Introduction to Digital Pathology

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CLIAC Meeting

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Outline

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- **Background**
- **Purpose for CLIAC Discussion**
- **Questions for CLIAC Consideration**
- **Introduction of Speakers**

Definition

❑ **Digital Pathology is an image-based information environment enabled by computer technology that allows for the management of information generated from a digital slide.**

❑ **Digital pathology is enabled in part by <u>virtual microscopy</u>, which is the practice of converting glass slides into digital slides that can be viewed, managed, and analyzed.**
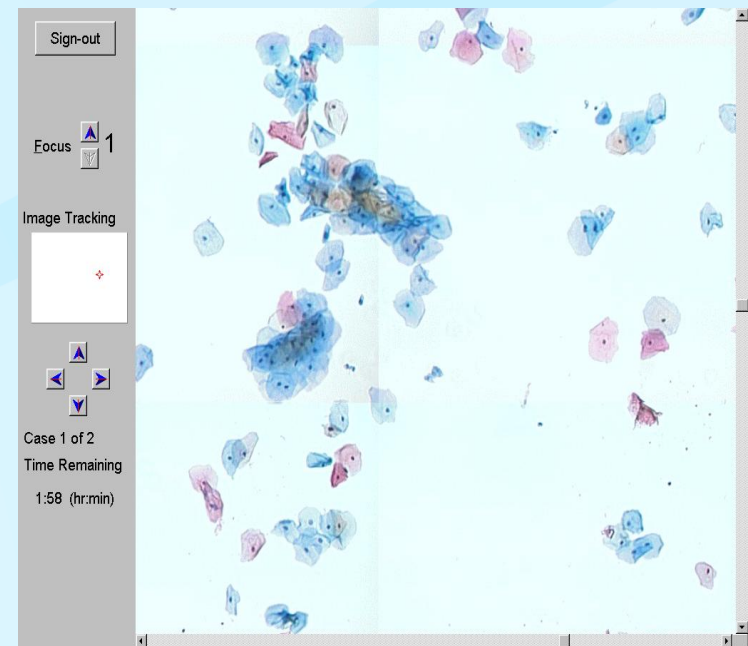
Background

- ❑ **1993: CDC Symposium on Cytology Proficiency Testing decided one alternative to glass slide testing might be a computer-based test**
- ❑ **1995: CDC awarded cooperative agreements**
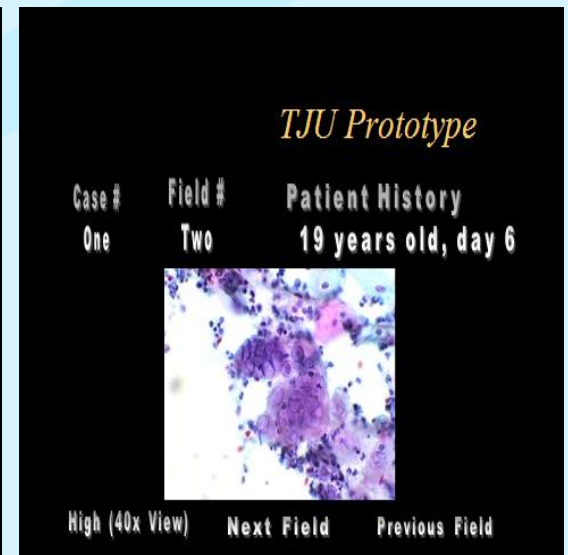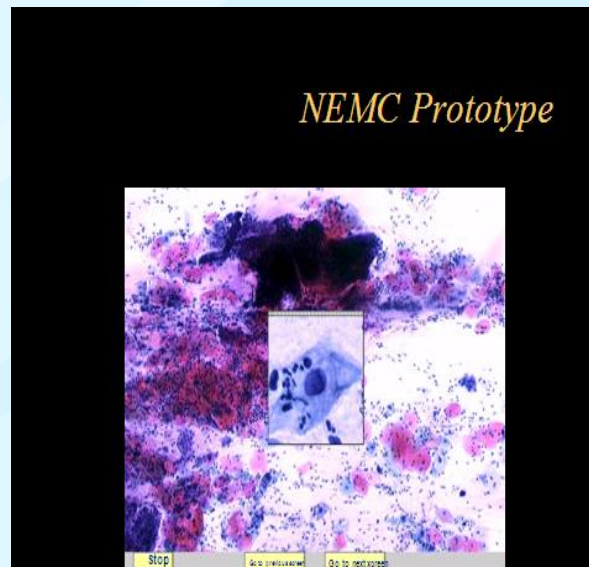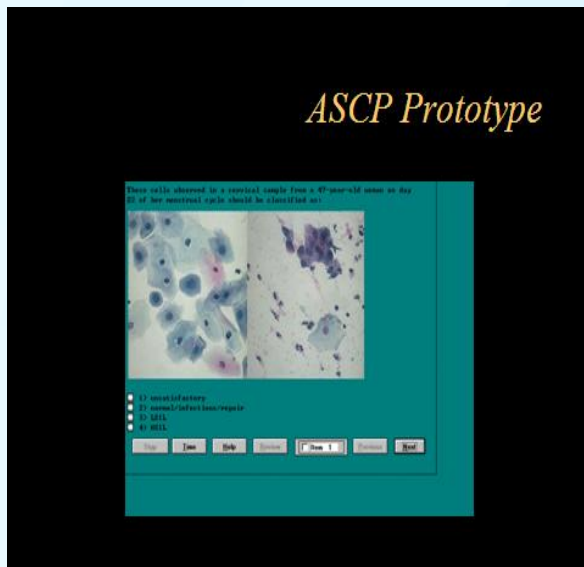
Background

❑ **1996: CDC developed a computer-based image capture system called MicroScreen**

❑ **1997: First demo of MicroScreen for CLIAC**

Background

□ **2003 First Annual Virtual Slide Symposium sponsored by the Medical University of South Carolina**

  ▪ First meeting for pathologists interested in digital pathology

  ▪ Only one meeting took place, but a publication resulted

  ▪ 2005 CRC published *Virtual Microscopy and Virtual Slides in Teaching, Diagnosis, and Research*

  ▪ 2006 Advancing Pathology Informatics Imaging and the Internet (APIII) added a track for imaging

  ▪ 2010 Pathology Informatics

    • APIII merged with ***Lab InfoTech Summit***
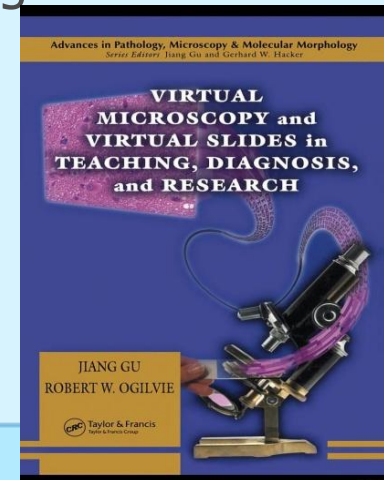
Background

□ **Technology Changes**

- Digital camera
- Stacker
- Viewer Programs
- Whole slide capability
- Portable options
- Focal plane

Source of Skylight image – Google images
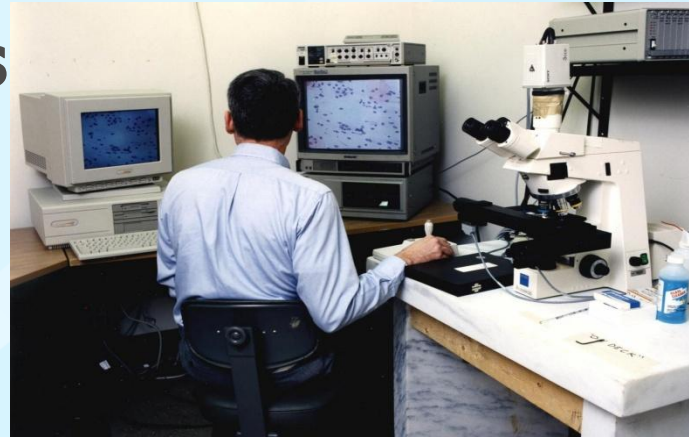
Glass slide Microscopy

- View with microscope
- Only view one slide at a time
- Subjective manual analysis
- Sharing FOV requires attachment
- Burdensome archive and retrieval
- Slides break
- Pointer and describe orally
- Multi planes to focus through

Digital Pathology

- View by computer monitor
- Tile multiple images for comparing
- Software analysis
- Share images with multiple sites
- Instant archive and retrieval
- Image is permanent
- Text annotation
- Best focal plane on flat image

Purpose for CLIAC Discussion

❑ **Introduce the topic of digital pathology for CLIAC consideration**

❑ **Raise issues relevant to implementation in CLIA-certified labs, such as:**

- Interpretation in a CLIA-certified laboratory
- Establishing or verifying performance
- How long to keep images

Issues in Digital Pathology Questions for CLIAC Consideration

1. **What steps can HHS take to facilitate the safe development and implementation of digital pathology?**

2. **Should HHS provide a clarification of the requirements that impact digital pathology? Possible CLIA issues might include:**
   a. Test system verification
   b. Personnel
   c. Definition of "laboratory"
   d. Record retention

3. **Are there non-CLIA regulatory issues to consider?**

Introduction of Speakers

❑ **Richard C. Friedberg, MD PHD, FCAP**

    Baystate Health

- *Digital Pathology: The Pathologist's Perspective*

❑ **Tremel Faison MS, RAC, SCT(ASCP); FDA-OIVD**

 - *FDA Regulation of Whole Slide Imaging (WSI) Devices: Current Thoughts*

❑ **Aldo Badano; FDA-OVID**

- *FDA Research and Scientific Issues in Digital Pathology*

❑ **Debra Sydnor; CMS**

- *CLIA Guidance for Digital Pathology*

For more information please contact Centers for Disease Control and Prevention

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

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