

Direct Access Testing

Introduction and
Overview

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Direct Access Testing

- Consumer chooses tests
- Consumer pays for tests
- Consumer responsible for interpreting tests
- Consumer responsible for follow-up to test results

Direct Access Testing “On line” or “By phone”

- Healthcheckusa.com
- Directlab.com
- Health-tests-direct.com
- QuesTest.com

Direct Access Testing “Storefront Services”

- 10-15% of hospital and commercial laboratories currently offer direct access testing
- Venues:
 - Laboratory collection centers
 - Pharmacies
 - Shopping malls
 - Grocery stores

Direct Access Testing

Test menus

- Some companies restrict consumer ordering to limited menus of familiar tests
 - Lipids, glucose, prostate specific antigen, HIV
- Other companies offer access to any laboratory test
 - One laboratory advertises 5,600 test selections
 - Genetic tests included in menus

Direct Access Testing Media Attention

- New York Times
- Washington Post
- Wall Street Journal
- Time
- Public Broadcasting System

Direct Access Testing- What the Media is Saying:

- Consumer/patient empowerment
 - Taking charge of your own health testing
 - Disintermediation
 - No doctor
 - No insurance company
- Convenience
 - Eliminating need for doctor's office visit

Direct Access Testing- What the Media is Saying:

- Cost savings
 - No doctor's office visit
 - Favorable pricing
- Privacy
 - No doctor
 - No insurance company
 - No medical record

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What the Media is Saying:

- Marketing “health screening”
 - Comprehensive wellness profile
 - Executive health profile
 - Women’s health profile
- Marketing to
 - “well-heeled”
 - “worried well”

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- Paradigm shift in health care
 - Move away from a physician focus
 - Move toward a consumer focus
 - Marketing and sales of health care services directly to consumer
- Role of government
 - Bystander?
 - Observer and monitor?
 - Regulator?

Direct Access Testing

What advice does the Clinical Laboratory Improvement Advisory Committee have for the Secretary of Health and Human Services about direct access testing?

Direct Access Testing Background Information to CLIAC

- Applicability of current CLIA regulations
- A physician's perspective
- A laboratory's perspective
- A consumer group's perspective
- Comments from various professional organizations
- Public comments

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Impact of CLIA

Rhonda Whalen

Branch Chief, Laboratory Practice Standards

Division of Laboratory Systems

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A Physician's Perspective

Verlin Janzen, MD.

Practicing physician, laboratory director

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A Laboratory's Perspective

Hughes Bakewell

Vice President, Consumer Testing

Quest Diagnostics

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A Consumer Group's Perspective

Charles Inlander
President,
People's Medical Society

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Comments

College of American Pathologists

American Society for Clinical Pathology

American Society for Clinical Laboratory
Science

American Association for Clinical Chemistry

Federal Trade Commission

Others...

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CLIAC Discussion

Where do we go from here?

Need for more information?

Advice to Secretary and Agencies?