

**Comments to the Food and Drug Administration (FDA) in response to their
Draft Guidance on analyte specific reagents (ASRs)**

February 22, 2007

Comments represent the opinion of Genetic Alliance and the undersigned organizations and individuals:

Genetic Alliance established the Consumer Task Force on Genetic Testing in September 2006. It is comprised of nine advocates (listed below) who have experience in genetic testing from a variety of perspectives. This Task Force has raised the participation level of consumers to a high level, allowing the various systems that desperately need consumer input to benefit from the consumer perspective. The Task Force is also instrumental in educating other consumers to be active participants in education and policymaking for genetic testing. In many cases, thus far, this has allowed competing entities or concepts to be measured by what is at stake at the core of the issue. Novel solutions, more moderate discourse and new facets of the issues have emerged as a result.

We present here the views of many concerned individuals, members of more than 600 disease-specific genetic support groups, professionals, and other stakeholders. These individuals number more than 25 million individuals affected by more than 1000 diseases. We transform the leadership of the advocacy community, build capacity in advocacy organizations, and promote consumer-informed public policies.

After reviewing the guidances, we have concerns, both about the guidances and about some of the rhetoric around ASRs and IVDMIAs from all stakeholders.

As individuals and families affected by genetic diseases, and as advocates, we are deeply concerned that we have not struck the correct balance and we are currently engaged in an inadequate dialogue to serve the end users of ASRs and IVDMIAs. We begin with overarching comments and then turn to the guidance.

Specific Comments on the Analyte Specific Reagent (ASR) Guidance

- * It is ambiguous.
- * It does not define “single moiety” and a “single endpoint”, though it does declare these as attributes of ASRs.
- * The guidance states that ASRs may only be one to a vial. Test developers and lab personnel will have to use many more steps to create and use a test if this is mandated. Thus will lead to unnecessary burdens on personnel, test development and ultimately access to tests, particularly from esoteric labs conducting rare disease testing.
- * The ASR Draft Guidance says that reagents that are extensively processed, for use on a specific instrument, or for use with specific software are not considered ASRs. This appears to include microarrays and beads and therefore will limit their emerging usefulness in testing, stifling innovation and freezing the development of many tests currently in production.
- * The requirement for products currently marketed as ASRs to obtain premarket clearance or approval may impair laboratories’ access to GMP-compliant ingredients or “building blocks” for laboratory developed tests (LDTs) – processes that will be overly burdensome for the many laboratories offering genetic testing.
- * At present, tests approved under the various FDA mechanisms need to be resubmitted if they change, subject to long approval times, increased time spent in gaining approvals and slow changes in tests.
- * The ASR Draft Guidance prevents laboratories from receiving useful information, such as peer-reviewed publications involving ASRs or development and validation information from other laboratories that have had experience with test development and validation using ASRs, thereby reducing the speed with which these tests are refined and iteratively made more useful.

Read the full text of the comments [here](#).