

# FOCUSED ON QUALITY

## HIGH QUALITY REAGENTS FOR FLOW CYTOMETRY

Beckman Coulter is focused on quality, aiming to provide laboratories with the necessary tools to perform clinical diagnostic and clinical research tests by Flow Cytometry under optimal conditions. The same stringent criteria are applied across the Beckman Coulter reagents portfolio, including products that can be used for research, clinical research as well as clinical diagnostics.

**Quality is the single most important function of every Beckman Coulter employee. Quality means always striving for excellence:**

- Meeting or exceeding our customers' expectations
- Complying with regulatory requirements
- Maintaining an effective quality management system
- Continuously improving

**Quality leadership is essential to industry leadership.**



### **cGMP aligned Manufacturing**

The entire Beckman Coulter Flow Cytometry Antibody portfolio is manufactured under conditions aligned with the current Good Manufacturing Practice (cGMP) guidelines in facilities that adhere and are certified to the highest standards in the industry. The facilities and the manufacturing processes are audited at regular intervals by national and international authorities, quality assurance bodies and internal quality experts. Current Good Manufacturing practices ascertain that optimal processes are followed over the whole life product life cycle, from design and development over manufacturing towards product updates and improvements. The cGMP regulation provide clear guidance for manufacturing under entirely controlled conditions. Products thereby consistently meet pre-defined specifications across lots and over time, by demonstrably addressing issues such as quality control and documentation. More than 30 years of experience in conjugated antibody development and manufacturing, associated with robust internal performance criteria, make Beckman Coulter a market leader in delivering excellent quality and trusted flow reagent products.

### **CE marking of In Vitro Diagnostic Medical Devices - IVDD**

CE-IVD-labeled products manufacturing follows the European Directive (98/79/EC) for in-vitro medical devices. European Directive (98/79/EC) indicates conformity to the legal requirements of the European Union (EU) for in vitro diagnostic medical devices with respect to safety and health.

CE-IVD marked products help customers to demonstrate quality of their analysis. Performances of CE-IVD marked products are established by the manufacturer, which facilitates verification instead of full validation of customers' assays.

### **ISO International Standards**

The compliance with standards such as ISO 13485:2016/ ISO 9001:2015 demonstrates continuous improvement of Beckman Coulter's quality management systems (QMS) and processes.

## RUO reagents

Per FDA regulation<sup>§</sup>, the RUO products are described as products “in the laboratory research phase of development and not represented as an effective in vitro diagnostic product.” The same regulation establishing the RUO category requires that RUO products bear the following labeling statement: “For Research Use Only—Not for use in diagnostic procedures.” Even if not required, Beckman Coulter manufactures all its RUO reagents under conditions aligned with the current Good Manufacturing Practice (cGMP) guidelines.

## ASR reagents

- FDA created the ASR status to ensure the quality of materials used as components of laboratory developed tests.<sup>§§§</sup>
- The Beckman Coulter Analyte Specific Reagents (ASR) are developed to meet the needs of clinical customers in the United States and are medical devices regulated by FDA. They are subject to general controls, including current Good Manufacturing Practice (cGMP, 21 CFR 820), as well as the specific provisions of the ASR regulations (21 CFR 864.4020). This ensures rigorous standards for development and manufacturing.
- While high quality standards are required to develop ASR reagents, according to FDA guidelines, no claims for clinical or analytical performance can be made for ASR products and the labeling must bear the following statement: “Analyte Specific Reagent. Analytical and performance characteristics are not established.”<sup>§§§</sup> Beckman Coulter has the largest portfolio of ASR reagents.

## CE-IVD reagents

Beckman Coulter develops CE-IVD marked reagents with the objective of optimizing performance and thus improving patient diagnostics. CE-IVD reagents help clinical flow laboratories validate their assays to be compliant with regulatory bodies and accreditation requirements (such as ISO15189 accreditation). Compliance to CE-IVD regulatory status requires the manufacturer to demonstrate and provide to the customer with the claimed performance.

	RUO	ASR	CE-IVD
Research use	✓	✓	✓
Diagnostic use*	✗	✓	✓
FDA General controls	✓	✓	✗
Manufactured under cGMPs	✗**	✓	✓
Labeling requirements	✓	✓	✓
Performance claims	✓	N/A	✓
Detailed IFUs in local languages	✗	✗	✓
Generate data to support performance claims	✓	N/A	✓
Facilitated laboratory accreditation	✗	✗	✓
Manufacturer audit by certification bodies	✓	✓	✓

\* ASR is recognized for diagnostic use only in USA while CE-IVD is only recognized outside US.

\*\* While manufacturing under cGMP isn't mandatory, BC manufacture all its reagents, including RUO labelled under cGMP.



Beckman Coulter has implemented the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). For each product, updated Safety Data Sheets (formerly MSDS) and Instructions For Use (IFU) are available on the web site.

<sup>§</sup> 21CFR 809.10 (c) (2) (i)

<sup>§§</sup> 21CFR 809.30

<sup>§§§</sup> Guidance for Industry and FDA Staff - Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions Document issued on: September 14, 2007