



THE GLOBAL LEADER IN GMO IDENTIFICATION

## Fifteen Questions to Ask Before Selecting A GMO Testing Lab

May 2003

Genetic ID NA, Inc.  
P. O. Box 1810  
Fairfield, Iowa 52556-9030  
USA  
1.641.472.9979 (phone)  
1.641.472.9198 (fax)  
[www.genetic-id.com](http://www.genetic-id.com)  
[info@genetic-id.com](mailto:info@genetic-id.com)

Copyright © 2003 by Genetic ID NA, Inc. All Rights Reserved

## Fifteen Questions to Ask Before Selecting a GMO Testing Lab

---

GMO testing labs vary widely in the accuracy, scientific rigor, and quality of their analytical services. The range of performance becomes obvious when one reviews the results of any ring trial or performance assessment study of GMO testing labs.

Selecting a lab is not a trivial decision, because the client must rely on that lab for business-critical information, information that may significantly affect the perception of their products in the marketplace and, consequently, their bottom line.

How to select the “right” lab? The questions outlined below are a good place to start when assessing the promise of any candidate lab.

---

### **1. Is the lab accredited to ISO 17025 by a respected third party accreditation organization?**

Accreditation to ISO 17025 assures that laboratory performance meets the recognized international standard for analytical laboratories. The accreditation process involves the following:

- \* Inspection of laboratory facilities to assure that all necessary equipment and facilities are available
- \* Auditing of the quality manual and thorough review of the quality system
- \* Auditing of records and documentation to verify that the laboratory is actually operating in accordance with the quality manual
- \* Review of the qualifications of all scientific and technical staff to assure that necessary expertise is present on site
- \* Review of extensive validation data for each method that is to be accredited, to assure scientific rigor and technical reliability

Not all accreditation organizations are equally accepted and respected by the food and agricultural industries. For instance, reciprocity agreements are not currently in place that allow accreditation carried out by US accrediting bodies to be accepted in the Europe. It is, therefore, essential to carefully select an accreditor that has a high level of respect and

acceptance in markets where the client intends to offer their products.

### **2. Does the laboratory’s testing methodology detect all GMOs currently in the marketplace?**

Only testing that is capable of detecting all GMOs in the marketplace is useful in mitigating risk related to the GMO issue. If a laboratory’s methods do not detect all commercialized GMOs, then a “GMO-negative” report may mask the presence of GMOs that may come to light when subsequent tests are conducted by government authorities or by buyers. Such a discovery could trigger a costly recall of the product from the market, or rejection of the product by the buyer, as well as brand damage. These are serious risks that can be avoided by use of comprehensive GMO testing methods.

### **3. Does the laboratory have methods that can identify and distinguish between approved and unapproved crop varieties?**

Detection of the presence of GM material is one thing. Identification of *which* GMO is present, is quite another. It is critical that the laboratory offer methods that definitively answer the second question—*which*. This question must be asked for all GMOs that have been commercialized. A partial answer will not suffice. This is because several GM crop varieties have been commercialized widely in North America that have not been approved for human food use in Europe, Japan, and other regions around the world. At present, regulations in most nations impose a zero-tolerance requirement on such “unapproved” GMOs. That is, the presence of these unapproved GMOs in a food product triggers immediate recall of that product from the marketplace, and often entails serious legal penalties. In order to protect the testing client from serious risk, it is essential that the laboratory have the capability of definitively identifying each genetically modified crop variety in the marketplace.

### **4. Do the laboratory’s testing methods operate to highly sensitive limits of detection and quantification?**

A limit of detection of 0.01% is the minimum standard in the industry, and at present, the technical limits of quantitative GMO testing methods set the practical limit of quantification at 0.1% for real-time quantitative

PCR. Recent advances in methodologies make it possible to achieve even more sensitive limits of detection, in the 0.005 to 0.002% range, which make it possible to composite samples for testing. Compositing saves money by reducing the number of PCR tests required, yet assures that over-all sensitivity still meets the standard of 0.01%. For instance, if the client requires screening of 5 samples for the presence of GM corn, they could be tested individually using a method with a limit of detection of 0.01%. Alternatively, equal amounts of the five samples could be composited and a single test conducted at a limit of detection of 0.002%. Any one of the 5 samples that contained 0.01% GMO or more would trigger a positive result for the test. Compositing reduces the number of tests required and thus significantly reduces costs. The innovation that has made it possible to improve limits of detection is the improvement of DNA purification procedures such that they more effectively remove PCR inhibitors and thereby make it possible to add larger amounts of DNA to each PCR reaction.

**5. Does the laboratory use statistically valid sample sizes?**

Highly sensitive limits of detection and quantification are meaningful only if sample sizes analyzed are statistically valid for the limit of detection used. Using sample sizes that are too small is a common cause of false negative test results. For instance, if a lot of corn contains 0.1% GM material, yet the sample size is only 300 g (1000 kernels of corn), there is only a 63% chance that the sample will actually contain even a single kernel of GM corn. In this case, no matter how sensitive and reliable the PCR method is, there is a 37% probability that the analysis will yield a false negative result. Some laboratories use samples as small as 100 kernels. With this sample size, the probability that the test would yield false negative results would be 90.5%. A sample size of at least 10,000 kernels is highly recommended for unprocessed grain or beans. A table suggesting suitable sample sizes of other products can be found at [www.genetic-id.com](http://www.genetic-id.com).

**6. Does the laboratory offer quantitative GMO analysis by real-time quantitative methodology, as well as conventional qualitative GMO analysis, and can they provide ring-trial (performance assessment) results that demonstrate their proficiency in quantitative PCR?**

Real-time PCR provides the most accurate quantitation possible over a wide range of GMO

concentrations. This powerful and versatile technique is technically very demanding, however. For this reason, it is important to verify that the laboratory has objectively demonstrated its ability to effectively and accurately carry out real-time PCR analysis. Two methods can be used in this verification. First, check that the lab has accredited its real-time analytical methods to ISO 17025, since such accreditation requires that the lab provide detailed validation data to the accreditation agency. Make sure that the ISO accreditation applies specifically to the real-time quantitative method that they intend to use with your samples. Second, ask the lab to document that they have performed satisfactorily in ring trials conducted by an independent organization, such as the US Department of Agriculture, the UK Food Analysis Performance Assessment Scheme, the American Oil Chemists Society, etc.

**7. What approach does the lab use for DNA extraction/purification? Do they use their own methods, or do they use off-the-shelf commercial kits?**

Many of the compounds naturally present in foods are actually strong inhibitors of the PCR process. It is essential to remove all such compounds from the DNA preparation before carrying out PCR analysis. If this separation or purification is not effective, the sensitivity of the PCR process will be greatly reduced and there will be increased “noise” in the analytical system. The result will be increased risk of false positive and false negative results. The inhibitor problem is compounded by the fact that foods and agricultural products are chemically highly complex. This means that a DNA extraction procedure that works well for one food will fail to work for another. In essence, it is necessary to customize DNA extraction methods for each kind of food product. The use of off-the-shelf DNA extraction kits, purchased from scientific supply houses will be successful with some kinds of foods, but not others. Thus, custom methods are necessary.

**8. What controls does the lab use routinely to detect problems with the sample, such as DNA degradation or the presence of PCR inhibitors?**

Two controls are critical for verifying sample quality. The first is a positive control using primers that target a gene present naturally in all varieties of the species of interest. If PCR amplification is reduced in reactions containing the sample DNA, compared to reactions containing a reference preparation of DNA from the species of interest, it is likely that inhibitors are present and/or the sample DNA is degraded. The second critical control is an internal control accomplished by

comparing PCR amplification of a known amount of a defined DNA template, by itself, and in the presence of sample DNA. If the sample DNA preparation contains inhibitors, PCR amplification will be reduced. By comparing the results obtained with the positive control and the internal control, the presence of inhibitors and the occurrence of degradation in the sample DNA can both be evaluated.

**9. What controls does the lab use routinely to ensure uniform and consistent performance characteristics of the analytical method?**

For every GMO targeted by a given analytical method, the lab should possess verified, quantitatively defined reference materials. These should be used to set up reactions that function as series of external quantitative reference points that can be used to calibrate the quantitative response of the assay and to ensure that the assay is operating correctly and consistently. Quantitative external reference reactions are a given for quantitative PCR, but are also essential for qualitative analyses, because without them it is impossible to be sure that the method is operating to the same level of sensitivity from day to day. Of equal importance, if verified reference material for each GMO of interest is not used as a control in the assay, the analyst has no way of ascertaining that the method is operating properly and detecting all GMOs of interest. The positive control reactions and internal control reactions, discussed in Point #8, are also important in verifying the consistency of performance of the analytical method.

**10. What controls and standard operating procedures does the lab use routinely to detect and correct errors due to operator mistakes or instrument malfunction?**

It is essential to detect such errors and quickly correct them, before results are submitted to the client. All of the controls, described above in Points #8 and #9, provide information relevant to this question. All of these controls must be used routinely in order to guard against error. Another essential precaution is to analyze every sample in duplicate from start to finish. This means that DNA should be purified from two independent, representative sub-samples, and these should be analyzed independently by PCR. If duplicate results do not agree, the whole analysis must be repeated. It is not sufficient to run duplicate PCR analyses of a single DNA preparation. Such a practice reduces the effort required to analyze any given sample, since DNA purification is the most

labor-intensive part of GMO analysis. However, adopting this approach significantly increases risk. Instead, it is recommended to carry out duplicate DNA extractions and then test these independently by PCR. Only then can risk of possible errors be significantly reduced. All controls and standards should also be analyzed in duplicate.

**11. What precautions does the lab use to ensure consistency in data-interpretation?**

The key elements are two: (1) implementation of standard operating procedures for data analysis, as well as for the actual laboratory processes involved in GMO analysis, and (2) thorough training and regular re-training of all analysts to ensure that they apply those operating procedures in a uniform and consistent manner. Standard operating procedures are a given for analytical processes. However, if data interpretation is not standardized just as rigorously as the analytical process, inconsistencies in reporting of results will inevitably arise.

**12. Does the lab empirically verify all new analytical methods?**

It is easy to go to a database of DNA sequences and design PCR primers that, *in theory*, should detect a certain GMO. Many labs make claims regarding the capabilities of their methods on such a theoretical basis. For rigor, it is essential to empirically validate the effectiveness of new primer sets using verified samples of the targeted GMO. Although it is sometimes difficult to obtain the necessary reference materials, only after such validation can the laboratory have confidence in a new method.

**13. Is the laboratory independent?**

Some parties are hesitant to accept analytical results reported by a laboratory that has corporate links to organizations that operate commercially within the food or agricultural industry. The need for the highest level of credibility dictates the use of independent laboratories.

**14. Does the laboratory offer high quality, responsive customer support and service?**

Are account managers knowledgeable, not only in technical matters related to testing itself, but also regarding national and international regulations and market conditions related to GMOs? Only individuals with this kind of background can provide guidance in configuring a testing regime that will most effectively and economically meet the business needs of the client.

- \* Is sample turn around time rapid and responsive to emergencies? A 3 day turn-around should be standard service, and 24 hour express service should be available for emergencies.
- \* Does the lab customize testing services and the formats of test reports to the business needs of the client? Each client has specific needs that are special to their business. The laboratory should be capable of adjusting to meet these special needs.

**15. Does the lab provide access to consistent and reliable testing world-wide?**

Food and agricultural exports must frequently pass multiple GMO tests conducted thousands of miles apart. If the labs involved test to different standards, conflicting results will frequently arise, creating significant business risk. For companies that operate in the international arena, it is highly useful to work with a lab that has affiliates in many locations around the world, all of which operate to uniform, standardized procedures, and thus assuring consistent testing of products, wherever they are moved around the globe.