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Monocyte Activation Tests Market Size and Forecasts (2020 - 2030), Global and Regional Share, Trends, and Growth Opportunity Analysis Report Coverage: By Source (PMBC and Cell Line), Products (MAT Kits and Reagents), and Application [Drug Development, Vaccine Development, Medical Devices, and Others (Research, etc.)]

https://marketpublishers.com/r/M2B7A2ABD2EEEN.html
Date: December 2023
Pages: 150
Price: US$ 5,190.00 (Single User License)
ID: M2B7A2ABD2EEEN

Abstracts

The monocyte activation tests market size was valued at US$ 65.174 million in 2022 and is expected to reach US$ 236.714 million by 2030; it is estimated to register a CAGR of 17.5% from 2022 to 2030.

The monocyte activation tests market analysis includes the study of market drivers such as a rise in patient safety concerns and a surge in demand for safer pyrogen testing methods in end-user industries such as pharmaceutical, biotech, and medical devices. Further, technological developments in monocyte activation test methods are anticipated to propel the monocyte activation tests market growth during the forecast period.

Based on the source, the monocyte activation tests market is bifurcated into PMBC and cell lines. The PMBC segment held a larger share in 2022 and is expected to continue a similar trend during the forecast period. Based on products, the monocyte activation tests market is bifurcated into MAT kits and reagents. The MAT kits segment held a larger share in 2022 and is expected to continue a similar trend during the forecast period. On the other hand, the reagents segment is anticipated to record a higher CAGR during the forecasted period. Based on application, the monocyte activation tests market is segmented into drug development, vaccine development, medical devices,

and others (research, etc.). The drug development segment captured the largest share in 2022 and is expected to witness the same trend from 2022 to 2030.

The monocyte activation test detects potentiated cytokine release from the synergistic effect of endotoxin and non-endotoxin pyrogens. The monocyte activation test (MAT) is an in-vitro assay designed to test parenteral drugs, biologics, and medical devices for all classifications of pyrogens. Over the last five years, vaccines that previously used the Rabbit Pyrogen Test as their release assay has been among the initial adopters of the monocyte activation test (MAT). Moreover, unlike MAT, bacterial endotoxin tests are often unsuitable for intrinsically pyrogenic products or those that include additives commonly included in vaccines, such as aluminum hydroxide, which tend to interfere with the assay. A few instances of MAT's uptake in testing vaccines included Neisseria meningitidis vaccine, Hyperimmune Sera, Meningococcal vaccines, Yellow fever vaccine, Shigella sonnei vaccine, Rabies vaccine, Hepatitis B Vaccine, and Tick-borne encephalitis virus vaccine.

Source-based Insights

Based on the source, the monocyte activation tests market is bifurcated into PMBC and cell lines. The PMBC segment held a larger share in 2022 and is expected to continue a similar trend during the forecast period. The same segment is expected to witness a higher CAGR from 2022 to 2030. Currently, two commercialized monocyte activation test cell sources are available globally—the Mono-Mac-6 (MM6) cell line and Peripheral Blood Mononuclear Cells (PBMC). The MM6 derives from the blood of a single acute monocytic leukemia patient; as a result, the monocytes sometimes do not have TLRs that reflect the stable expression required to consistently detect pyrogenic contaminants and initiate the release of cytokines by a healthy human. Hence, the reproducibility of MAT results is low using this cell source. The Ph. Eur. (2.6.30) also describes MM6-based MAT kits as 'limited' in detecting non-endotoxin pyrogens.

On the other hand, PBMC-based MAT kits source their PBMC from the pooled blood of screened, healthy donors—which means that when incubated with a spiked product sample, the monocyte activation can assist the growth of a healthy human being. As a result, results for MAT kits based on this cell source have been consistently found to be reproducible. The Ph. Eur. (2.6.30) counts this cell source as proficient in detecting both endotoxins and non-endotoxin pyrogens.

Currently, three other commercialized PBMC-based monocyte activation test vendors are on the market. Each has a LoD of 0.125 EU/ml, 0.02 EU/ml, and 0.016 EU/ml. The

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CTL-MAT assay has a market-leading LoD of 0.004 EU/ml, making it the most sensitive monocyte activation test available worldwide.

Products-based Insights

Based on products, the monocyte activation tests market is bifurcated into MAT kits and reagents. The MAT kits segment held a larger share in 2022 and is expected to continue a similar trend during the forecast period. On the other hand, the reagents segment is expected to register a higher CAGR during the forecasted period.

Regional Analysis

The monocyte activation tests market is segmented based on region: North America, Europe, Asia Pacific, South & Central America, and the Middle East & Africa. North America captured the largest market share in 2022 and is expected to continue a similar trend during the forecast period, followed by Europe. Regulatory practices of monocyte activation tests by organizations such as United States Pharmacopeia (USP) and the Government of Canada have further fueled the overall growth of the monocyte activation tests market in the region. Also, increasing focus on patient safety concerns and improved healthcare outcomes is one factor aiding North America's market growth.

Merck KGaA, Darmstadt, Germany and/or its affiliates; Charles River Laboratories International, Inc.; Thermo Fisher Scientific; Sanquin; and Lonza Group are among the leading companies operating in the monocyte activation tests market.

In October 2023, Lonza launched two new rapid monocyte activation test (MAT) systems, the PyroCell MAT Rapid System and PyroCell MAT Human Serum (HS) Rapid System, to streamline and ease rabbit-free pyrogen testing. The systems will replace Lonza’s traditional MAT system kit offerings, and the newly launched products contain the new PeliKine Human IL-6 Rapid ELISA Kit that minimizes hands-on time and reduces time-to-results from two days to two hours. The new tests give pharmaceutical and biotechnology manufacturers easier MAT testing options for product safety testing while helping to reduce the reliance on animals.

Some sources referred while conducting the monocyte activation tests market are Therapeutic Goods Administration, The Humane Society of the United States, and the National Institutes of Health, among others.

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