

Direct to Consumer Testing

Irene Tebbs, Ph.D.

Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health

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Overview

Examples of cleared tests

Benefits and Risks

Interpretation of results

Device performance

Labeling

Human factors

DTC genetic testing: additional labeling considerations

What is a DTC test?

- This term describes a scenario where the testing is initiated by the consumer.
- “Over-the-counter (OTC)” and outside of the typical patient-doctor relationship

Examples of DTC type tests that FDA Regulates

Test	Collect sample	Perform test	Interpret results
Glucose	Yes	Yes	Yes
Pregnancy	Yes	Yes	Yes
Drugs of abuse	Yes	Yes	Yes
Breath alcohol	Yes	Yes	Yes

Examples of DTC type tests that FDA Regulates

Test	Collect sample	Perform test	Interpret results
Bloom Syndrome Carrier screening test	Yes	No	Yes***

What are the Benefits of DTC Tests?

- Condition/disease that needs to be monitored at home
- Example: Diabetes

Home glucose meters monitor the management of diabetes home user under care of a physician

Not for diagnosis – no performance data for that claim

What are the Benefits of DTC Tests?

- Condition/disease that can be identified to allow for early detection at home
- Example: Pregnancy (urine hCG tests)
Users have the option to retest, go to Healthcare Provider (HCP) for additional information

What are the Benefits of DTC Tests?

- Condition/disease that can be screened for at home
- Example: Drug detection (Home DOA urine test)

These are not definitive tests

Mitigation for risk of false positives – positive results should be followed up by sending a sample for confirmation testing

What are the Risks of False or Inaccurate Results at Home?



- Failure to seek treatment
- Delay in seeking treatment
- Improper self management/treatment
 - What could the user do with this information?
 - Cease taking prescribed medication? Change dosing?
- No follow up with health care provider
- Unnecessary worry
- False sense of security (if user is not aware test may be wrong)

Considerations for DTC Tests?

- Is the consumer device robust?
 - Simple to use
 - Works correctly every time
 - Not affected by environmental conditions or different operators
- Can a home user read instructions and
 - Collect the sample correctly
 - Perform the test (if applicable)
 - Get accurate results and interpret results

**Do the benefits outweigh the risks? If yes,
then...**



Evaluate Performance of the Test in the Hands of the Intended User



Should assess whatever aspect(s) of the device that the user interacts with. If the user does not perform the test, may be appropriate to assess effective use of collection device (if not previously cleared for that intended use).

Lay User Study

- Compare lay user results to laboratory method
- How well the test should work at home depends upon benefit and mitigation of risks
- This study should evaluate the likelihood of incorrect results which will be included in labeling



How Do Human Factors Play a Role in Home Tests?

- People have different abilities to follow directions
- Home users are not trained users so no “good laboratory practice” standard for them
- Fail to get adequate or appropriate sample
- Can perform test incorrectly
- Can interpret results incorrectly

Labeling



Does the labeling provide adequate information so home user can perform the test and interpret the results for safe and effective use?





How Does FDA Review Labeling for DTC Tests?

- Written at 8th grade reading level
- Simple instructions
- Pictures and diagrams on how to obtain a sample and perform test (if applicable to the device)

How Does FDA Review Labeling for OTC/DTC Tests?

- Clear instructions on how to interpret the results including:
 - What to do with the results? (examples might include calling HCP or retesting)
 - How the user will know if device did not work?
 - What the user should do if device does not work?
 - Telephone number to call for assistance

Additional labeling considerations for DTC genetic testing

For many traditional OTC tests, the relevant information and context necessary for safe and effective use of the device is common knowledge or simple to convey. This is not necessarily the case for DTC genetic testing.

Pregnancy Test Example:



Q: Who should take this test?

A: Women who suspect they may be pregnant

Q: What is the result?*

A: You are pregnant

Q: What is the impact to the user and what should the user do next for more information?

A: You are going to have a baby! Follow up with your OB/GYN.

*If result is provided as a symbol, users' ability to correctly interpret the symbol based on the labeling should be assessed as part of the lay user study.

Hereditary Hemochromatosis Genetic Test Example :



Q: Who should take this test?

A: Clinical practice guidelines exist but there are several factors to consider.

Q: What is the result?

A: You are a H63D/S65C heterozygote for the *HFE* gene

Q: What is the impact to the user and what should the user do next for more information?

A: ???

Pre-test labeling:

- Can the user assess if the test is appropriate for them prior to purchase (for example, is the test relevant given their ethnic background?). Example: Hypertrophic cardiomyopathy variant
- Does the user have sufficient information to decide if they want to know the result of the test? Example: Huntington's disease

Interpretation of Results

- Correct interpretation of the test result is part of the safe and effective use of the device.
- Labeling should provide sufficient context to ensure the patient understands the result and its implications for their health.

Impact of Results

- Accurately conveying the impact of a genetic result to a user can be difficult.
- Providing some background information may be necessary

Impact of Results: Hypothetical Example I

- Your genetic results mean that your risk of disease ABC is doubled

OR

- In the general population, 1 out of every 1000 people develop disease ABC. Based on your genetic result, your risk of developing this disease is 1 in 500

Impact of Results:

Hypothetical Example II

- Your genetic results mean that your risk of disease XYZ is 25% greater than the general population

OR

- In the general population, 1 out of every 10,000 people develop disease XYZ. Based on your genetic result, your risk of developing this disease is 1 in 8,000

User comprehension

A pre-market submission for a DTC genetic test should include an assessment of user comprehension of the test results.

Example from only DTC Genetic Clearance to Date

- DEN140044: Carrier screening test for Bloom Syndrome
- Users must go through an educational module prior to receiving results.
- Test report provided to user with results and some interpretation.
- User comprehension assessed prior to clearance by testing lay users who have reviewed hypothetical test reports
- The sponsor offers information on how to contact a genetic counselor

Summary – FDA Principles for Regulation of Direct to Consumer Tests

- Benefits vs. risks
- Mitigation of risks
- Interpretation of results by lay user
- Performance of the device by lay user
- Labeling
- Human factors

Resources:



Website for Database Search for Home Use Tests:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm>

Molecular and Clinical Genetics Panel Meeting:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/ucm245447.htm>

FDA Public Workshop on Return of Genetic Results (archived webcast available):

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm478841.htm>

Thank You!

Irene.Tebbs@fda.hhs.gov



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