Clinical
Laboratory
Improvement
Amendments

An update: June 5, 2001

Background and Regulatory Framework

- Hospital labs
- Commercial labs
- Clinics
- Patients

Stakeholders

- Lab users
- Hospital groups
- Commercial labs
- POLs
- American Association for Clinical Chemistry
- American Society for Clinical Laboratory Science
- American Medical Association
- American Association of Family Practice Physicians
- American Society of Clinical Pathologists
- American Society for Microbiology
- IVD Trade Associations
- IVD Industry

Government

- HCFA
- CDC
- US States

What does each group want and why?

CLIA vs. FDA Review

- **A 510K review is based on substantial equivalence to another device and may include performance data**
- **A CLIA review is based on complexity of testing with no review of performance data**
- **Complexity categorization is where a new cleared 510(k) IVD is assigned**

moderate ***or*** ***high***

COMPLEXITY CATEGORIZATION BASED ON

- Knowledge
- Training and Experience
- Reagents or Materials Preparation
- Characteristics of Operational Steps
- Calibration, Quality Control, or Proficiency Testing Materials
- Troubleshooting and Maintenance
- Interpretation and Judgment


SCORING

Knowledge

1. **Minimal scientific knowledge needed to perform the test**
2. **Some basic laboratory related scientific knowledge**
3. **Specialized scientific knowledge**

Training and Experience

1. Minimal training and experience
2. Some training or experience is required
3. High level of training and experience

Reagents or Materials Preparation

1. Reagents and materials usually prepackaged or need minimal handling
2. Some preparation or handling is required
3. Reagents or materials are extremely labile, or require precise measurements

Characteristics of Operational Steps

1. **Automatically executed or easily performed**
2. **Not fully automatic and/or require some watching, timing, or simple calculations**
3. **Steps are extensive or complex**

Calibration, Quality Control or Proficiency Testing Materials

1. **Materials are stable, well defined, and readily available**
2. **Materials do not validate the entire analytic process**
3. **Materials have no potential of being made available**

Troubleshooting and Maintenance

1. **Automatic, self correcting and requires minimal judgment**
2. **Require some judgment, technical skill, or intervention by the analyst**
3. **Not automatic and requires a high level of decision-making and extensive intervention to resolve problems**

Interpretation and Judgment

1. Simple directions outlined by the manufacturer to perform the test
2. Some interpretation and judgment before releasing results
3. Required throughout the testing process

Score of >12 = High Complexity

Score of 12 or less = Moderate Complexity

***Waiver* = degree of simplicity**

The End Product

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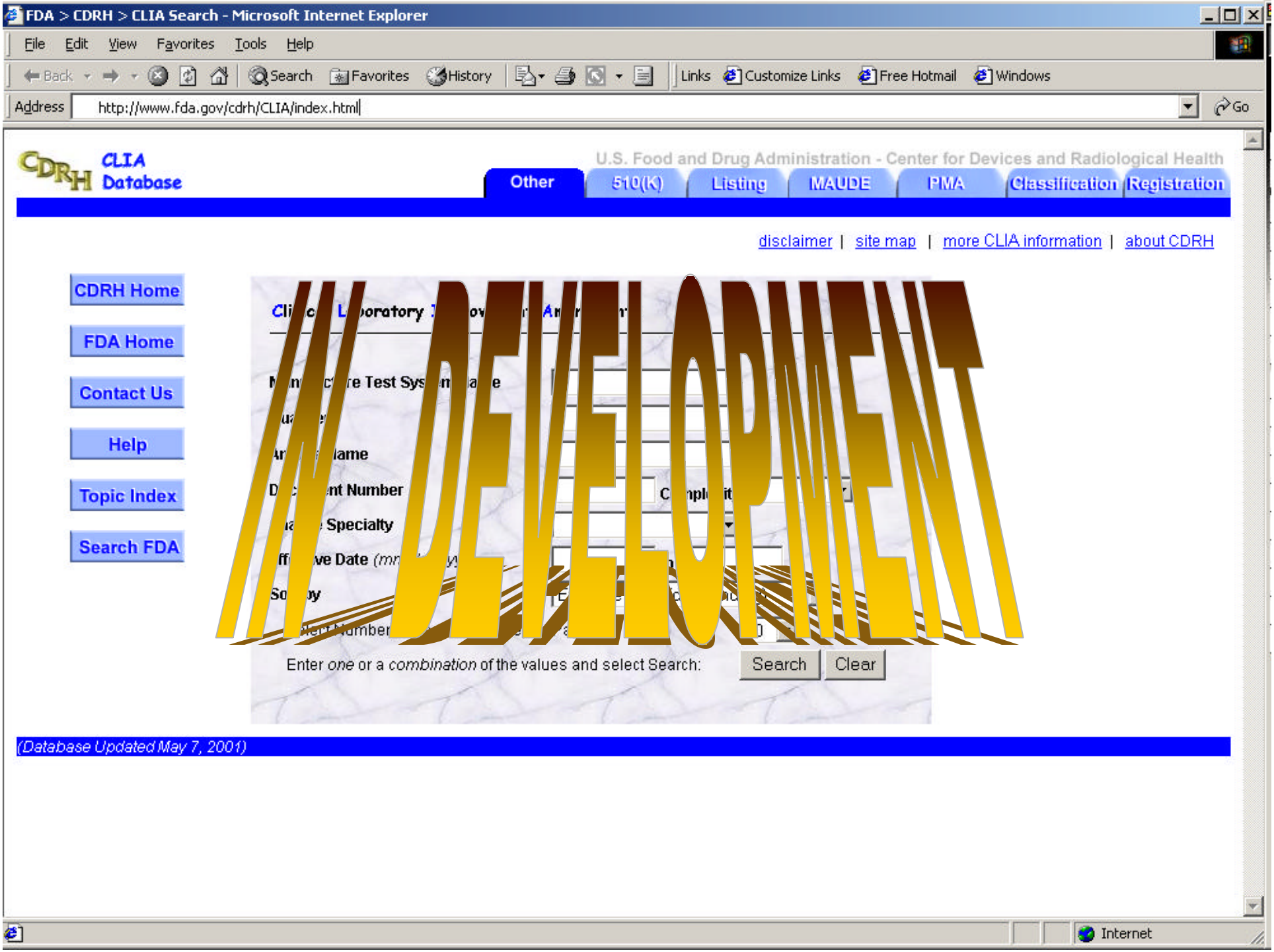
Over 27,000 Categorizations

Laboratory Inspectors, Laboratories, Manufacturers, and Other Stakeholders Want to Know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Policy Issues

Pros and cons

- access
- patient care
- quality of result