



# Direct Access Testing (DAT)

## Clinical Laboratory Improvement Amendments (CLIA) Requirements

CLIAC Meeting  
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Rhonda Whalen, MS  
Chief, Laboratory Practice Standards Branch  
Division of Laboratory Systems  
Public Health Practice Program Office  
Centers for Disease Control and Prevention

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# Direct Access Testing (DAT)

Testing in which individuals request testing and receive test results independently of a physician.



# CLIA Requirements Impacting DAT

- All non-waived testing requirements apply
- Specific requirements to consider
  - Definitions
  - Facilities
  - Quality Systems
  - Personnel



# Authorized Person

An individual authorized under State law to order tests or receive test results, or both.

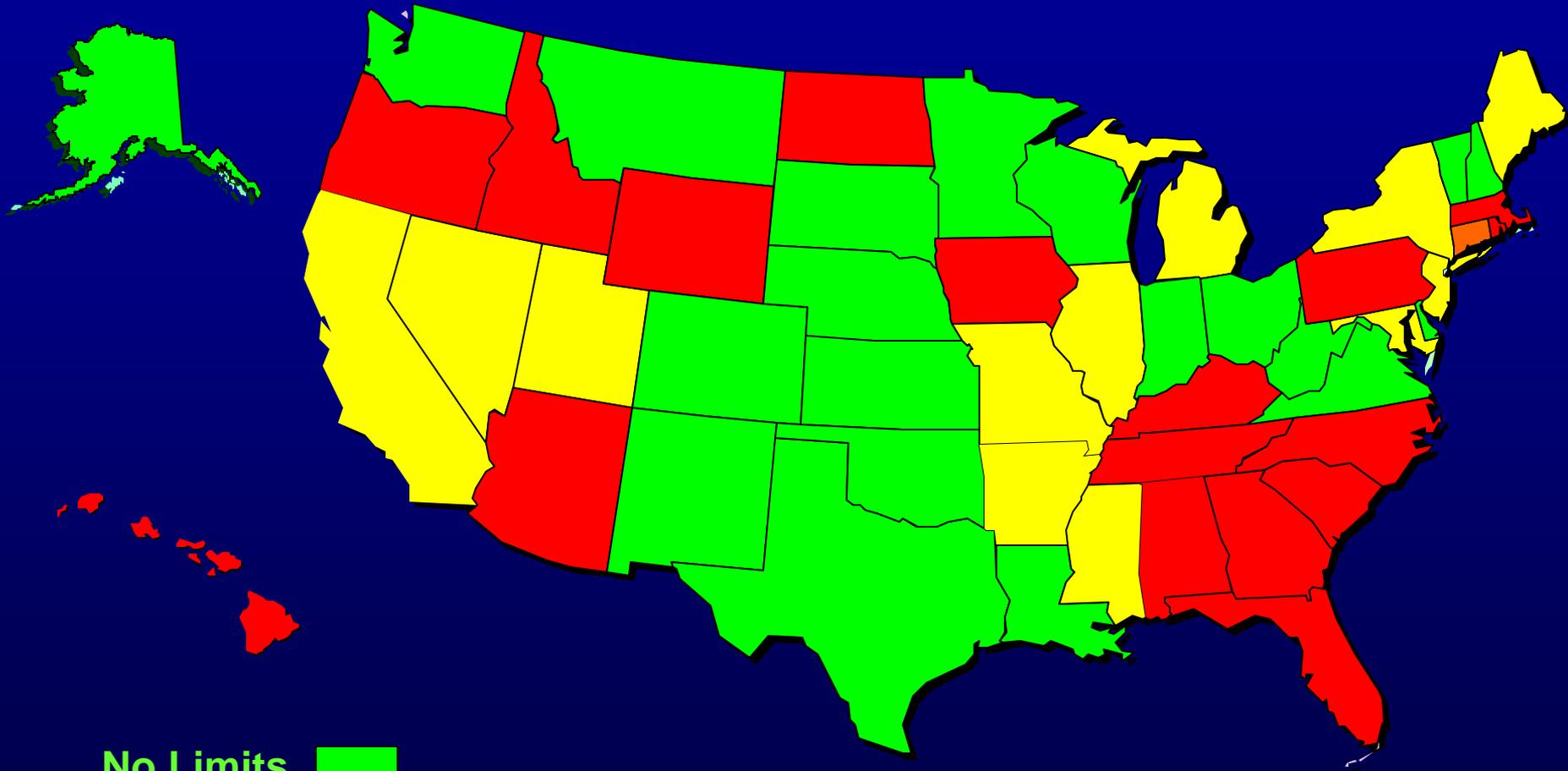


# Facilities

***As of April 24, 2003, laboratories must comply with applicable Federal, State and local laboratory requirements.***



# DAT Demographics



- No Limits ■
- Limited ■
- Prohibited ■

Source ASCP



# Quality Systems

- January 24, 2003 regulation includes
  - Minor changes to requirements affecting DAT
  - New format rearranging requirements as -
    - General
    - Preanalytic
    - Postanalytic
    - Personnel



# Quality Systems General Laboratory

- Communications
  - System to identify and document breakdowns in communication between the laboratory and authorized person who orders/receives test results



# Quality Systems Preanalytic

- Test Request
  - Written or electronic request from an authorized person
  - Must solicit
    - Identifiers of authorized person requesting test
    - Contact person to report panic values



# Quality Systems

## Preanalytic (con't)

- Test Request (con't)
  - Must solicit
    - Patient's
      - name/unique identifier
      - ***Sex, age or date of birth***
    - Test(s) to be performed
    - ***Specimen source, when appropriate***
    - Date ***and, if appropriate, specimen collection time***
    - Additional information necessary for testing



# Quality Systems

## Preanalytic (con't)

- Specimen submission, handling, referral
  - Establish and follow written policies and procedures for
    - Patient preparation
    - Specimen
      - Collection
      - Labeling
      - Preservation
      - Processing/acceptability
      - Referral



# Quality Systems Postanalytic

- Test Report
  - Includes
    - Test result
    - Units of measurement or *interpretation, if applicable*
    - Reference intervals (normal values) available to the authorized person ordering/using the test(s)



# Quality Systems

## Postanalytic (con't)

- Test Report (con't)
  - Laboratory must, upon request, make available to clients
    - List of methods employed
    - Performance specifications
    - Information that may affect interpretation of test results
  - Test results released to authorized persons



# Quality Systems

## Postanalytic (con't)

- Test Report (con't)
  - Laboratory must immediately notify individual requesting/using test of panic values
  - Laboratory must provide clients updates whenever changes occur affecting test results or their interpretation
  - When errors occur in reported patient test results, laboratory must
    - Notify authorized person ordering the test
    - Issue corrected reports promptly to authorized person ordering the test



# Personnel Responsibilities

- Laboratory director must
  - Ensure reports include information required for test interpretation
  - Ensure consultation is available to laboratory's clients



# Personnel Responsibilities (con't)

- Clinical consultant must
  - Provide consultation to laboratory's clients
  - Assist clients in ordering appropriate tests
  - Ensure reports include information required for specific patient interpretation
  - Ensure consultation is available, communicated to laboratory's clients including
    - Quality of test results reported
    - Test result interpretation related to specific patient conditions



# Committee Discussion



- Considerations
  - ◆ Appropriateness of CLIA requirements to DAT
  - ◆ Alternatives to regulations (guidelines)
  - ◆ Other options/approaches