

Exclusive Licenses For Home-Brew Genetic Tests: Some Questions And Answers

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1. What is the role of genetic testing in clinical laboratories in teaching hospitals?

Teaching

Medical education is based on the principle that trainees learn clinical medicine from actual patients during the process of diagnosis, treatment, and prevention of disease. Although didactic activities are also essential, they can not substitute for the experience obtained by working directly with patients and their specimens. With regard to clinical laboratory diagnosis, physicians in training learn how to use and interpret diagnostic tests through exposure to actual case material. For example, surgeons review biopsies to correlate clinical and surgical findings with histopathologic findings. Internists review items such as peripheral-blood smears or Gram stains of pathogenic organisms to understand the diagnostic process for their patients.

The same principle applies to new diagnostic tests for genetic diseases. To learn to use and interpret these tests, physicians in training should be able to review the primary laboratory data. Medical specialty boards recognize these needs in their training requirements for board certification. For example, the American Board of Medical Genetics has these requirements for trainees seeking certification in clinical molecular genetics:

- actual handling of case material in the diagnostic laboratory

- a logbook with a minimum of 150 clinical cases covering a wide variety of genetic diseases and test methods

Research

A base of clinical testing is essential for the following types of health-services research:

- Development and validation of new or improved diagnostic tests
- Clinicopathologic correlation, such as establishing reference ranges or identifying patient genetic variants that give erroneous results with existing test methods
- Outcomes analysis: determining the medical and psychosocial effects of genetic testing on patients and families, and its impact on the healthcare system and society

Clinical Care

University laboratories provide services not always available from commercial reference laboratories, such as:

- Consultation on complex or difficult-to-diagnose patients
- Enrollment of selected patients in research studies
- Continuity of care for patients or families undergoing complex genetic evaluations
- Service to all patients regardless of ability to pay

2. Is an exclusive license needed in order to make a patented genetic test available to the public?

Usually not. The development of a home-brew diagnostic genetic test is a relatively simple matter. For most genetic tests, it typically takes about 2-6 months and about \$10,000-\$50,000 to develop and implement a clinically usable diagnostic test. Thus, there are usually multiple laboratories willing and able to offer such tests.

In contrast, an exclusive license for the sale of kits might be justified for a company willing to develop an FDA-approved diagnostic kit for a genetic disease, in order to allow it to recoup the costs of kit development, clinical trials, and FDA approval.

3. Does an exclusive license of a genetic test to a commercial laboratory meet all societal needs?

Generally not, unless the licensee can provide all of the following:

- Training programs for physicians and allied-health students
 - Availability of raw laboratory data for review by clinical trainees, and participation of laboratory directors in regular clinical teaching conferences
 - Access to retained specimens and laboratory records for purposes of approved health services research related to genetic testing
 - Physicians on staff who review and interpret test results and provide consultation with ordering physicians
 - Testing for patients with no insurance coverage
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4. Can sole-source testing have deleterious effects on medical practice?

Yes, such as the following:

- Lack of a peer group for method validation and proficiency testing
 - Lack of diversity in analytical methods and test interpretation
 - Lack of a second laboratory for confirmatory testing in unusual cases
 - Possible restricted access to testing for indigent patients
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5. Can "commercial use" be separated from research and teaching?

This is very difficult to do at a teaching hospital due to the integration of research and teaching with clinical care. It is also well accepted that an academic health center derives some of its budget from fees for patient care; no teaching hospital can provide free care to all patients. Nevertheless, collection of fees for patient care does not mean such activities are inherently commercial in nature.

6. How can non-commercial genetic testing laboratories be identified?

Some of the following indicators can be used:

- Parent institution has non-profit status
- Established role as training site for accredited residency and fellowship programs in
- pathology or medical genetics
- Established role in research, as evidenced by publications, etc.
- Local or regional service area (versus national service area)
- Lack of organized marketing and advertising activities
- Lack of budgetary self-sufficiency on the basis of clinical testing revenue
- Some clinical testing performed at reduced charge or no charge