



Direct Access Testing

Overview and Summary March 2003 CLIAC Meeting

Toby L. Merlin, M.D.
Associate Director for Laboratory Medicine
Division of Laboratory Systems

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Direct Access Testing

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- Description of direct access testing
- CLIA
- State laws and regulations
- Perspectives – physician, laboratory, consumer
- Discussion
- Public comments

Direct Access Testing

General Characteristics



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

Direct Access Testing Distribution Channels



- Internet websites
- “800” phone numbers
- Free-standing stores
- Existing hospital & commercial laboratory sites
- Cards or vouchers available at pharmacies, groceries

Direct Access Testing

Snapshot of current industry



- Very small portion of total laboratory industry
- 10-15% of hospital & commercial laboratories offer direct access testing as a sideline
- Usual model to add volume to existing laboratory testing capacity
- Broad range of test menus
- A lot of experimentation

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Media Attention



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

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CLIA



CLIA applies to all facilities that perform:

“examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings”

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CLIA Requirements



- Certification
- Based on complexity of testing:
 - ❖ Proficiency testing
 - ❖ Quality control
 - ❖ Personnel standards
 - ❖ Patient test management
 - ❖ Inspection

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CLIA Requirements



- Test requisition from an “authorized person” for moderately and highly complex tests
- No specifications regarding who may be an “authorized person”
 - ❖ States determine who may order laboratory tests

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State Laws & Regulations



- Heterogeneity
- Some states do not restrict test ordering
- Some states limit test ordering to certain professionals
- Some states restrict tests that can be ordered by non-professionals to a limited menu

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Summary of Perspectives, March 2003



- Consumer-demand driven
- Risk of harm greater for some tests than others
- Correct test ordering problematic
- Correct test interpretation problematic
- Correct test follow-up problematic
- Physicians do not want to receive results on tests they have not ordered or authorized

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Committee Discussion, March 2003



- Proper test selection and interpretation require pretest probability
- Laboratory should ensure consultation is available to clients
- Unbiased information is needed for consumers
- Potential for malutilization
- Potential for fraud

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Public Comments



- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- College of American Pathologists
- Direct Access Testing Trade Association

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CLIAC's Consideration



- How to assure appropriate direct access testing
 - ❖ Role of education
 - ❖ Role of guidelines
 - ❖ Role of regulations
- CLIAC's role