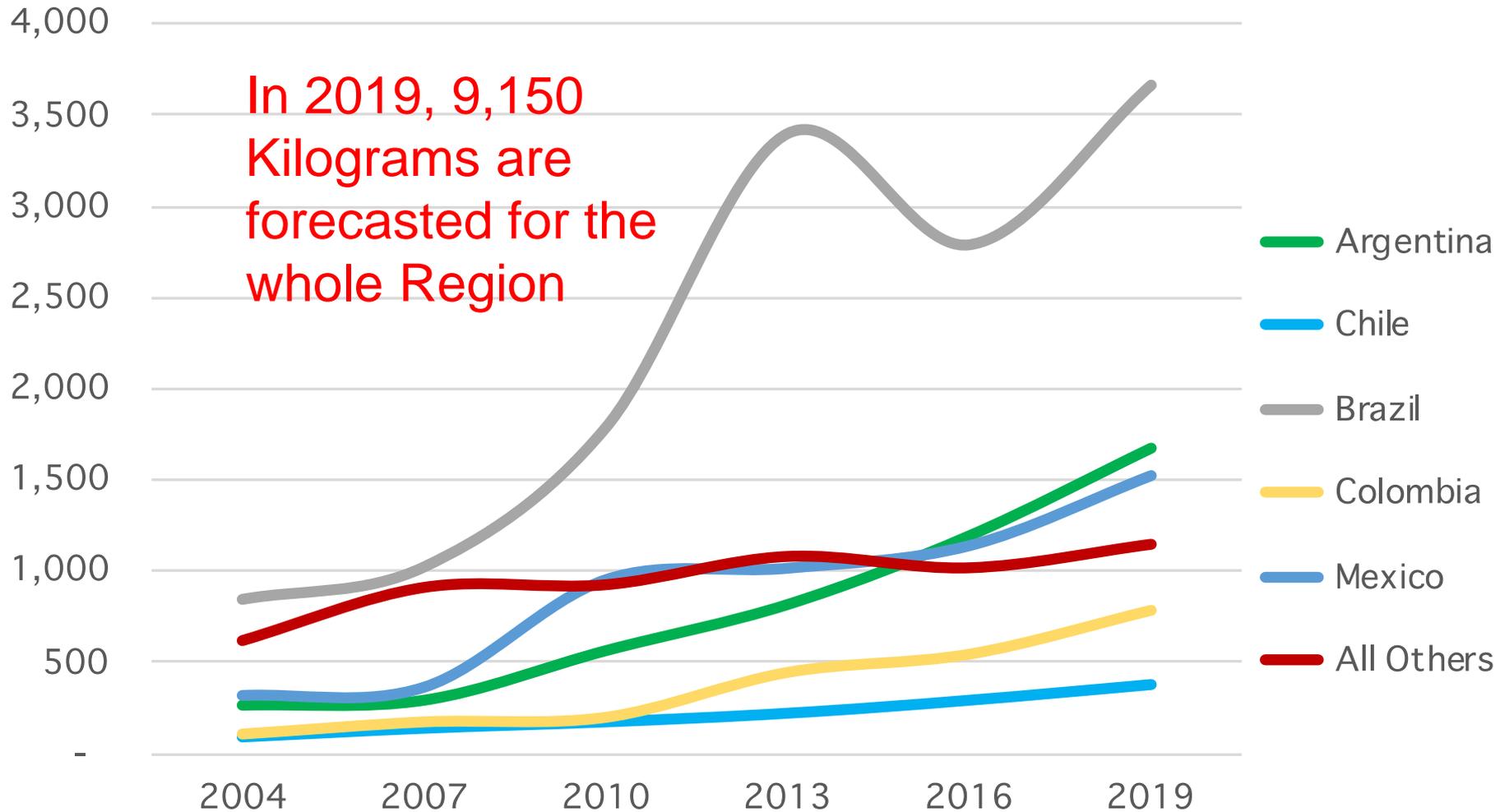
## IgG CONSUMPTION IN LATIN AMERICA FROM 2004 TO 2016 (KILOGRAMS)



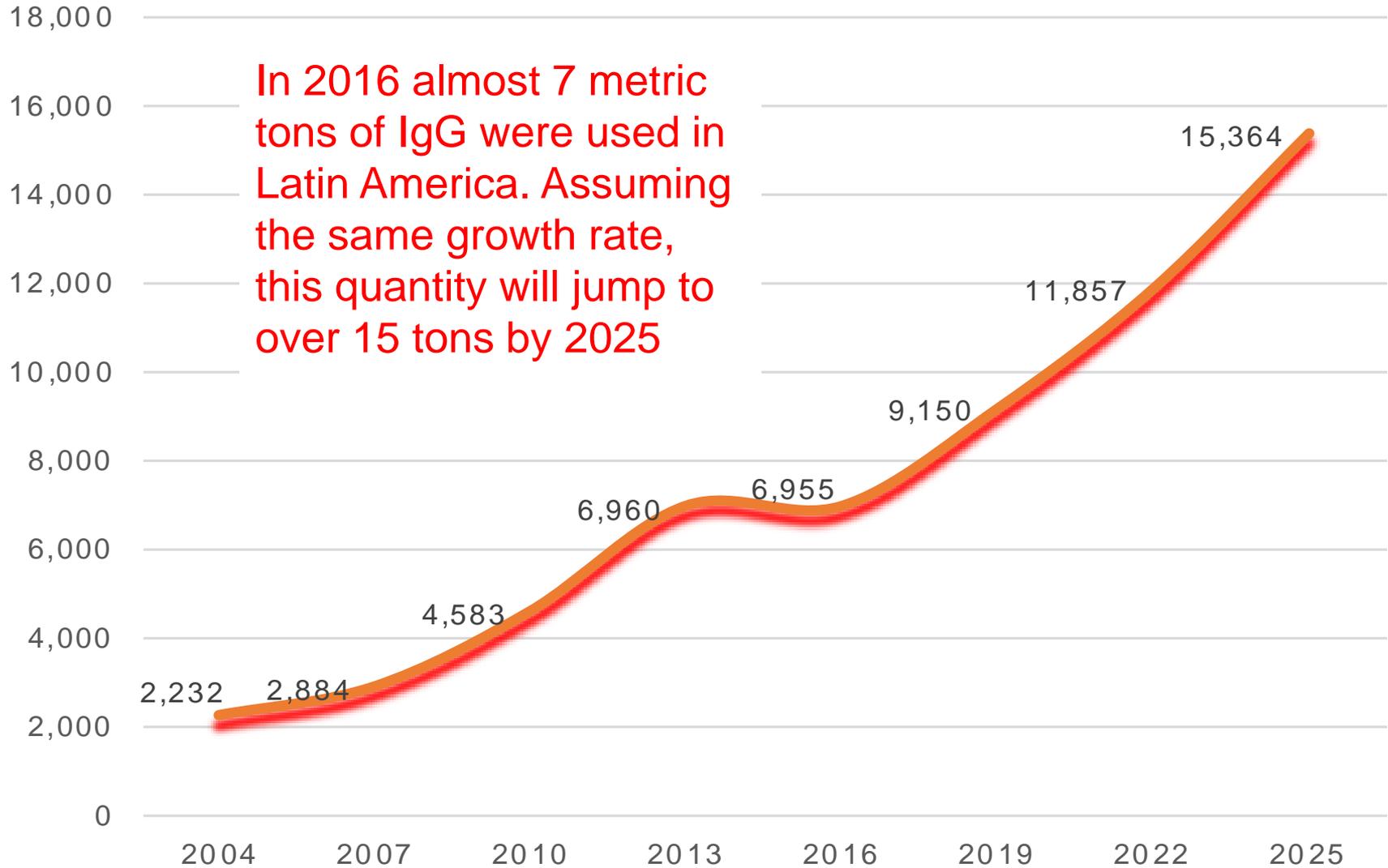


### IgG CONSUMPTION IN LATIN AMERICA FROM 2004 TO 2019 (Est.) (KILOGRAMS)

**In 2019, 9,150  
Kilograms are  
forecasted for the  
whole Region**

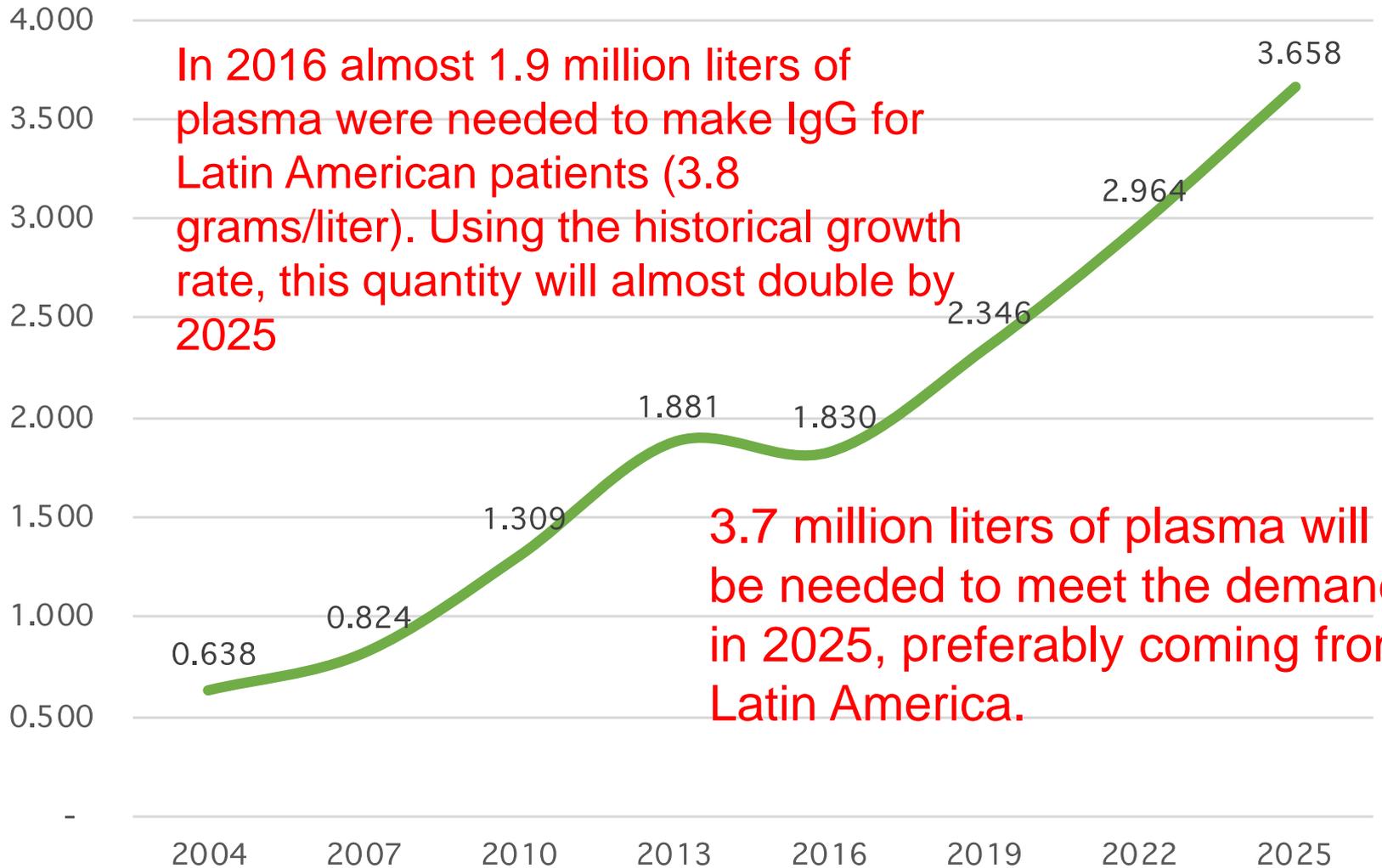


## FORECAST OF IMMUNGLOBULIN CONSUMPTION IN LATIN AMERICA TO THE YEAR 2025 (KILOGRAMS)





## FORECAST OF THE VOLUME OF PLASMA NEEDED IN LATIN AMERICA TO THE YEAR 2025 (MILLION LITERS)



In 2016 almost 1.9 million liters of plasma were needed to make IgG for Latin American patients (3.8 grams/liter). Using the historical growth rate, this quantity will almost double by 2025

3.7 million liters of plasma will be needed to meet the demand in 2025, preferably coming from Latin America.

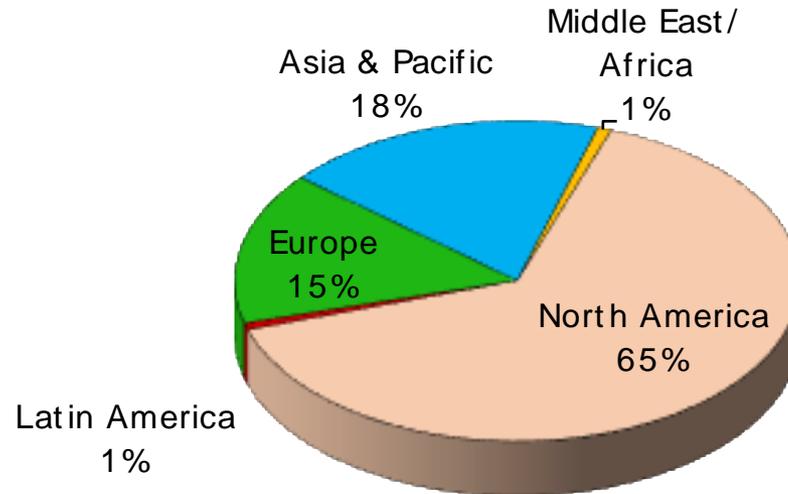
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- **More Plasma from Latin America!**



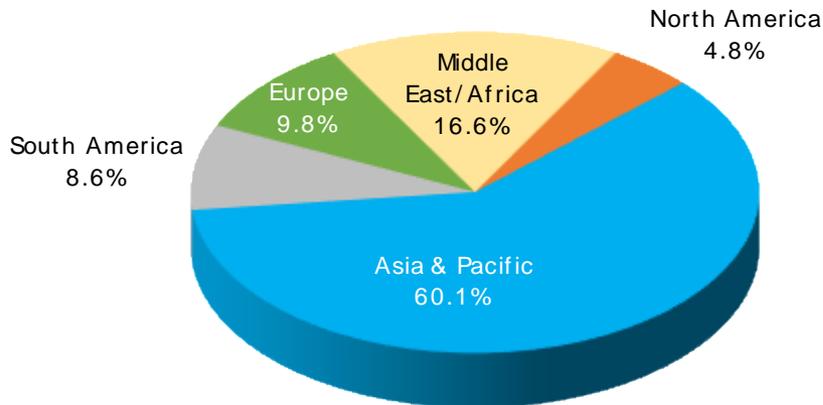
The United States generate 65% to the world's plasma for fractionation (source and recovered) with only 5% of the world population.

### Plasma for Fractionation by Region 2017 (Recovered & Source)



**Total: 56,854,000 liters**

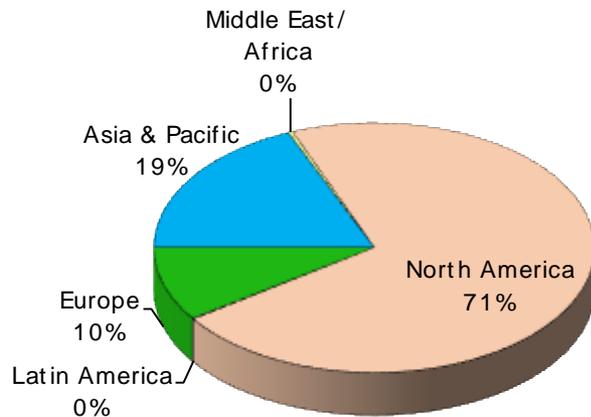
### World Population by Region - 2016



Source: PopulationReference Bureau

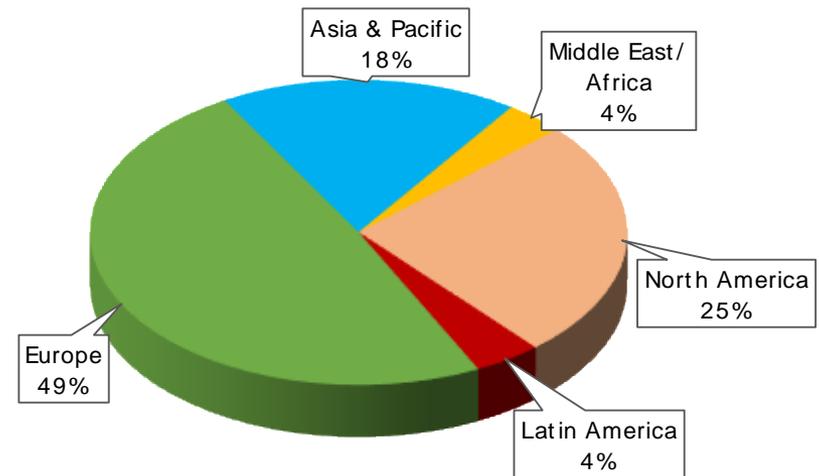
Latin America has almost 9% of the world's population but produces only 1% of the plasma for fractionation

**Plasma for Fractionation by Region 2017  
(Source)**



**Total: 48,514,000 liters**

**Plasma for Fractionation by Region 2017  
(Recovered)**



**Total: 8,340,000 liters**

The United States generates 71% to the world's source plasma for fractionation, and Latin America, less than 1%.



## Conclusion

- The IgG demand in Latin America has grown faster than in several other regions.
- IgG is an expensive therapy, which limits its penetration but funding is becoming available for chronic diseases treatment in Latin America.
- The dependency on the United States for the global supply of source plasma is now challenged. A diversification of supply appears desirable for political, socio-economic and health policy reasons.
- To ensure an adequate supply of IgG in future years, more source and recovered plasma should come from Latin America.

# **THANK YOU FOR YOUR ATTENTION**

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