

# CDC Update

**Devery Howerton, Ph.D.**

**Director, Division of Laboratory Science and Standards**

**CLIAC Meeting**

August 31, 2011

Atlanta, Georgia

The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



# Outline

- ❑ CLIAC recommendations summary
- ❑ Proficiency testing activities
- ❑ Good laboratory practices for waived testing sites
- ❑ Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)<sup>TM</sup>
- ❑ Laboratory Medicine Best Practices (LMBP)
- ❑ Next-Generation Sequencing: Standards of Clinical Testing

# **SUMMARY OF CLIAC RECOMMENDATIONS**

# CLIAC Recommendations Summary 1993-2010

Category	#	Completed	Partial & Pending
Quality Control	4	4	0
Personnel	17	13	4
Waived Testing	17	16	1
Test Categorization	6	6	0
Genetic Testing	7	7	0
Proficiency Testing	31	8	23
Miscellaneous	12	8	4
<b>Total</b>	<b>94</b>	<b>62</b>	<b>32</b>

# **PROFICIENCY TESTING ACTIVITIES**

# Status of Proficiency Testing Regulatory Revisions: Microbiology

## □ Possible Changes

- Levels of Service
- Required Categories of Test
- Major Groups of Microorganisms
- Gram Stain PT
- Mixed Culture Requirements
- Antimicrobial Susceptibility Testing
- Direct Antigen Testing
- Monitoring Performance over Time

## □ Next Steps

# Status of Proficiency Testing Regulatory Revisions: Specialties Other than Microbiology

## ❑ Inclusion Criteria

- Following CLIAC's advice
  - PT availability
  - Test Volume
  - Medical Relevance
  - Considerations of Cost/Impact

## ❑ Criteria for Acceptable Performance

## ❑ Next Steps

# Proficiency Testing Focus Group Project

## ❑ **Collaboration with APHL**

- Small, large, microbiology, and public health laboratories
- Commercial, academic, specialty, and physician office lab settings
- Focus group sites: Atlanta, Boston, New Orleans, and Houston

## ❑ **Discussion Topics**

- Perceived costs and benefits of PT
- Use of PT beyond meeting regulatory requirements
- Demonstrating proficiency without commercial PT
- Potential impact of required PT for more analytes
- Ungraded PT challenges
- How to improve PT

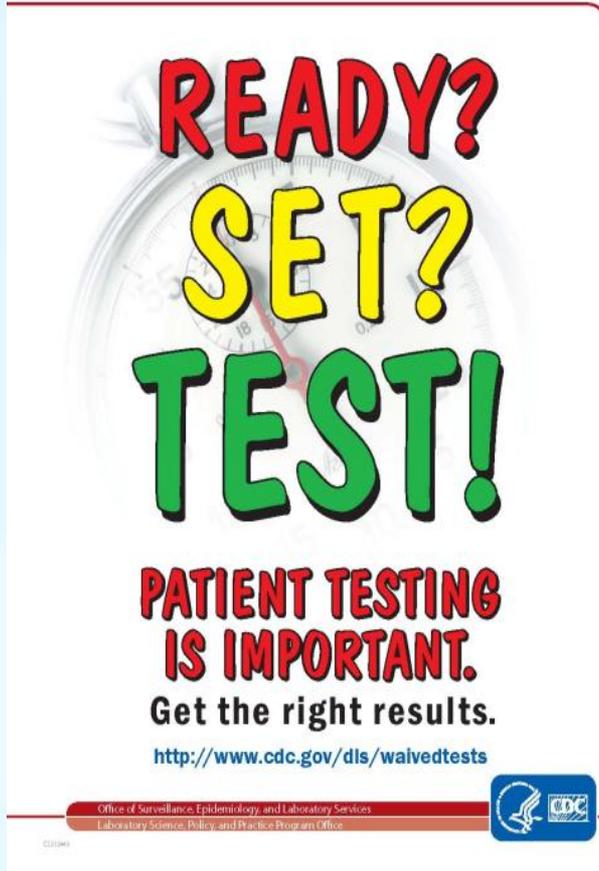
## ❑ **Summary report and manuscript(s) in development**

# **GOOD LABORATORY PRACTICES FOR WAIVED TESTING SITES**

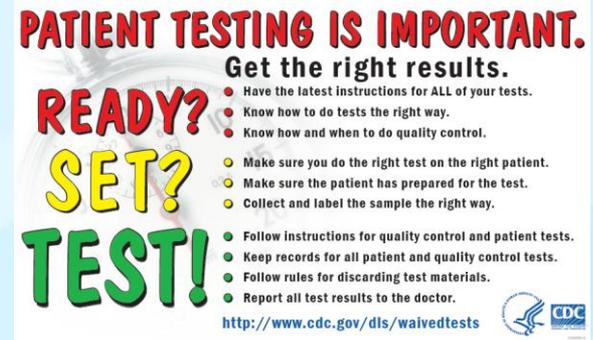
# Promoting Good Laboratory Practices for Waived Testing Sites

- ❑ Published booklet in 2011 **READY? SET? TEST!**
- ❑ Enthusiastic reception for materials
- ❑ Distribution by CMS surveyors, at professional meetings and via website inquiries
- ❑ **January-July 2011 distribution**
  - Postcards: 6155
  - Educational Booklets: 1946
  - Posters: 1207
- ❑ **Expected launch of online training module September 2011**

# Good Laboratory Practices for Waived Testing Sites



Educational booklet with job aids



Poster and postcards



On-line Training

# Sample Pages from **READY? SET? TEST!**

## Introduction

### BACKGROUND

Health care providers use test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. Current practice shows an increased trend for medical decisions based on simple tests performed at the point of care. Many of these tests are called waived tests and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those tests approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

criteria. The FDA list of waived tests is continuously being revised as new tests are waived. The most current information on FDA cleared waived tests can be found at the following website: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm>

### PURPOSE

CLIA requires that waived tests must be simple and have a low risk for an incorrect result. However, this does not mean waived tests are completely error-proof. To decrease the likelihood of incorrect results, waived testing needs to be performed correctly, by trained personnel and in an environment where good testing practices are followed.

Although not routinely done, the Centers for Medicare & Medicaid Services (CMS) will inspect waived testing sites under certain circumstances such as:

- if a complaint is made,
- to determine if the testing site is performing tests not permitted with a certificate of waiver,
- if there is risk of harm to a patient due to inaccurate testing, and
- to collect information about waived tests.

This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

The CLIA requirements for testing under a Certificate of Waiver can be found here: [http://www.cd.gov/clia/regs/subpart\\_b.aspx](http://www.cd.gov/clia/regs/subpart_b.aspx)

*Although some of the recommendations in this booklet exceed CLIA requirements for waived testing, following these good testing practices will likely lead to reliable, high quality test results and will enhance patient safety.*



### Tracking of QC results

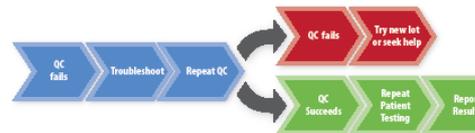
Documenting and tracking QC results can show whether a test is being performed correctly if the test is working correctly. A periodic review of QC records can show whether the QC results are changing over time. This information can help identify problems that may be affecting patient testing and need to be addressed. See [Appendix C](#) for examples of QC logs and result logs.

### Actions for unexpected QC results

If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- ✓ Check to see if the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error such as outdated reagents or test devices.
- ✓ Check to see if reagents were stored correctly.
- ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching containers.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site specific procedure.
- ✓ For additional assistance, contact the manufacturer, technical representative, and/or the person who directs or supervises the testing.

Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient sample(s) and report the final acceptable results.



## Tips, Reminders, and Resources

### READY?

- Clean work surfaces before and after testing.
- Perform testing in a well lit area.
- Check and record temperatures of the testing and reagent storage areas.
- Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
- Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- Check that all kit reagents came from the same kit lot. Do not mix reagents.
- Inspect reagents for damage, discoloration, or contamination, and discard if found.
- Prepare reagents according to manufacturer's instructions.
- Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
- Inspect equipment and electrical connections to be sure they are working.
- Perform calibration checks, as needed, following the manufacturer's instructions.
- File the old manufacturer's instructions and replace with the new copy if there are changes.
- Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.
- Treat and test quality control (QC) samples the same as patient samples.
- Perform QC as recommended in the manufacturer's instructions.



### SET?

- Check patient identification and test orders.
- Discuss pretest instructions and counseling needs with the patient.
- Wear appropriate personal protective equipment (PPE) such as gloves.
- Collect and label a good sample for testing.
- Clean hands and change gloves between patients.
- Use the proper biohazard containers to dispose of waste and sharps.

### TEST!

- Do not test samples that are improperly collected or handled.
- Have the manufacturer's instructions or a quick reference guide at the work station.
- Follow the manufacturer's instructions in the exact order.
- Follow required timing for testing.
- Identify and correct problems before reporting test results.
- Identify and report critical values in a timely manner.
- Perform or refer confirmatory or additional testing, if needed.
- Make sure patient reports are legible and reported in a timely manner.
- Make sure reports are standardized and easily distinguishable from referral laboratory test reports.
- Report patient test results only to authorized persons.
- Document verbal reports, followed by a written test report.
- Report public health diseases.
- Dispose of biohazardous waste safely.
- Participate in proficiency testing (PT).



Tips, Reminders, and Resources — 11

# Sample Forms from **READY? SET? TEST!**

Facility: Dr. Smith's Office  
 Location: 123 Main Street  
 Atlanta, GA 55555

## Results Log with QC – Quantitative Test

Test Name: XYZ ALT

Reportable Range: 5-400 U/L

Date	Sample ID / Patient ID	Test Results	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1	5/5/2012 / 5/5/2012 / Steve Smith	Male: 304 U/L	CO	0849/06-01-2013	lot #: 9195056-6 range: 43-78 U/L result: 279 U/L	lot #: 9195056-6 range: 132-242 U/L result: 203 U/L
2	5/5/2012 / 5/5/2012 / Chris White	Male: 224 U/L	CO	0849/06-01-2013	lot #: 9195056-6 range: 43-78 U/L result: 28 U/L	lot #: 9195056-6 range: 132-242 U/L result: 221 U/L
3	5/7/2012 / 5/5/2012 / Sam Jones	Female: 14 U/L	CO	0849/06-01-2013	lot #: 9195056-6 range: 43-78 U/L result: 279 U/L	lot #: 9195056-6 range: 132-242 U/L result: 221 U/L
4					lot #: range: result:	lot #: range: result:
5					lot #: range: result:	lot #: range: result:
6					lot #: range: result:	lot #: range: result:
7					lot #: range: result:	lot #: range: result:
8					lot #: range: result:	lot #: range: result:
9					lot #: range: result:	lot #: range: result:

\*Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually listed in the manufacturer's instruction for the test.

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 Location: 123 Main Street  
 Atlanta, GA 55555

## Temperature Log for Multiple Instruments

Temp/ Acceptable Range	Month												Year																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Room temp/ (18 to 30°C)	25	26	24	22	27	#	#	26	23	20	17	23	#	#	22	23	25	26	22	#	#	23	24	25	23	#	#	24	22	26
25°C Incubator/ (23 to 27°C)	25	25	25	25	25	#	#	25	26	25	25	25	#	#	25	25	26	25	25	#	#	25	25	24	25	25	#	#	26	25
37°C Incubator/ (35 to 39°C)	37	37	37	36	37	#	#	37	38	38	36	37	#	#	38	38	30*	36	35	#	#	36	37	38	35	36	#	#	38	37
Refrigerator/ (2 to 8°C)	5	6	4	5	4	#	#	6	5	4	4	5	#	#	6	6	6	5	5	#	#	6	6	5	6	4	#	#	5	6
Freezer/ (-25 to -35°C)	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30
Initials	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO

Temperatures should be read first thing in the morning.  
 Record temperature in degrees Celsius for all equipment requiring temperature monitoring.  
 Enter # for weekends and holidays when temperature is not monitored.

Report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate corrective action.  
 Comments: \* Incubator door left open. Closed door and checked temperature prior to using for testing purposes. Temp was 3.5.

\_\_\_\_\_

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Reviewed by: Joe Smith, MD Date: 4/31/2012

# Online Training for **READY? SET? TEST!**

CDC Centers for Disease Control and Prevention  
Your Online Source for Credible Health Information

HOME ABOUT | COURSE MAP EXIT

## READY? SET? TEST!

**PATIENT TESTING IS IMPORTANT.**  
Get the right results.

Launch Course

Version 2.0, published 06/2011

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### About This Course

The goals of this course are to promote reliable, high quality testing, enhance patient safety by explaining steps of the waived testing process, and provide the learner with additional resources for on-the-job assistance.

By taking this course, the learner will be able to:

- Identify basic requirements for performing waived testing
- Follow manufacturer's instructions for the test
- Recall good laboratory practices to be used while performing waived tests

The buttons found at the top of each page can be used to access a section quickly. Throughout the course, look for important additional information here:

**CLIA Requirements**  
These boxes present requirements that must be met before performing waived testing.

**Good Laboratory Practices**  
These boxes present important laboratory practices that help you achieve the best possible results when performing a test.

This icon indicates helpful tips, suggestions, or other information.

Resources Downloads and links can be found whenever this button appears.

BACK NEXT

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HOME ABOUT | COURSE MAP EXIT

INTRO **READY?** SET? TEST? SCENARIOS

### Introduction to Waived Testing

Each year, an estimated 10 billion laboratory tests are performed in the United States. These test results influence a large portion of medical decisions and play a critical role in health assessments.

Health care providers use laboratory test results to diagnose diseases, determine prognoses, and monitor a patient's treatment or health status. Current practice shows trends in increasing medical decisions based on the use of simple tests that are performed at the point of care. This testing is performed very near the patient, including at the bedside, and results can be provided within minutes.

Many of these tests are waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and can be performed without routine oversight under a Certificate of Waiver from the Centers for Medicare and Medicaid Services (CMS).

Resources



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INTRO **READY?** SET? TEST? SCENARIOS

### The Testing Process

The testing process can be broken into three phases: **Ready**, **Set**, and **Test**. Click on each shaded section of the stopwatch for an overview of each phase. When you are ready to begin, follow the **Ready**, **Set**, **Test** order to complete the course.



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INTRO **READY?** SET? TEST! SCENARIOS

## The Testing Process

The testing process can be broken into three phases: **Ready**, **Set**, and **Test**. Click on each shaded section of the stopwatch for an overview of each phase. When you are ready to begin, follow the **Ready**, **Set**, **Test** order to complete the course.

**Test!**

Once you have collected a sample, the testing phase begins. This section will cover topics, such as interpreting test performance results, recording, and reporting results. You will be able to:

- Identify at least two good laboratory practices for testing.
- Identify at least two good laboratory practices for recording and reporting results.

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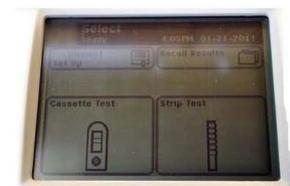
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INTRO **READY?** SET? TEST! SCENARIOS

## Test!

Once the sample is collected, the **Test!** phase begins.

Testing includes performing the test and interpreting, recording and reporting the test results.



**Good Laboratory Practices**

- Follow the testing steps in exact order as they are in the manufacturer's instructions.
- Test QC following the manufacturer's instructions.
- Keep the manufacturer's instructions in the testing area.
- Use timers and follow the required timing intervals before reading test results.

CUA requires that you follow the manufacturer's instructions for the tests you are performing.

Quick reference or color charts may be used to help with the test performance and result interpretation.

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INTRO **READY?** SET? TEST! SCENARIOS

## Knowledge Check

Section: Set  
Page 8 of 9

List at least two good laboratory practices that ensure the right sample type is collected properly. Select Submit to view suggested responses.

Do not substitute swabs

Fingerstick and venipuncture collection devices are for one-time use only and should never be reused.

Submit

Suggested responses include:

- Do not substitute swabs that come in a sample collection kit. Swabs can be made of different materials and using the wrong swab may interfere with the test result.
- Finger stick and venipuncture collection devices are for one-time use only and should never be reused. Retestable collection devices are preferred.
- Finger stick devices come in various sizes from pediatric to adult so be sure to use the appropriately sized device for your patient.

Which of the following are NOT acceptable for waived tests?

A. Urine

B. Plasma

C. Oral fluid

D. Throat swab

E. Whole blood

The correct answer is B. Waived tests may only be performed using unprocessed samples. Examples of unprocessed samples include whole blood (fingerstick or anticoagulated blood collected by venipuncture), urine, throat swab, nasopharyngeal swab, nasal wash or aspiration, stool, and saliva, or oral fluid.

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INTRO **READY?** SET? TEST! SCENARIOS

## Scenarios

Waived testing can be performed at different sites, many of which are not traditional laboratories. Three scenarios have been provided. Select the **nursing home**, **hospital**, and **doctor's office** buildings identified below to read each scenario and answer the corresponding questions.



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# Future Waived Testing Products

- ❑ **To Test or Not To Test? Considerations for Waived Testing**
  - Booklet will be designed to assist those who want to initiate or direct testing under a CLIA Certificate of Waiver
  - Expected completion of booklet in early 2012
- ❑ **Access waived testing materials:**  
**<http://www.cdc.gov/dls/waivedtests>**

**CLINICAL LABORATORY  
INTEGRATION INTO HEALTHCARE  
COLLABORATIVE (CLIHC)<sup>TM</sup>**

# Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)<sup>TM</sup> Project Update

- ❑ **Clinician Test Selection and Result Interpretation**
  - Survey of clinicians' challenges
  - Diagnostic algorithms
  - Nomenclature
  - Improvements in test selection and results interpretation
- ❑ **Medical School Education**
  - Survey of US medical schools
  - Clinical pathology residency education

# CLIHCTM

## Survey of Clinicians' Challenges

- ❑ **Focus groups completed**
- ❑ **Clinician survey approved through OMB**
- ❑ **Questionnaire section headings**
  - Test Ordering: Uncertainty, Influences, Challenges
  - Result Interpretation: Uncertainty, Challenges
  - Test Utilization Enablers (e.g. test selection and result interpretation aides)
  - Laboratory Consultation Practices
  - New Test Awareness
  - Diagnostic Evaluation Processes
  - Practice Characteristics
  - Demographic Information
- ❑ **Expect results early 2012**

# CLIHCTM

## Clinician Test Selection and Result Interpretation

### □ Diagnostic algorithms

- For evaluating patients with prolonged Partial Thromboplastin Time
- Launched prototype app for smart-phones (CDC innovations award) - pilot results due mid-2012

### □ Test nomenclature

- Addressing complexity of laboratory nomenclature
- Publication to raise awareness of issue in preparation
- Investigating search technology tools instead of standardization

## Evaluation of Improvements in Test Selection and Result Interpretation

- ❑ **Vanderbilt unpublished mini-study\* completed**
- ❑ **Reviewed one week of consultation requests; 53 cases total**
  - 29 cases had appropriate test orders (55%)
  - 19 cases had incomplete test orders (36%)
  - 5 cases had inappropriate test orders (9%)
- ❑ **Diagnosis impacted in 2 of the 24 cases in which tests were added or deleted following consultation**
  - The timing of the diagnosis in the other cases was not impacted only because of the near real-time addition of tests.

\*Information and analysis provided by Jennifer M. Giltane, MD, PhD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center

# CLIHCTM - Medical School Education

## □ Survey of US Medical Schools

- Raise awareness of gaps in laboratory medicine training
- Yale School of Medicine leading survey
  - Expect results early 2012

## □ Clinical Pathology Residency Education

- Establish the nature and amount of clinical consultation education provided to clinical pathology residents
- Results published in CAP Today in August<sup>1</sup>

<sup>1</sup>**Robert D. Hoffman, MD, PhD** (August 2011). In CP training, are we teaching consultation? *CAP Today*. <http://tinyurl.com/3lg23h5>

# **LABORATORY MEDICINE BEST PRACTICES (LMBP) INITIATIVE**

# Laboratory Medicine Best Practices Initiative: March – July 2011 Highlights

- ❑ **Publication of laboratory medicine systematic review methods - A6 Methods**
  - Christenson RH, Snyder SR, Shaw CS, Derzon JH, Black RS, Mass D, Epner P, Favoretto AM, and Liebow E. *Laboratory Medicine Best Practices: Systematic Evidence Review and Evaluation Methods for Quality Improvement*. *Clinical Chemistry* (2011); 57(6):816–825.
  
- ❑ **Online tutorial now available**
  - <http://www.futurelabmedicine.org>
  - Snyder SR, Shaw CS, Liebow E, Mass D, Christenson RH, Derzon JH, Epner P, and Black RS. *The A-6 Cycle: Review and Evaluation Methods for Quality Improvement*. Atlanta: CDC; 2011.

# Laboratory Medicine Best Practices Initiative, continued

- ❑ **A6 Methods – three new systematic review topics in progress**
  - Hemolysis
  - Cardiac markers
  - Blood stream infections
  
- ❑ **A6 Methods – four national presentations**
  - Academy of Clinical Laboratory Physicians and Scientists: St. Louis, MO (poster)
  - American Association for Clinical Chemistry/National Academy of Clinical Biochemistry: Atlanta, GA (workshop )
  - American Association for Clinical Chemistry: Atlanta, GA (poster)
  - American Society for Clinical Laboratory Science: Atlanta, GA (presentation)

# **NEXT-GENERATION SEQUENCING: STANDARDS OF CLINICAL TESTING**

# Next-Generation Sequencing: Guidance for Clinical Testing

- ❑ **Why: New sequencing technologies integrating into practice**
  - Provides novel data for the diagnosis of hereditary disease, selection of treatment for cancer therapy, and classification of infectious agents
  - Can be cost-effective compared to existing methods
- ❑ **Problem: No guidance available for application of regulatory and professional standards**
  - Focus: Test validation, quality control, proficiency testing, reference materials
- ❑ **Solution: National workgroup to develop guidelines**
  - Target audience: Policy makers, laboratory directors, platform developers, clinicians, professional organizations, other government agencies

# **Next-Generation Sequencing: Guidance for Clinical Testing - Update**

- ❑ Kick-off meeting in April / continuing input from workgroups**
- ❑ Draft manuscript completed, in workgroup review**
  - Initial focus – hereditary sequence variations**
- ❑ Initiated effort to develop standard reference sample/sequence useful to clinical laboratories (through the Genetic Testing Reference Materials Program - GeT-RM)**

# **Genetics in Clinical Practice: A Team Approach Ver. 2**

*Dartmouth Medical School and CDC*

- ❑ **Interactive multimedia web-based training program**
- ❑ **1<sup>st</sup> ver. released 2001**
- ❑ **CMEs from the American Medical Association**
- ❑ **Need: Genetic testing is increasing; knowledge is limited**
- ❑ **Update:**
  - Added case scenarios
  - Didactic sessions: New information on HIPAA, DNA microarrays
  - Dissemination: Recently released through Aetna healthcare
    - AMA release in progress
    - Public release / available to schools-near future

# Genetics in Clinical Practice: A Team Approach Ver. 2



**Genetic  
Counseling**



**Clinical  
Encounter**



**"The Virtual Clinic"**

**Resource  
Center**



**Laboratory  
Tour**

Patient Visit Roster				
Prenatal Genetic Screening, Testing, and Counseling	Genetics and Hereditary Cancer	Direct-to-Consumer Genetic Testing	Genetic Evaluation in a Child	Evaluation of a (Relatively) Common Genetic Condition
Joan Singer (28 yo, 2 months pregnant)	John Martin (46 yo, brother with advanced colon cancer)	Jan Simpson (32 yo, wellness/preventive care visit)	Thomas Harrison (7 yo, developmental delay, learning disability)	Belinda Santos (43 yo, recent diagnosis of hemochromatosis)
AVAILABLE	AVAILABLE	AVAILABLE	AVAILABLE	AVAILABLE
Joan and Harrison Singer (couple counseling)	John Martin (follow-up visit)	Jan Simpson (follow-up visit)	Please select a case...	
UNAVAILABLE	UNAVAILABLE	UNAVAILABLE		
Joan and Harrison Singer (couple counseling)				?
UNAVAILABLE				

*Questions?*

*Comments?*

