



ANALYTE SPECIFIC REAGENTS (ASR)

Frequently Asked Questions



1 What is an ASR?

ASR stands for **Analyte Specific Reagents**. ASR are regulated by the **US Food and Drug Administration (FDA)**. The FDA defines ASR as “**antibodies**, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are **intended for use in a diagnostic application** for identification and quantification of an individual chemical substance or ligand in biological specimens”.

The FDA created this regulatory status to ensure availability of individual reagents meeting specific quality requirements for clinical laboratories to use in developing Laboratory Developed Tests (LDTs). Many flow cytometry in vitro diagnostic tests fall into this category. The ASR regulatory status aims to provide US clinical laboratories with consistently manufactured reagents to ensure the quality of their LDTs. This status was developed by the US FDA and is not recognized in countries outside of the United States.

2 What aspects of the regulation ensure consistency of the product?

ASR are medical devices that are regulated by the FDA, which will notably audit the facilities and the supplier manufacturing processes. ASR are subject to medical devices reporting and general controls, which provide guidelines to medical device companies and also help the FDA to keep track of effectiveness and safety of clinical products.

Another aspect of the regulation that contributes to product quality is that all ASRs must be manufactured under current Good Manufacturing Practices (cGMPs).

3 What are the benefits of cGMP Manufacturing?

Current Good Manufacturing Practices are regulations that outline a system approach to the development, manufacturing, monitoring, and packaging of medical devices. It ensures optimal processes are followed from product design and development to manufacturing and product updates. GMP regulations provide guidance to ensure products are manufactured under controlled conditions so that they meet consistent specifications across lots and over time by addressing issues such as quality control, complaint handling, or sanitation.

Beckman Coulter follows this standard in the manufacturing of all of its products. Our facilities are certified so that they adhere to the highest standards in the industry.



4 What does “performance characteristics are not established” mean?

ASR regulation requires the following statement on product labels: “Analyte Specific Reagent. Analytical and performance characteristics are not established.” This statement may be misinterpreted by laboratories that are not familiar with the ASR regulation and requirements. The purpose of this statement is to prevent the manufacturer from making any clinical or analytical claim. The performances must be validated by the individual laboratory developing the LDT assay using this reagent.

This statement does not mean that the products were not tested to meet specifications for consistent quality. During product development, performances are strictly assessed and optimized to ensure the ASR will provide optimal performances. These products do follow rigorous procedures and meet strict criteria under the cGMP regulations.

5 Why can't I find performance information or instructions to help me evaluate the quality of ASR products?

It is the laboratory's responsibility to prove performances characteristics of any LDTs that they develop for their clinical testing. Therefore, under the ASR regulation, manufacturers are not allowed to provide any specific protocol or performance claims. Hence, product documentation, such as the Instructions For Use or Product Datasheet, do not include information such as:

- Recommended protocol or procedure, including recommended volume per test
- Specific analytical or clinical performance claims
- Literature regarding an ASR's clinical utility and clinical performance
- Instruction for use in a particular test or application
- Instruction for validation of a specific test using the ASR
- Suggested companion products (markers, buffers, controls, etc.)

6 Why is Beckman Coulter commercializing ASR outside of US?

Even though the ASR status is not recognized outside of the United States, we feel strongly that the consistency and quality that are inherent in following these standards contributes to the delivery of high quality products that help laboratories in their work. Beckman Coulter has the largest offering with over 650 ASR single color conjugates.

We also invest considerably in developing CE-IVD cleared reagents, to ensure we meet our customer needs and help them be compliant with their regulatory bodies in all geographies.

7 Is there a resource that I can use to learn more about ASRs?

More information on ASR and related requirements can be found in the following documents from FDA:

- Guidance for Industry and FDA Staff. Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions. FDA. Document issued on: September 14, 2007
- 21 CFR - Code of Federal Regulations Title 21