Direct Access Testing (DAT)
Clinical Laboratory Improvement Amendments (CLIA) Requirements

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