Counterfeit Detection Device Version 3+

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Counterfeit Device Evolution
Technology Improvements

- Low power LEDs
- Cooled Low power LEDs
- High power LEDs
- CD1
- CD2
- CD3
- CD3 *Plus*
- CDx
- Note: capabilities and improvements were made from requests over time by many users

CDx Designs, Manufacturing, and Lab Method Developments

CD3 At Work

(Size: 6.2” x 3.5” x 1.0”)

How and where is the CDx currently manufactured?

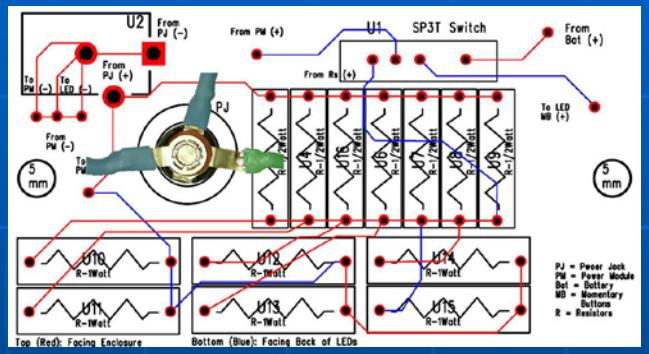
Brief Mfg. Processes / Steps

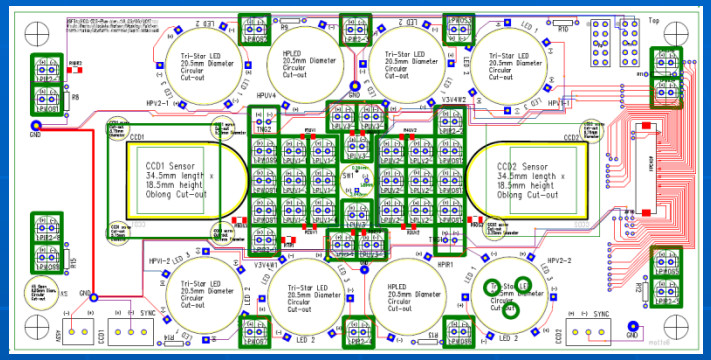
- CDx Team meets
  - Discussions
    - Added Features
    - Designation of Duties
    - Supplies are reviewed
    - Overall design modifications
- Purchasing of all (many 100's of supplies) electronic components are placed
- New plans/designs are tested
- PCBoards are modified, reviewed, and then sent for printing
- Received supplies are packaged and shipped for assembly on pcboards
- CDx parts arrive FCC and assembly of CDx is done at FCC
- Assembly of filters is done at FCC
- Micro-controller codes written and are uploaded onto the devices
- Image and video Library is modified and uploaded onto devices

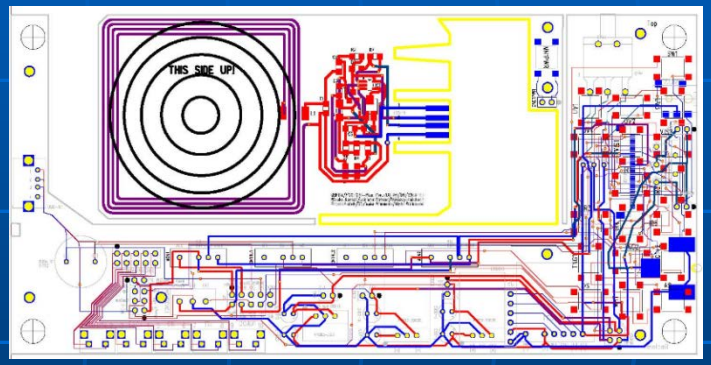
Evolution of the CD Device

Technology Improvements

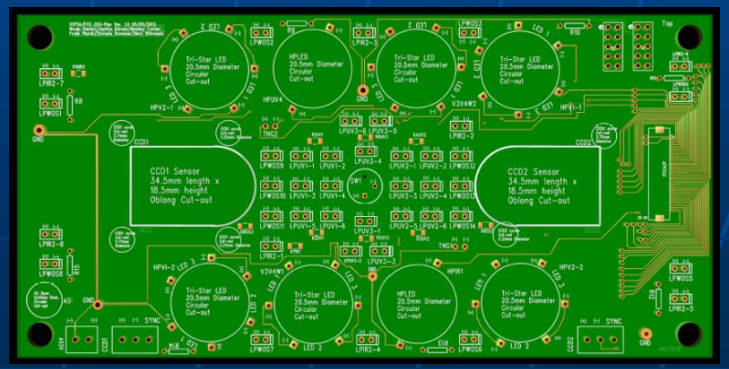
- High power LEDs
- CD1





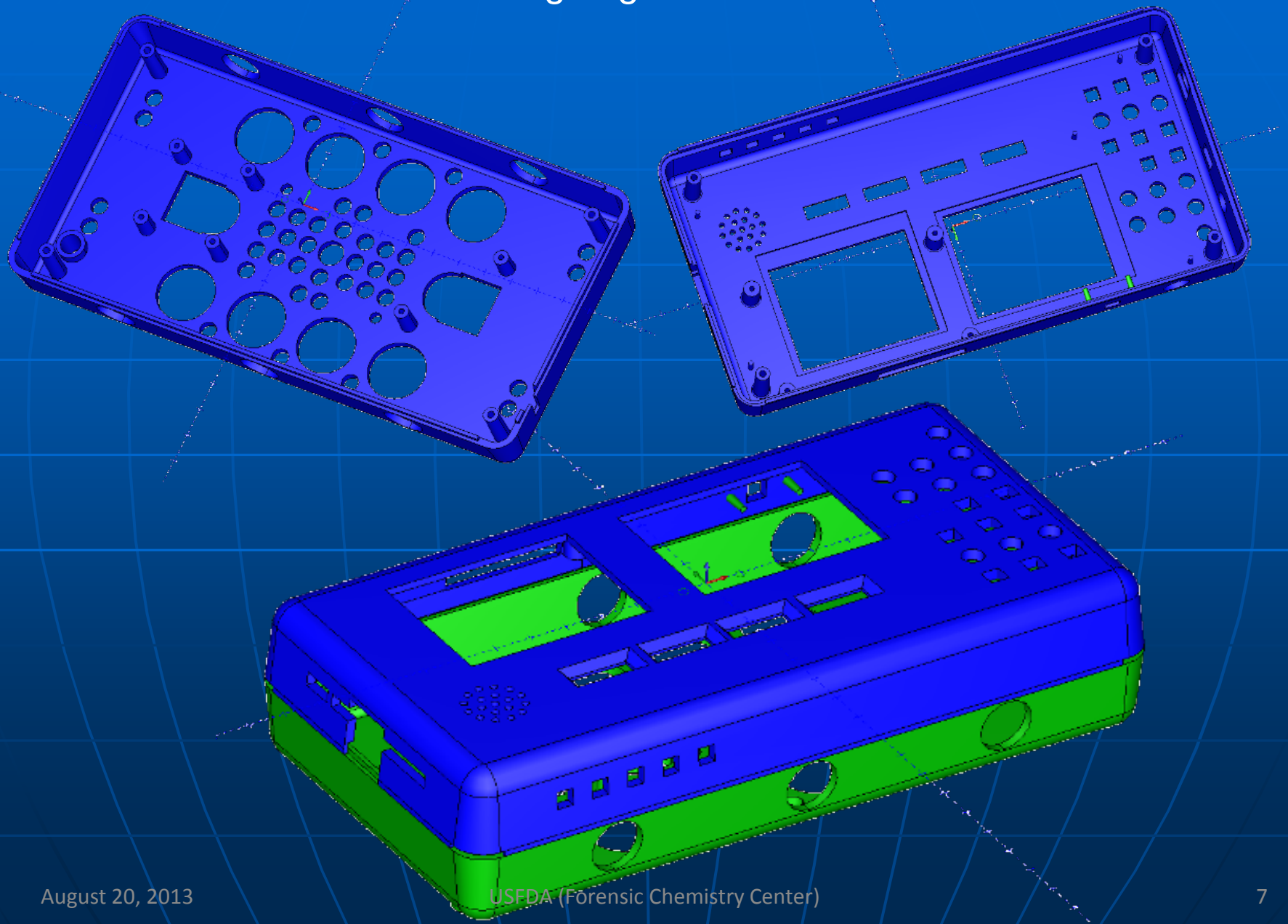


+

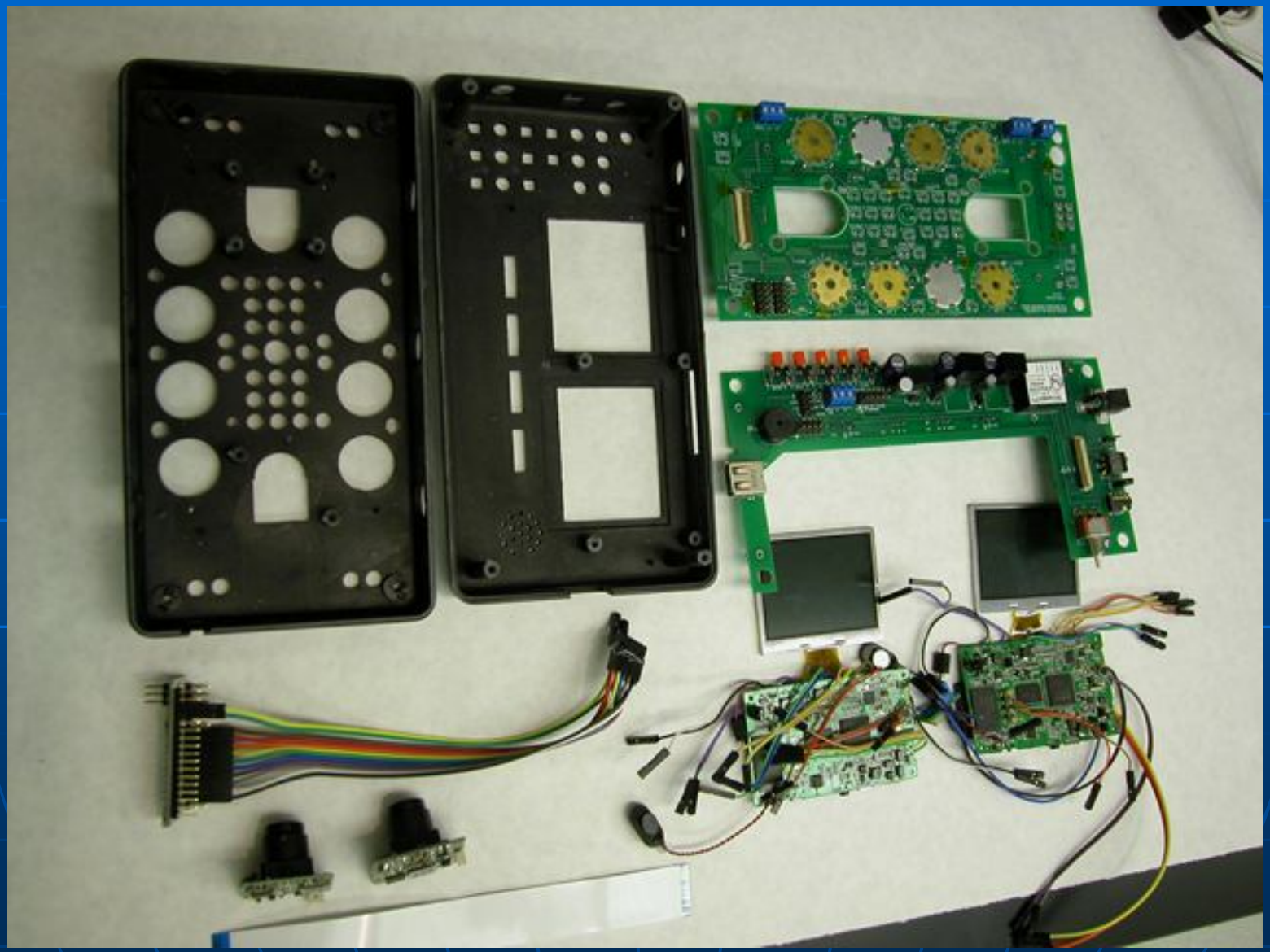


Enclosure design!

Enclosure Modifications and Designing:

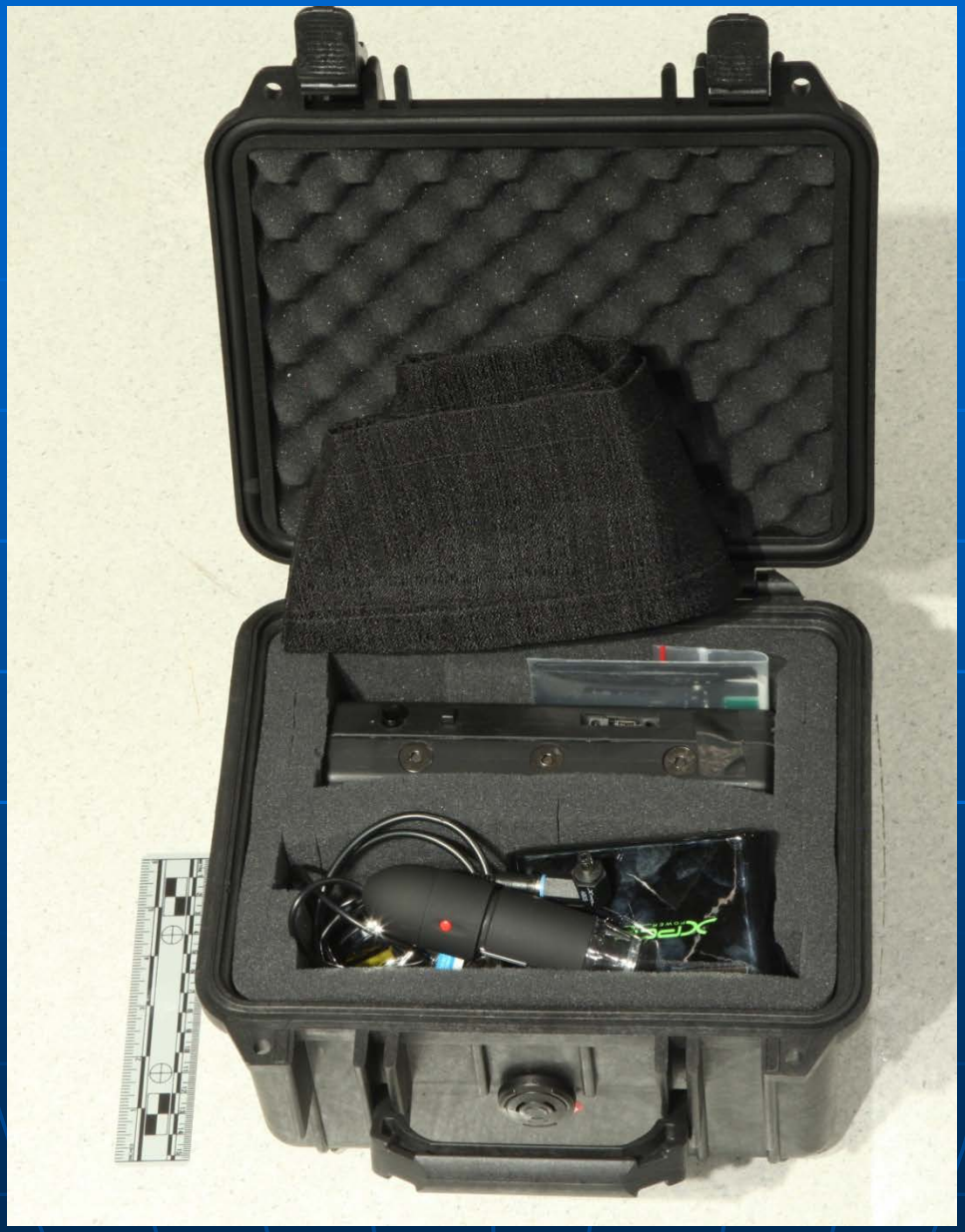


CD3+ Finalized components – Ready for assembly!



CD3+ Kit components

Assembled CD3+ Kit



CD3+ Technology Improvements

Highlighted Buttons

- Light sources
  - *Short Wave UV
  - Medium and Long Wave UV
  - Visible
  - Infrared imaging
  - Infrared rich Tungsten lights.
  - Two new wavelengths.
- Dual Monitors
  - Dual CCD viewing, digital microscope, stored images from device versus live viewing.
- Interchangeable lens
  - Macro (default), Wide and High Power Lens viewable under different wavelengths
- Anti-Stokes
- Frequency Detector (FD) or FD chips (passive or active) – monitors Electromagnetic changes alert (i.e RFIDs)
- Oscillating, fourteen white LEDs used for Holograms, optical variable devices (OVDs), color shifting inks, security text/micro-text, and animated patterns
- Snap-on Shades
- Updated Image Library including packaging
- Etc.

*Not on all devices.

CD3+ Technology Improvements

Dual Monitors

UV-VIS and IR side by side live view mode comparison

Stored Image and UV-VIS live view mode comparison*

*Stored Image can also be compared with Infrared live view mode

CD3+ Technology Improvements

Snap-on Shades

Male end of magnetic snaps

Female end of magnetic snaps

CD3+ Technology Improvements

Interchangeable Lens

Filters

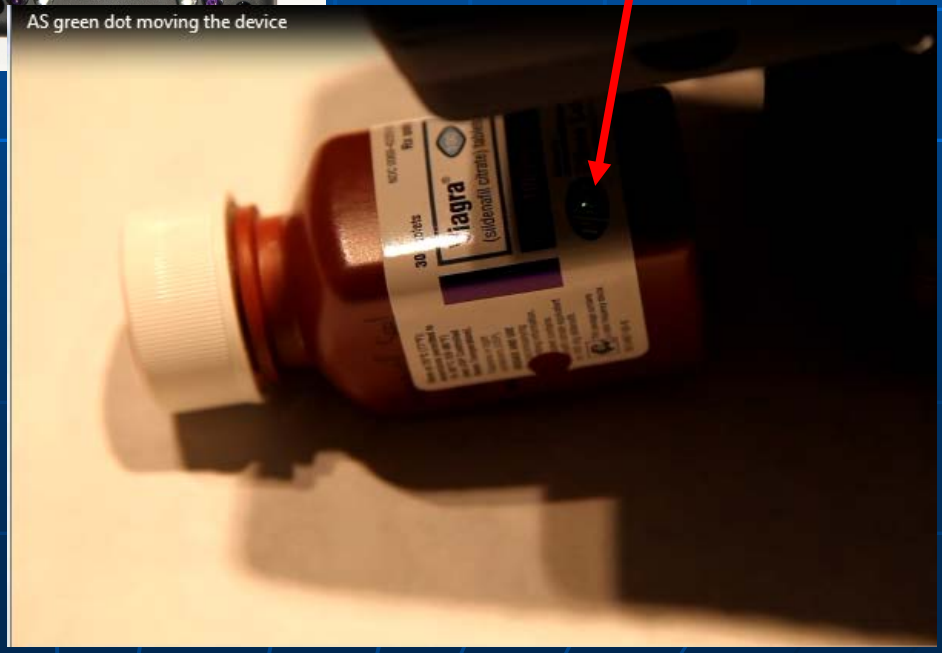
- Orange
- Yellow
- IR 1
- IR 2

CD3+ Technology Improvements

Anti-stokes

Infrared beam w/ a specific wavelength

Detection of Anti-stokes properties (Notice Green Dot)



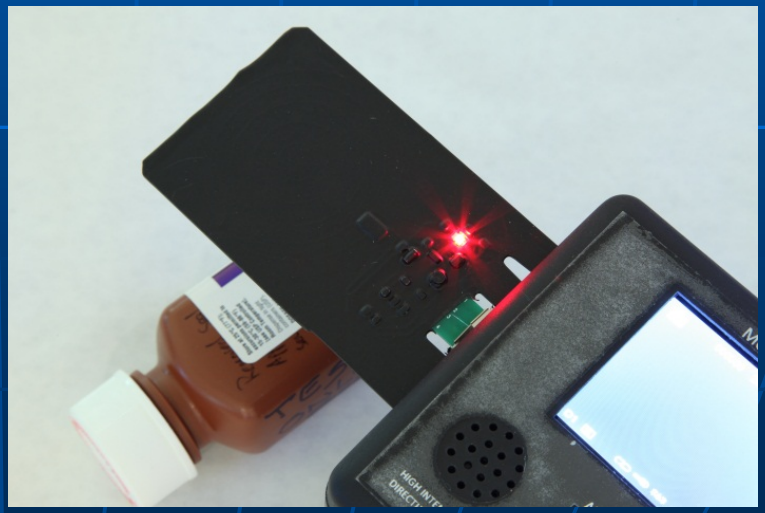
CD3+ RFID Detection Improvements

FD card application

FD card slot

FD card before scanning for RFID chip

FD card only



FD card after scanning RFID chips (notice red light)

CD3+ Technology Improvements

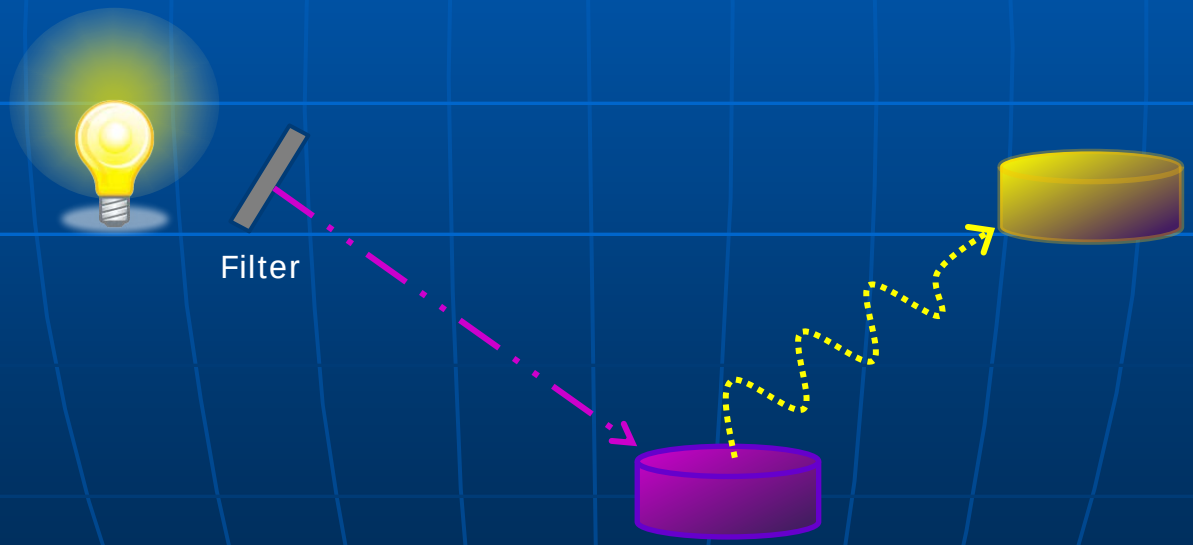
Oscillating Lights

Optically Variable Devices (OVD), Holograms, color shifting inks are now easily detected using the oscillating light feature

CDx How Does It Work?
(UV-Vis-IR imaging)

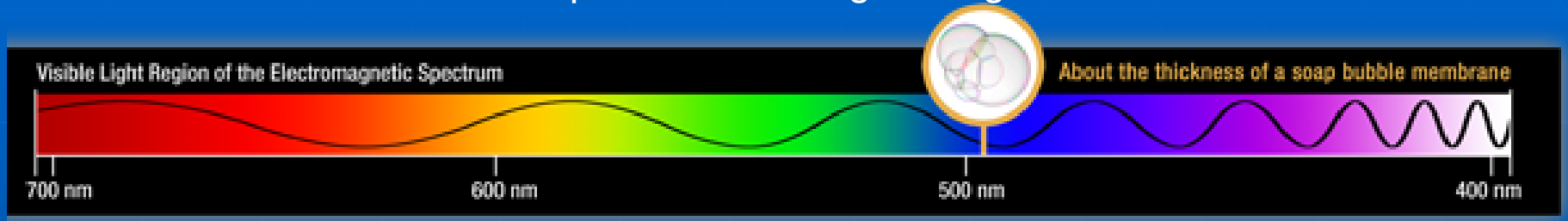
Mostly due to the phenomenon of fluorescence

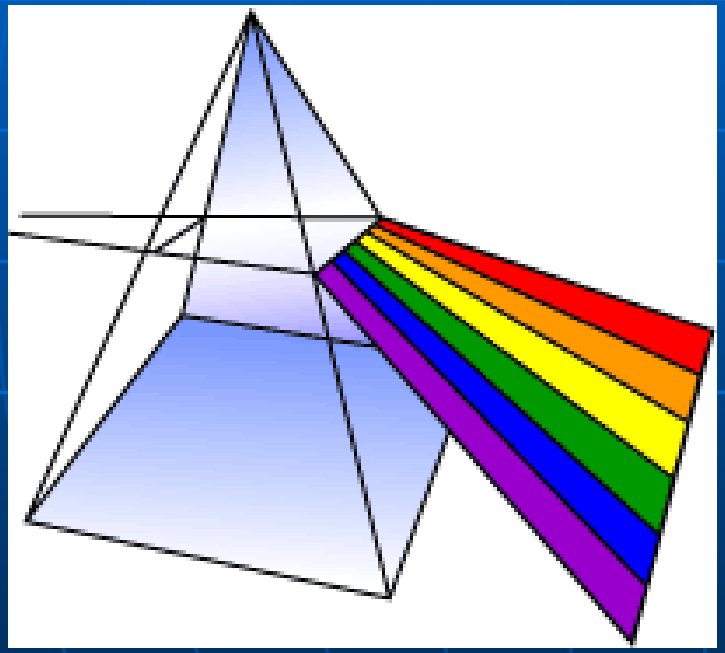
Fluorescence occurs when a molecule absorbs a photon of radiant energy at a particular wavelength and then quickly re-emits the energy at a slightly longer wavelength. This can cause certain objects or substances to appear remarkably more visible than the surrounding material, with the aid of an appropriate filter.

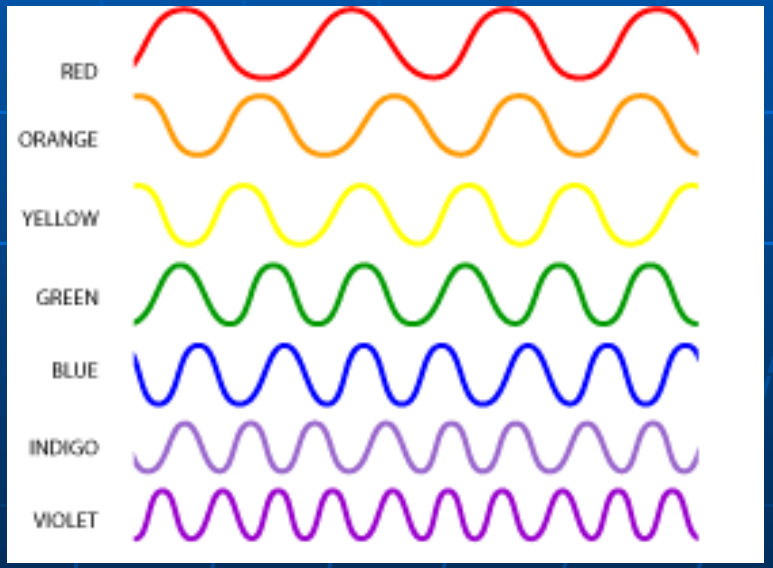


How UV-Vis-IR Imaging Works

The human eye preceives color as reflected from an object at a specific wavelength of light



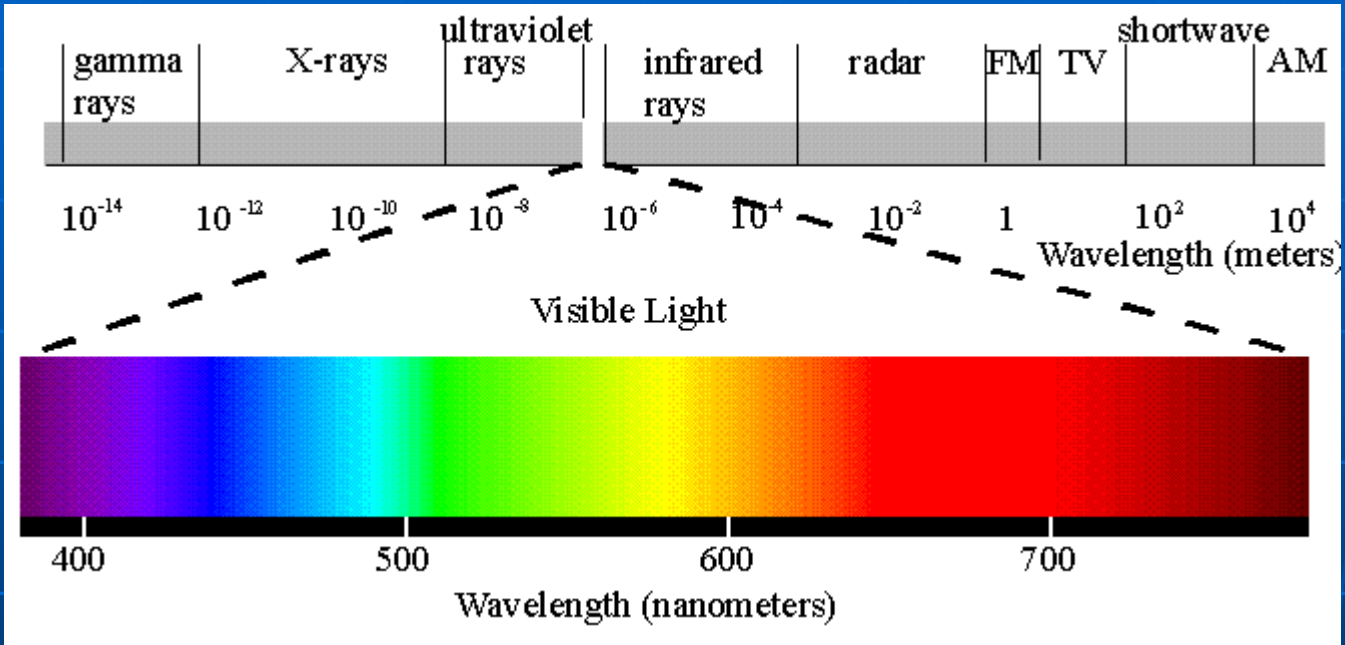




Source: http://missionscience.nasa.gov/ems/09_visiblelight.html

Note: slide created by Dr. James Herrington, MPH, Director Division of International Relations Fogarty International Center National Institutes of Health

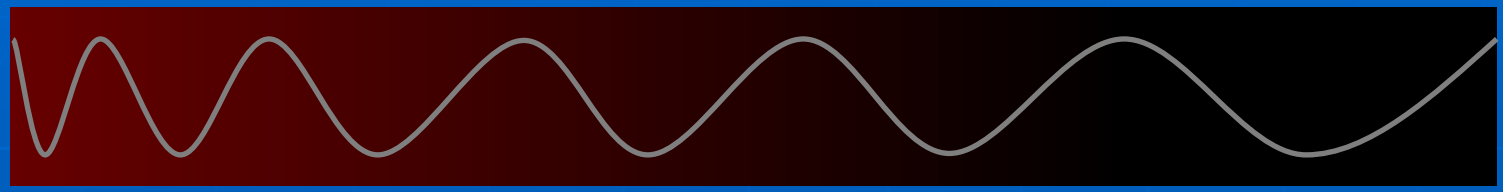
Visible Light Spectrum
~380nm to 760nm
ROYGBIV



CDx displaying capability ranges from UV to infrared, beyond the human eye's ability

Invisible Infrared Light Spectrum

CDx capable of displaying 750nm and up to ≥1100nm



Sources of infrared radiation:

Many common sources of radiation emit infrared:

- Sunlight
- Tungsten lamps
- Halogen lamps
- Xenon lamps
- Lasers
- Light Emitting Diodes (LEDs)

*CDx purpose most practical source are LED and tungsten

*Ambient or daylight would be an unpredictable source of infrared due to different variable lighting conditions from place to place

CDx How Does It Work?

(UV-Vis-IR imaging)

Animation of how it all works!

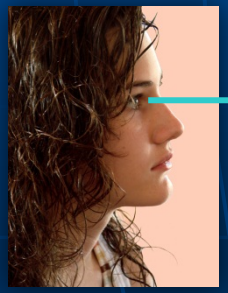
UV-aided eye "like" viewing UV-Vis Mode without filter

OD3 Imaging assisted UV-Vis Mode

UV Mode without filter assisted IR Mode

UV-Vis CCD

IR CCD



Unaided eye

Alternate Light Source Setup

415nm

Alternate Light Source Illumination

Prism

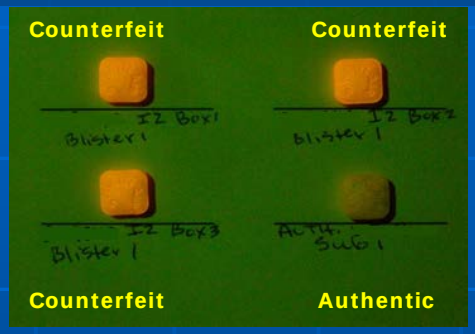
Filter

CDx How Does It Work?

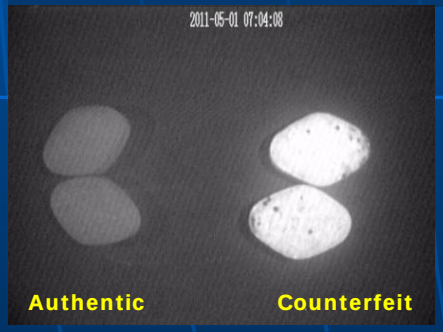
(UV-Vis-IR imaging)

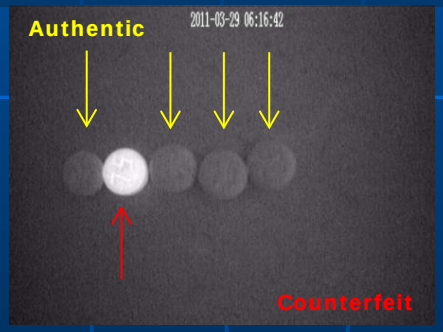
Actual results showing how components respond to the various illuminations available

UV-Vis Mode

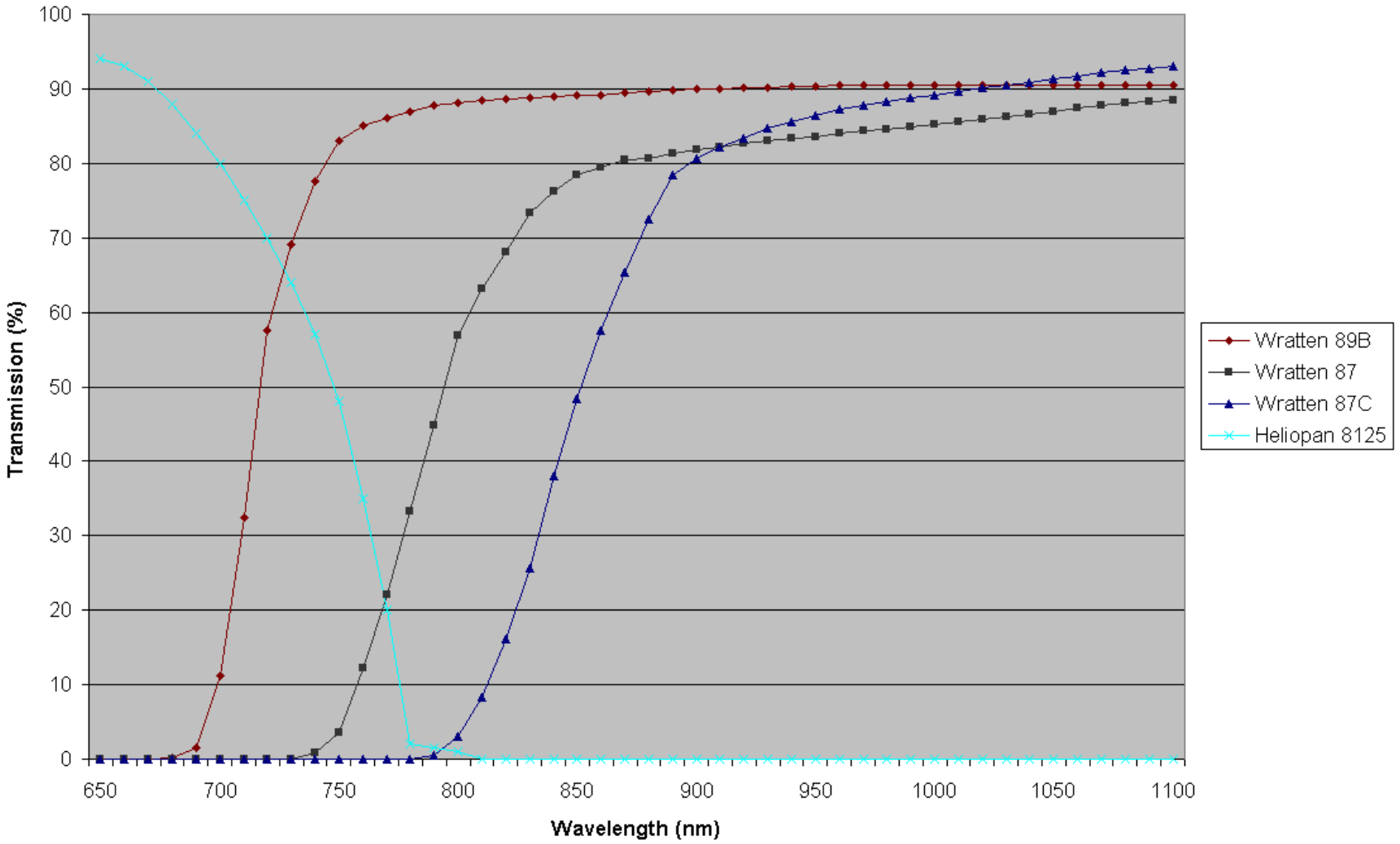


IR Mode





Infrared Imaging Filters
How they work!



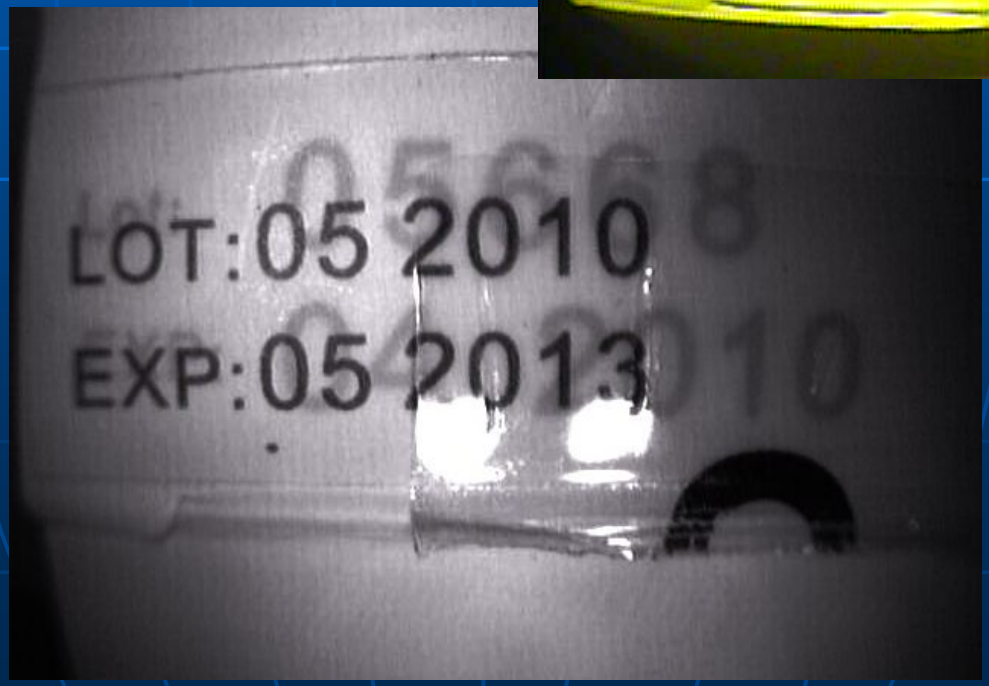
Current CD3 infrared image capture cut-off filters to increase the sensitivity of the CCD

- F4 IR Filter and F3 IR Filter

CD3 and Imaging in UV-Vis and IR Modes

(CDx-IR2)

White Light



Bodily Fluids Examination

(UV-Vis Mode)

Blood Stains on DARK clothing

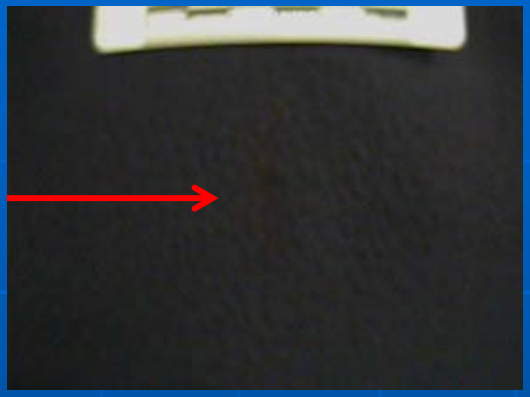


Photo 1: Dark jacket with blood stain under white light

Photo 2: Dark jacket with blood stain under brighter white light/enhanced photo

Photo 3: Dark jacket with blood stain under IR imaging 850

Photo 2: Dark jacket with blood stain under IR imaging 1050

Note: Photo 2 is saturating the CCD; Photo 3 shows no difference in the vials under UV-Vis

Bodily Fluids Examination

(UV-Vis Mode)

Urine on "clean" appearing bowls – don't try this at home or hotels

Photo 1: Flushed bowl; note "clean" to the naked eye

Photo 2: UV-Vis un-flushed toilet

Photo 3: UV-Vis flushed toilet and small area wiped

Photo 4: "Clean" appearing bowl

Photo 5: bowl under UV-Vis

Photo 6: closer view of bowl side under UV-Vis

Note: Photo 2 is saturating the CCD; Photo 3 shows no difference in the vials under UV-Vis

CD3+ Lens Enhancements

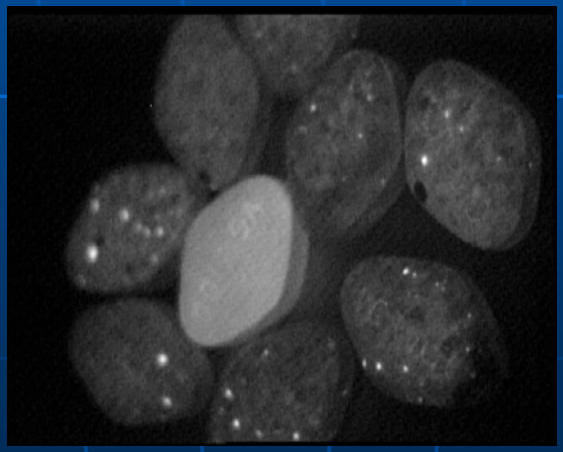
Lens options

Wide Lens

Macro (default) Lens 5” away from sample

Macro (default) Lens 3.5” away from sample

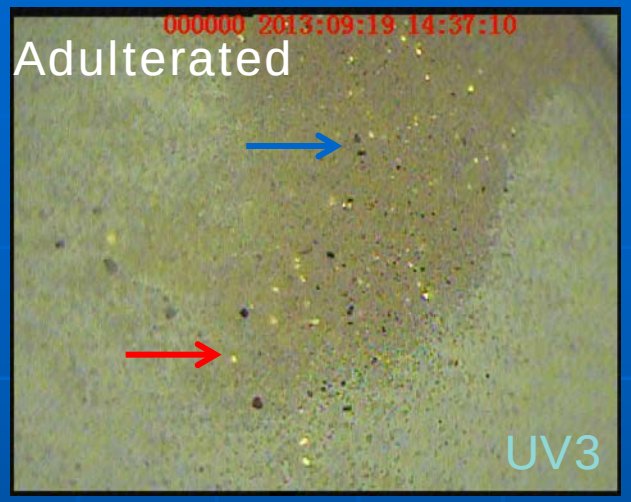
Wide Lens



Macro (default) Lens 5” away from sample

Macro (default) Lens 3.5” away from sample

Comparison of adulterated and unadulterated wheat glutens
CD3+ Scans by UV-Vis and IR imaging

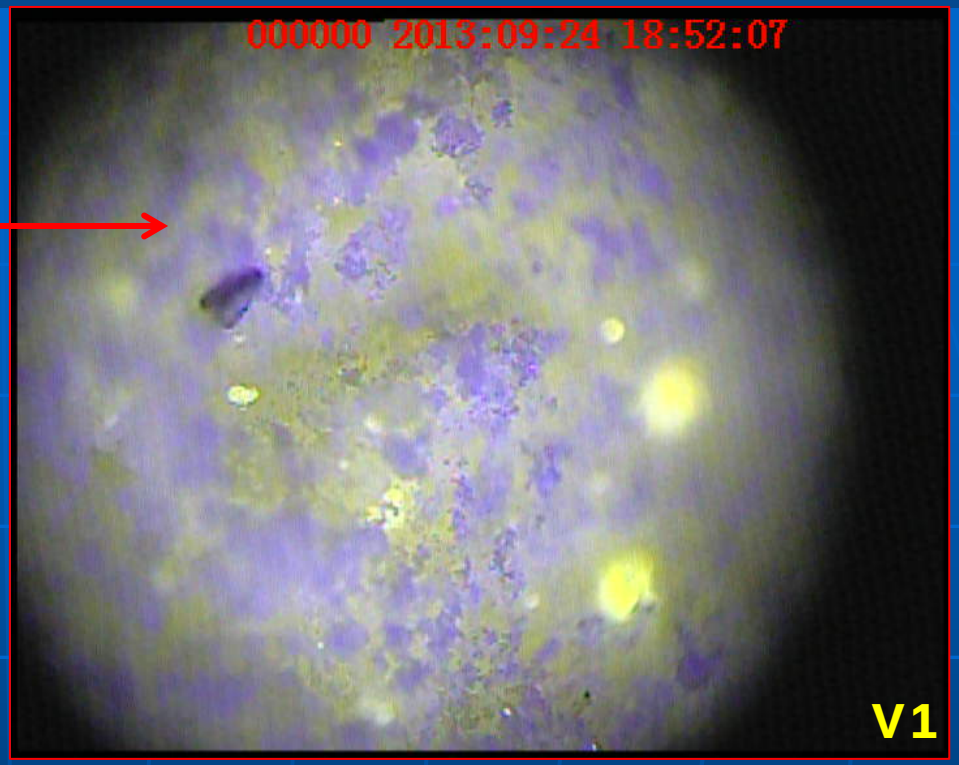


370188 – By HPLC: Melamine 4.7% (w/w) – Cyanuric acid 2.6% (w/w)

379586-1 – By HPLC: No noticeable contamination; Melamine ND (w/w) – Cyanuric acid ND (w/w)

Note: arrows point to particles – red fluorescent and white black; ND = Not Detected

Comparison of Macro and High Power lens of adulterated wheat glutens



370188 – By HPLC: Melamine 4.7% (w/w) – Cyanuric acid 2.6% (w/w)

CDx Macro (default) Lens

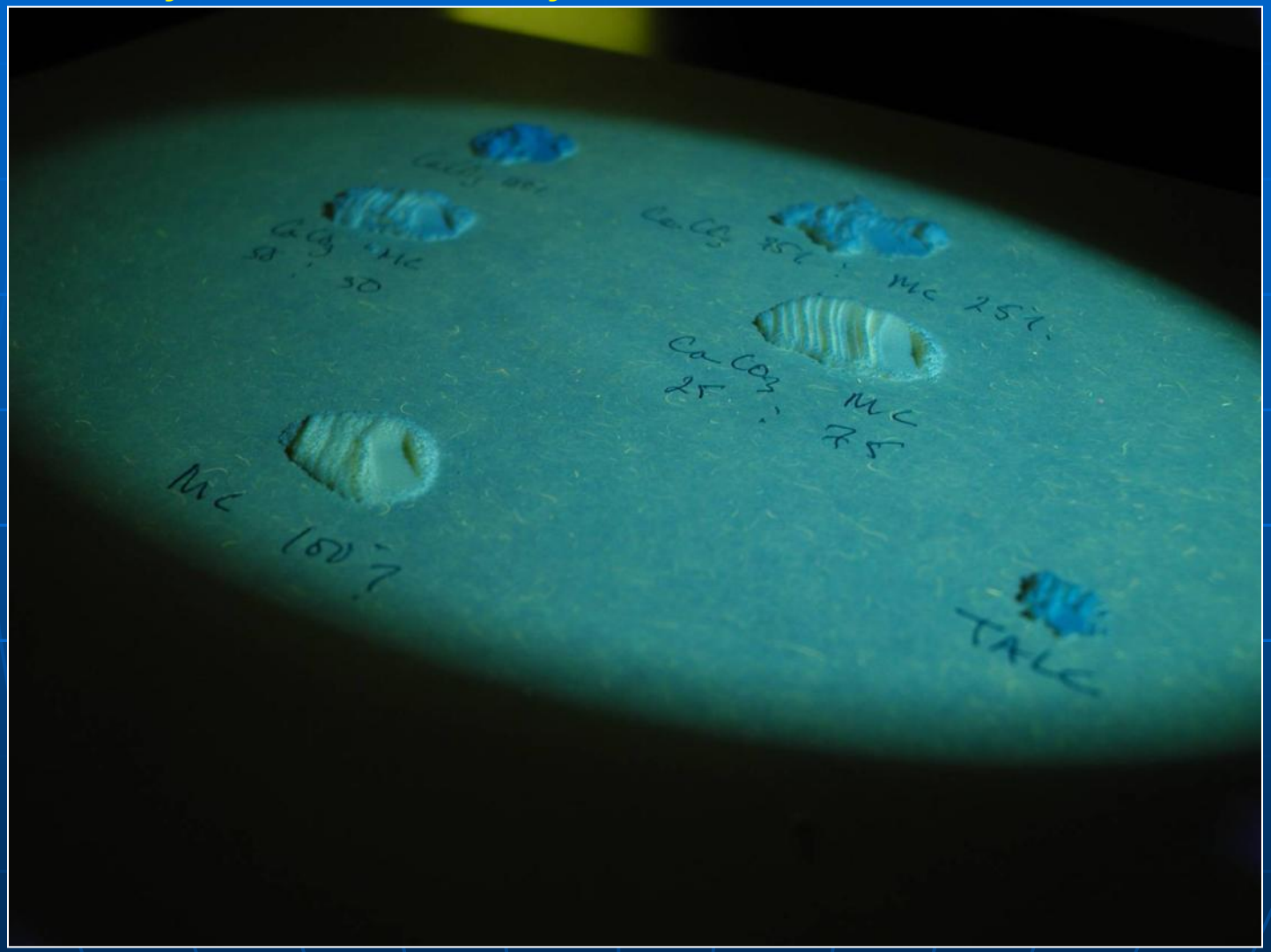
***CDx High Power Lens**

*High Power lens can be used for particles, printing and surface contaminants using **ANY** of the CDx variable wavelengths

Test Sensitivity of Tablet Excipients

(Use of UV-Vis imaging)

Excipients Sensitivity for Counterfeit Analysis



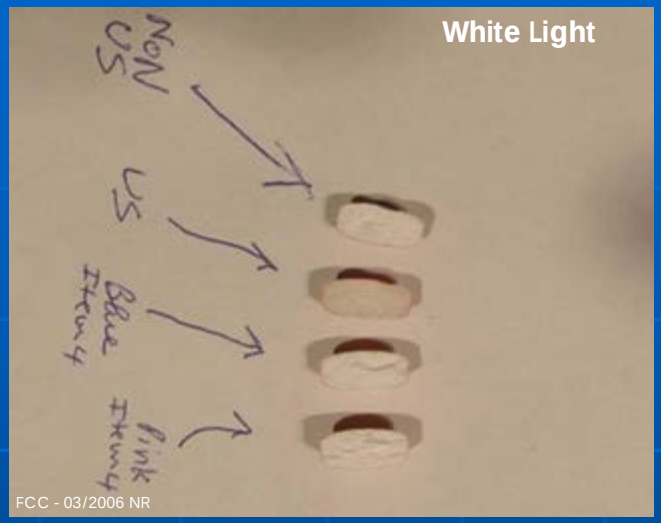
Note: pure individual excipients under UV-Vis

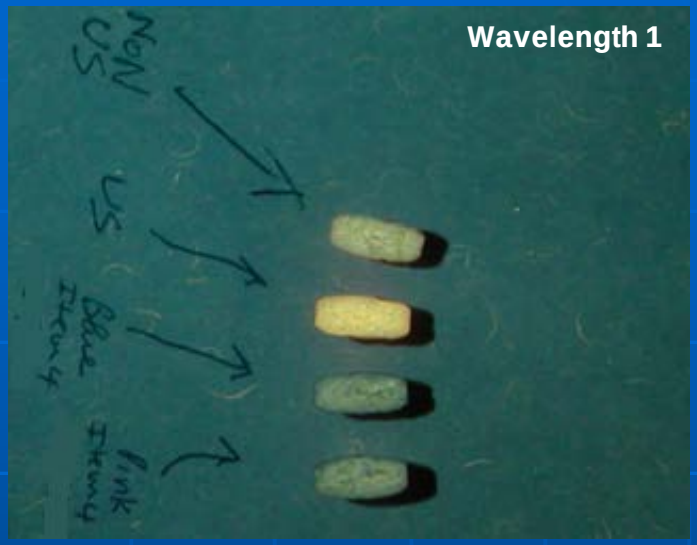
Examination of Tablet Cores

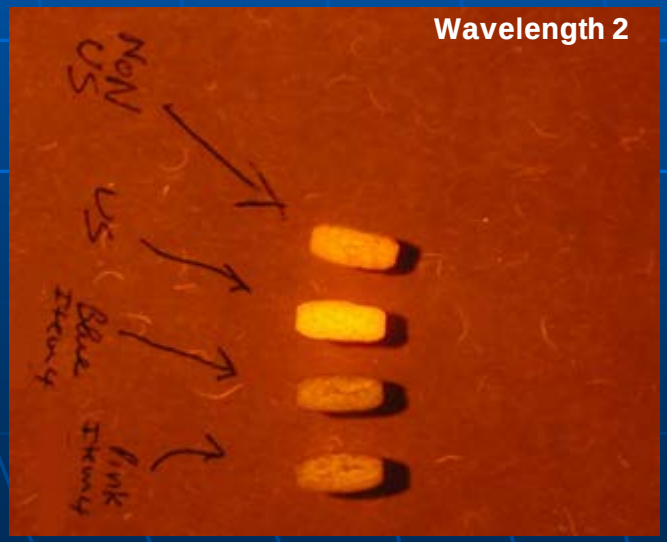
(Use of UV-Vis imaging)

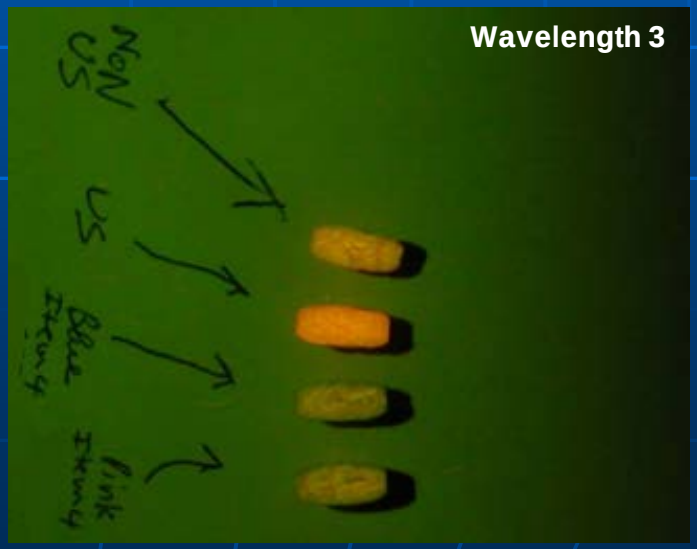
Actual Case

Tablet Core – Counterfeit









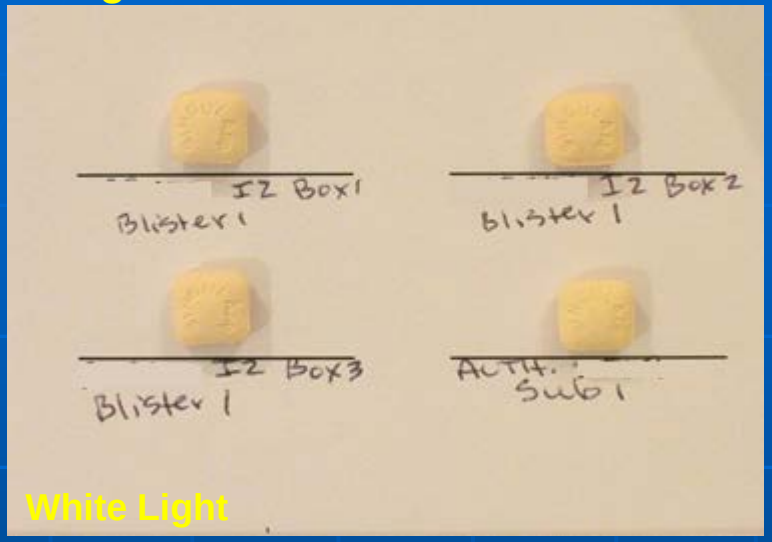
Note: tablet cores are all white under white lighting but noticeable under UV-Vis

Examination of Tablet Coatings

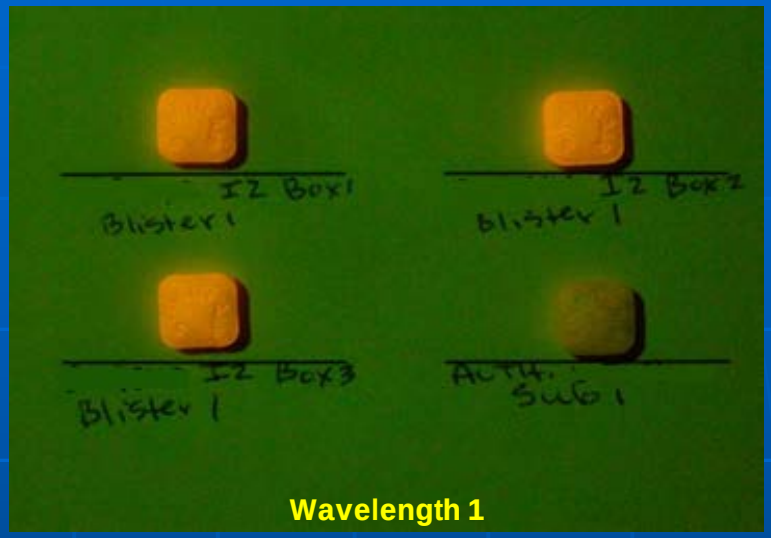
(Use of UV-Vis imaging)

Actual Case

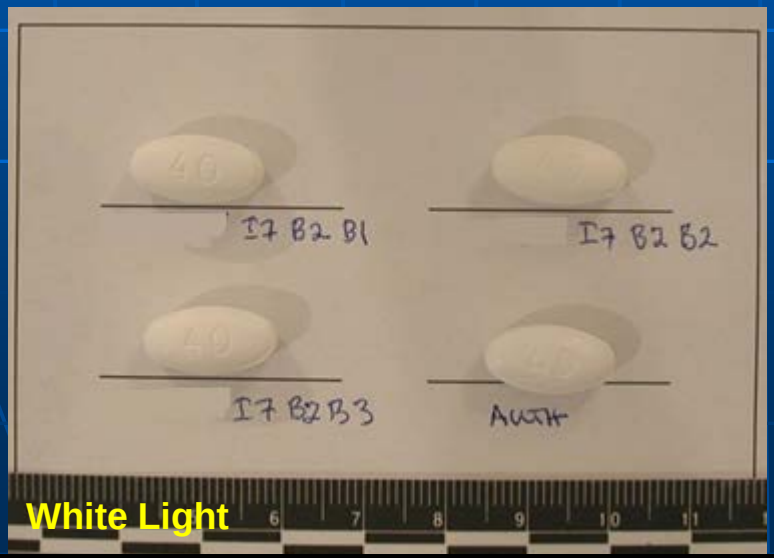
Tablet Coating – Counterfeit



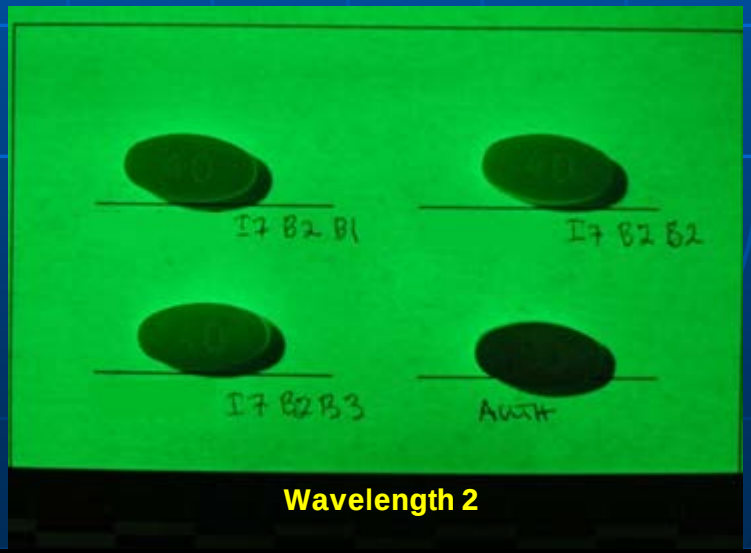
White Light



Wavelength 1



White Light



Wavelength 2

Note: tablet coatings are indistinguishable under white lighting but noticeable under UV-Vis

Images of Examinations of Large Samples

Actual Cases

(Use of UV-Vis range imaging)

Counterfeit

Note: scanning through blister packs viewing many at one time

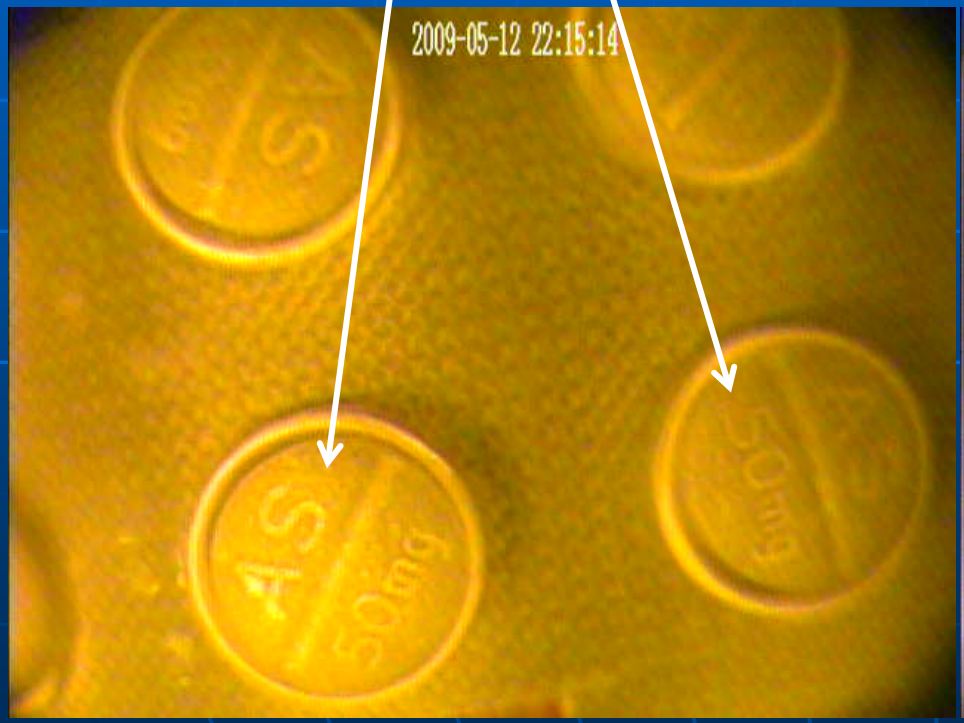
CD3 on Anti-malarial Drug Products

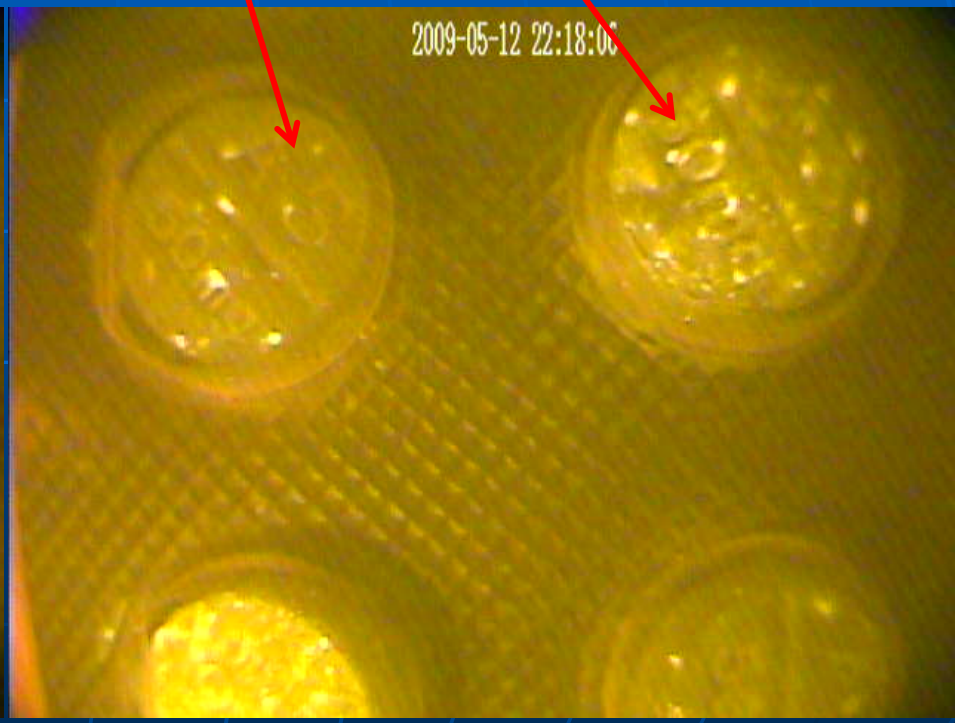
(UV-Vis-IR Modes on white tablets through blister-packs)

Tablet Homogeneous Blending

Genuine tablets show distinct debossing patterns and homogeneous quality of excipient

Counterfeit tablets show poor debossing patterns and heterogeneous quality of excipient





Note: poor quality control of blending of counterfeit tablets; also, blister pack embossing pattern difference noticeable

Reveal Evidence of Product Diversion

(Use of UV-Vis range imaging)

Actual Case

Diverted Product

Note: indistinguishable differences under white lighting but noticeable under UV-Vis

Revealing Covert Markers

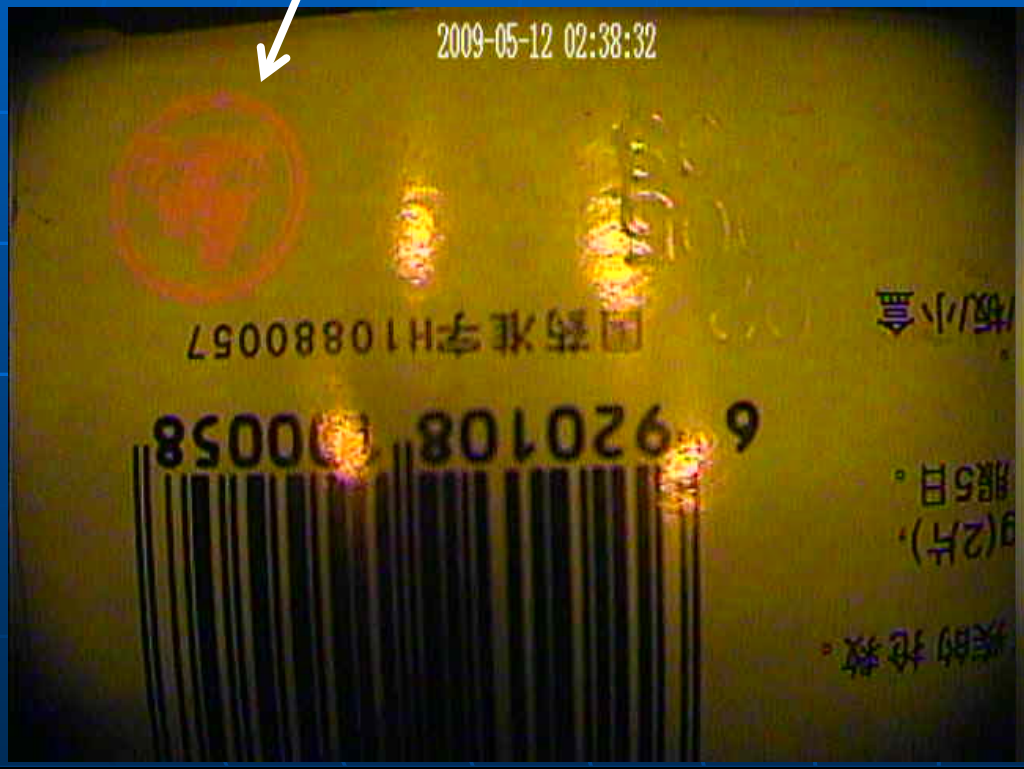
(Use of UV-Vis range imaging)

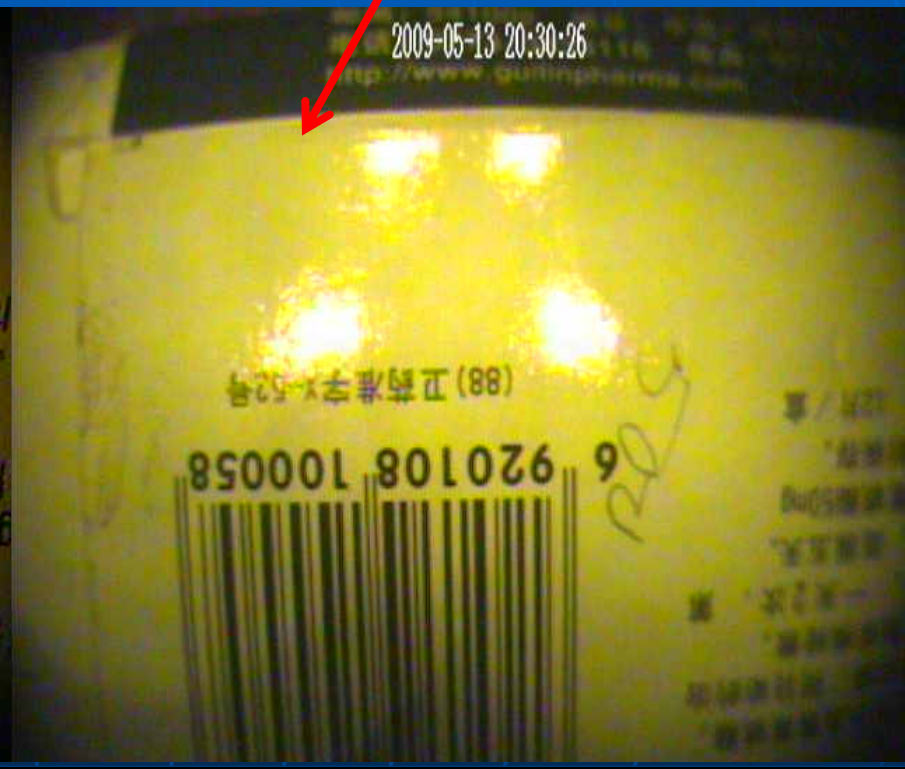
Actual Case

Covert Markings

Genuine covert marking present

Covert marking absent





Note: uncovering covert markers with use of UV-Vis

Infrared Imaging of capsules

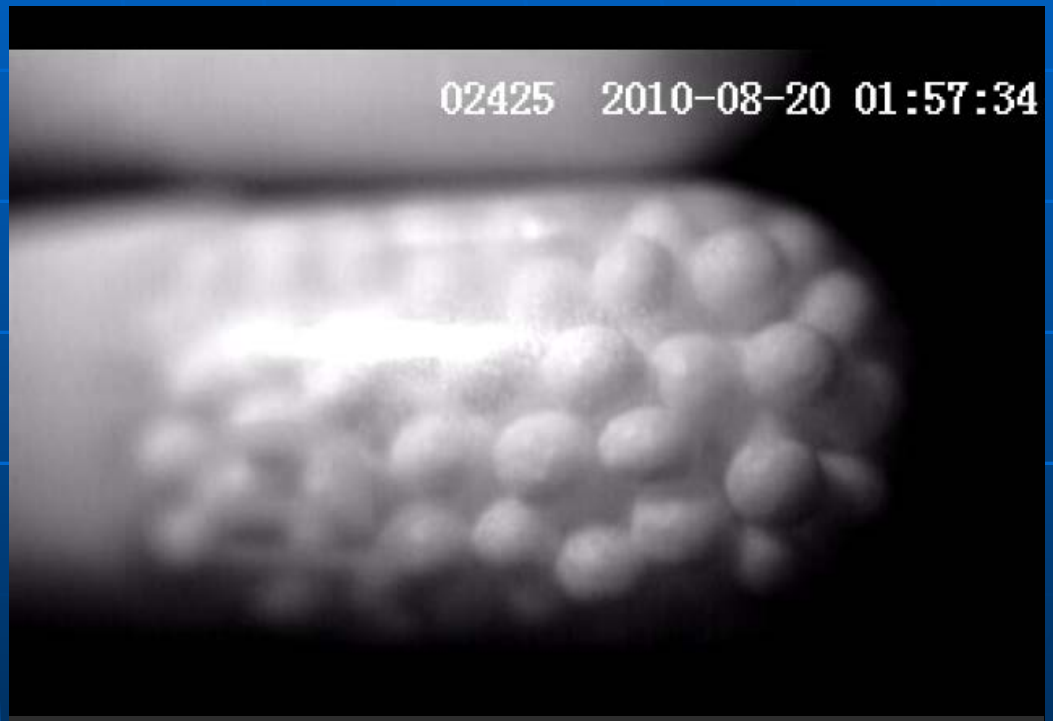
(Use of IR visible range through gelatin capsules)

Actual Case

Gelatin Capsule Contents

Capsules under white light

See beads shape or beads vs powder through gelatin capsules



Closer view IR Imaging

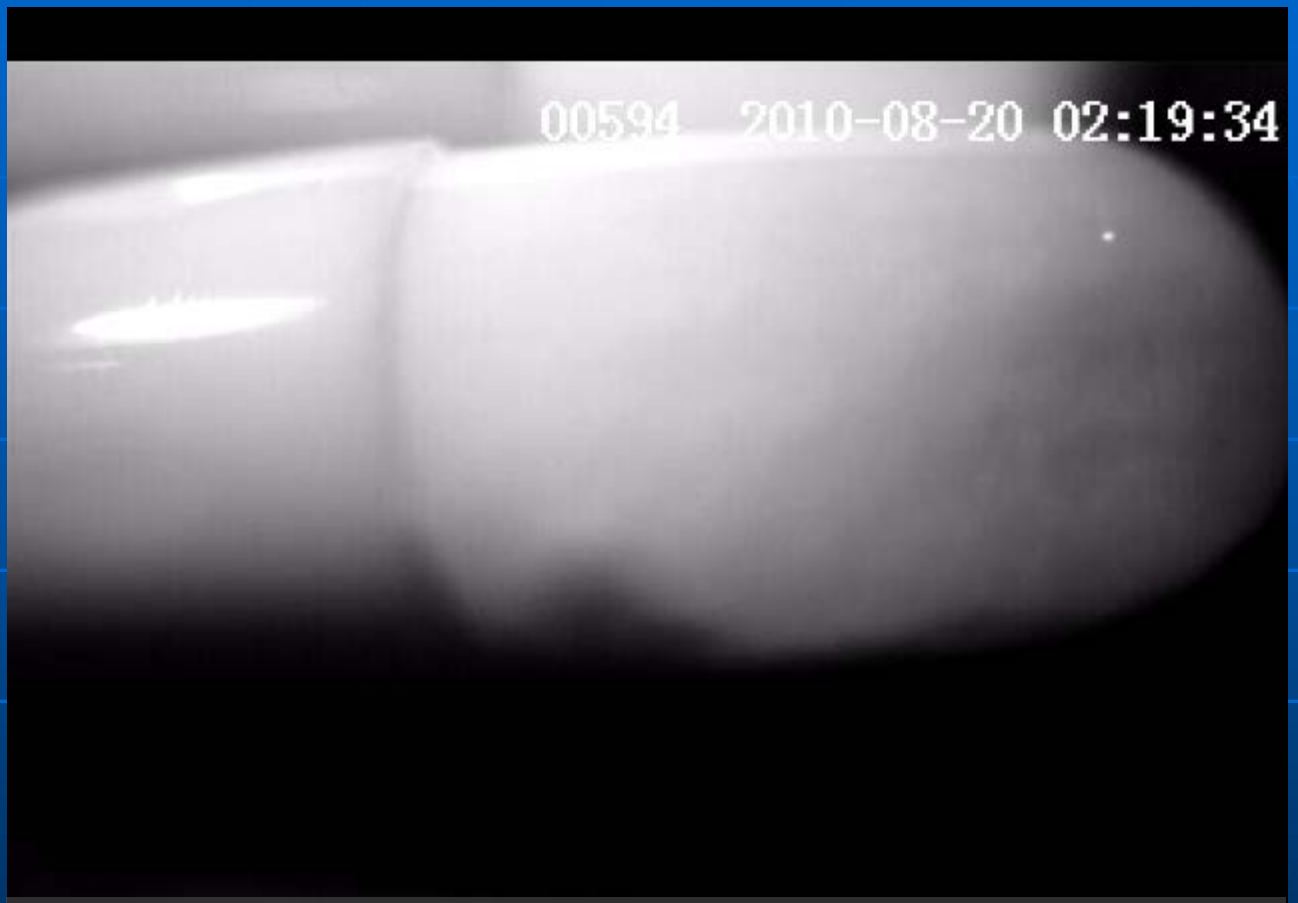
Note: beads seen through gelatin capsules

Infrared Imaging of capsules

(Use of IR visible range through gelatin capsules)

Gelatin Capsule Contents

Capsules under white light



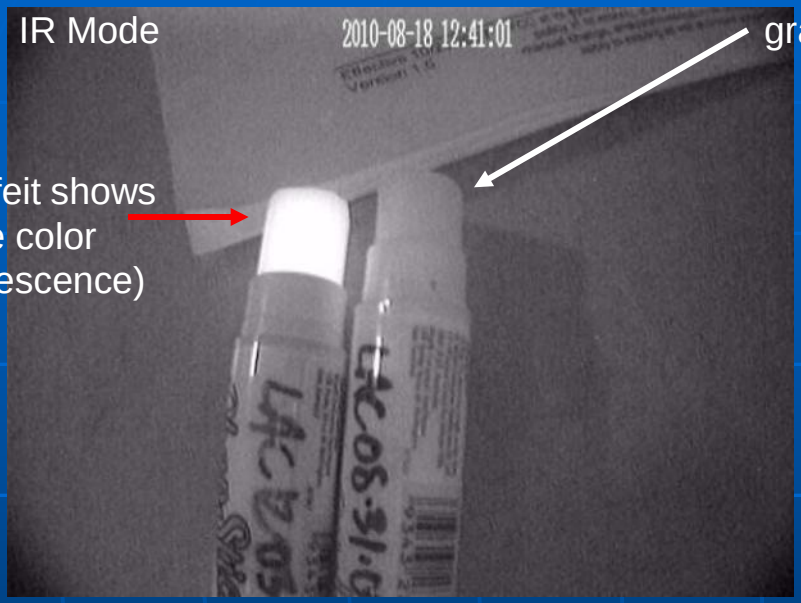
See powder through gelatin capsules by IR Imaging

Note: powder seen through gelatin capsules

UV-Vis-IR Imaging of Cosmetics

(Use of IR visible range)

Contents Examination – Counterfeit



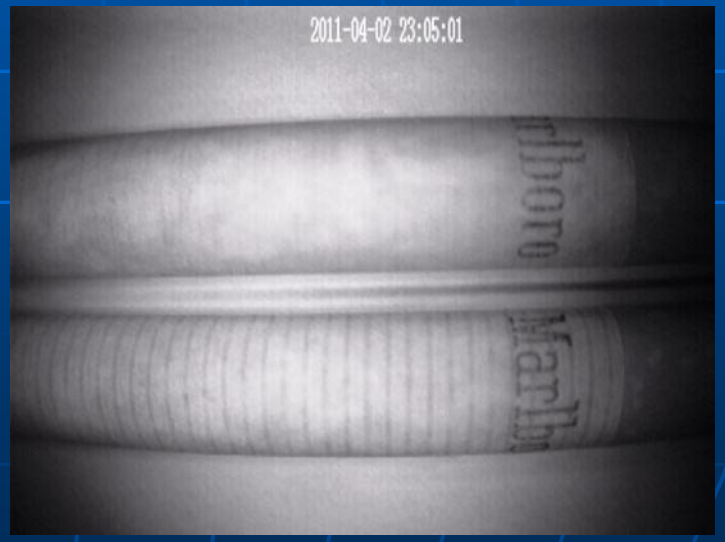
Note: indistinguishable tube content under white light

Imaging of Tobacco Packaging and Contents

(Use of visible and infrared range imaging)

Actual Case

Counterfeit

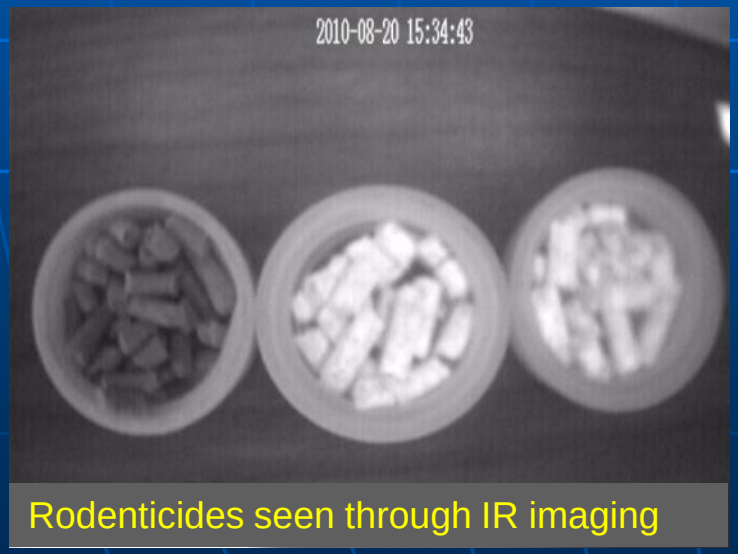


Note: packaging and cigarette paper type differences

Imaging of Packaging, Liquids, and Solids

(Use of visible and infrared range imaging)

Counterfeit



Rodenticides seen through IR imaging

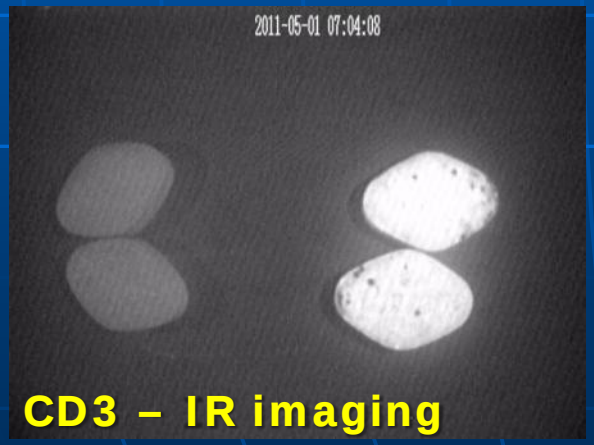
Diluted Veterinary liquid meds

Note: differences of packaging, liquids, and solids

UV-Vis Imaging of Packaging

(Use of visible range imaging)

Counterfeit



Note: differences of packaging

Infrared Imaging of Tablets

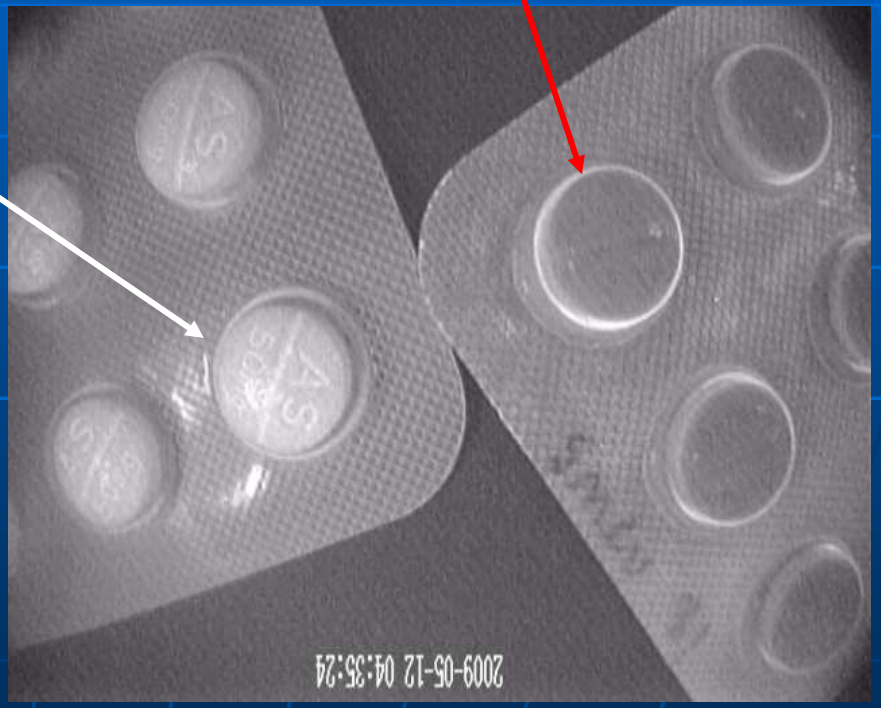
(Use of IR visible range through blister packs)

Actual Case

Counterfeit

Genuine tablets show white color (IR fluorescence)

False tablets appear gray under IR mode

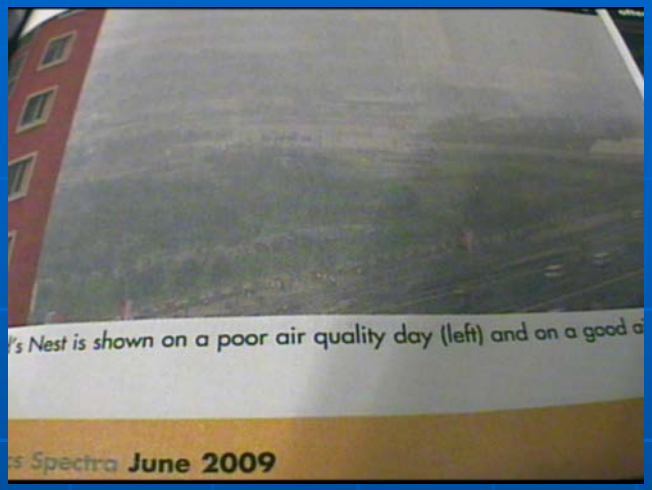


Note: tablets seen through blister pack

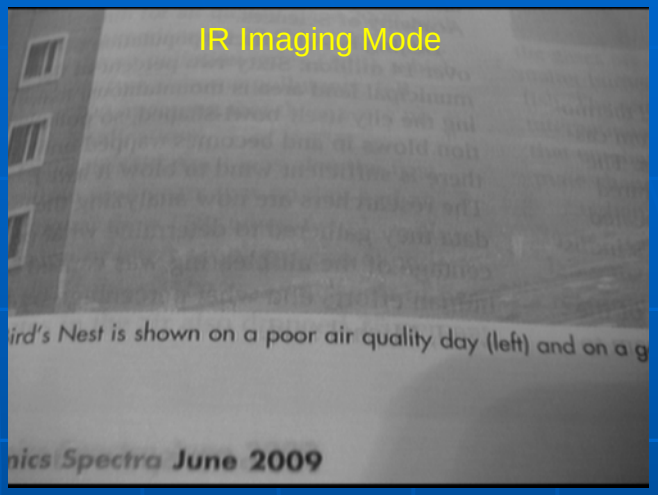
IR Imaging Creativity – See Through Paper

(Use of IR imaging)

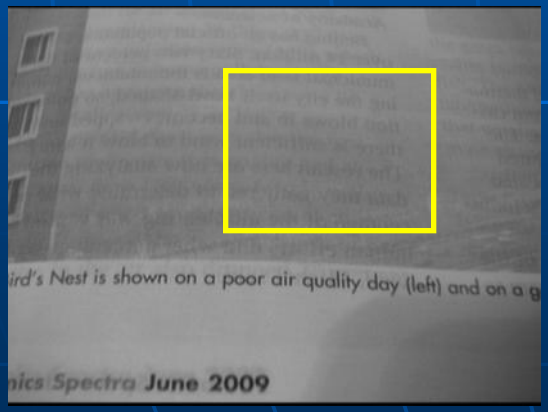
Document Examination Technique?

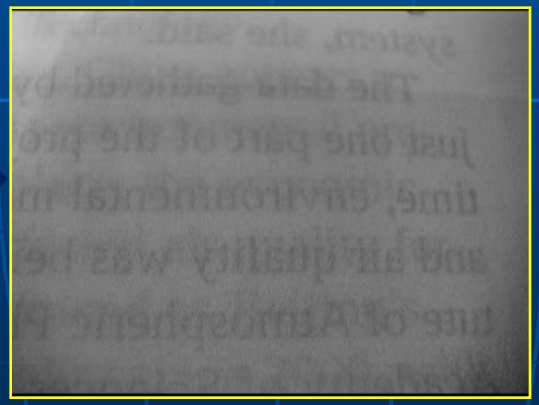


Magazine sheet seen in white light – text opposite side of sheet not visible

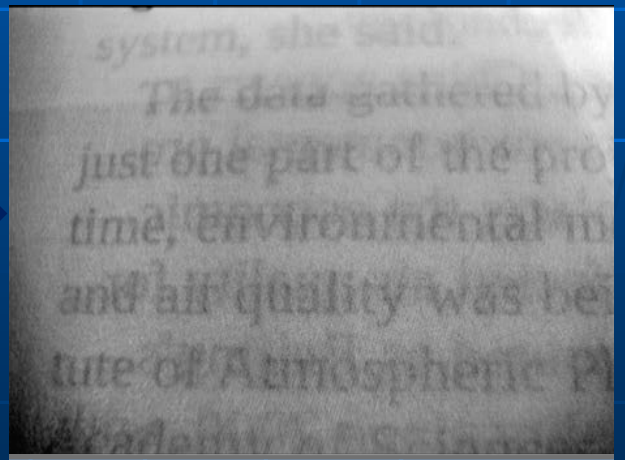


Magazine opposite side sheet text visible





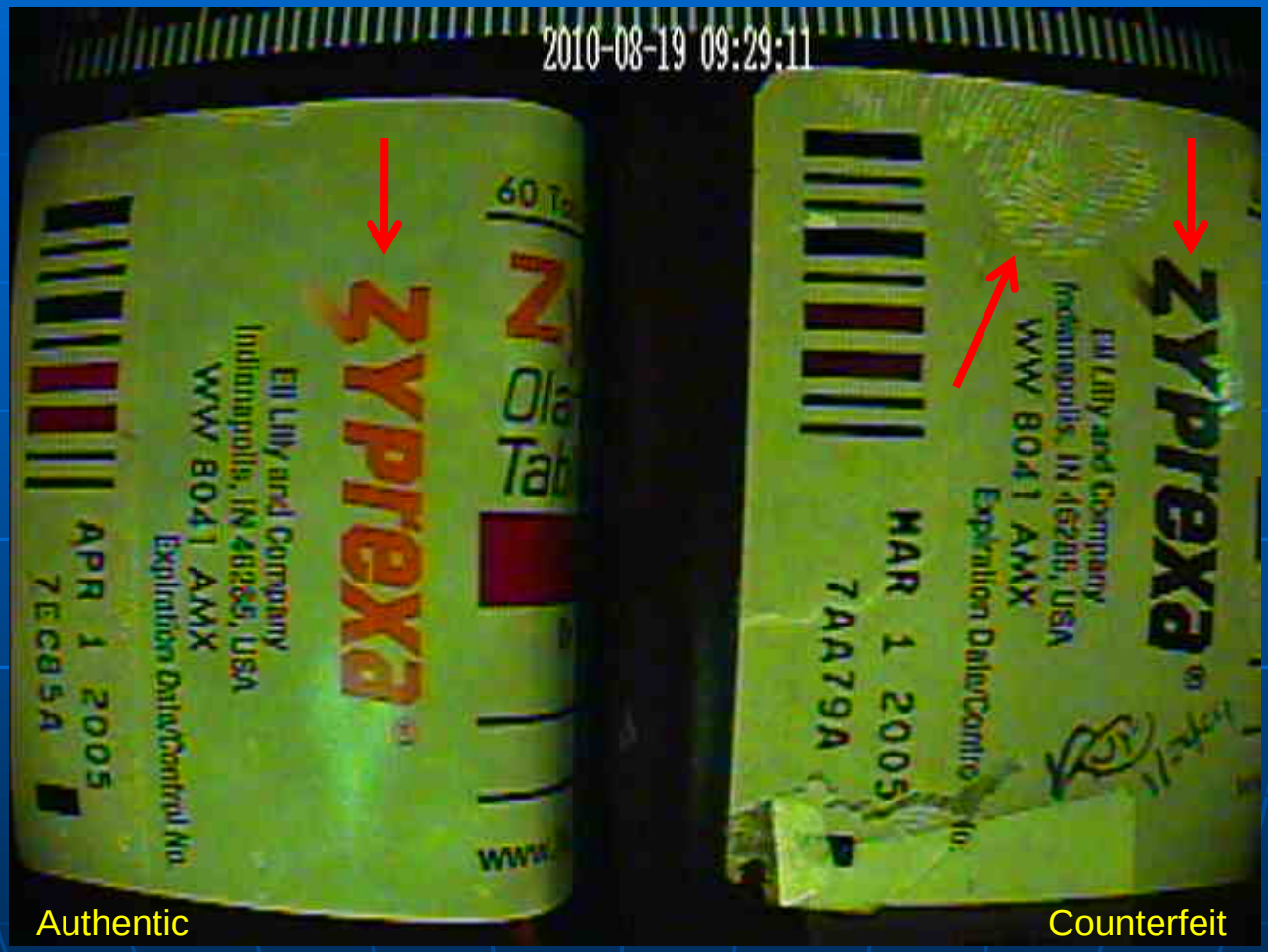
IR image close-up



Mirror image of close-up

Note: image of one side of sheet can be see through the use of infrared imaging

UV-Vis imaging of inks (pigments/dyes) on labels
Indistinguishable differences under normal lighting



Latent Fingeprints

Extra Virgin Olive Oil (EVOO) versus Canola Oil Mixtures (Dilutions)
Visual and CD3 View in UV-Vis Mode

EVOO / Canola Oil
(5:1)

EVOO / Canola Oil
Rating: Visual = 0; CD3 = 5

EVOO / Canola Oil
(4:2)

EVOO / Canola Oil
Rating: Visual = 0; CD3 = 9

EVOO / Canola Oil
(2:4)

EVOO / Canola Oil
Rating: Visual = 0; CD3 = 10

EVOO / Canola Oil
(1:5)

EVOO / Canola Oil
Rating: Visual = 0; CD3 = 10

Note: red arrows point to the vial with the mixture of oils

Extra Virgin Olive Oil and Pure Olive Oil
CD3 Scan in UV-Vis Mode

Two wavelengths ON – OFF
High/Low IR fluorescence

Blood Red Color
indication of having EVOO components

Noticeable Difference Rating:
Visual = 5 CD3 = 10

Note: Olive Oil (O1) displays no IR fluorescence at 630

Extra Virgin Olive Oil (EVOO) versus Flax Oil Mixtures (Dilutions)
Visual and CD3 View in UV-Vis Mode

EVOO / Flax Seed Oil
(1:1)

EVOO / Flax Seed Oil
Rating: Visual = 8; CD3 = 10

Note: red arrows point to the vial with the mixture of oils

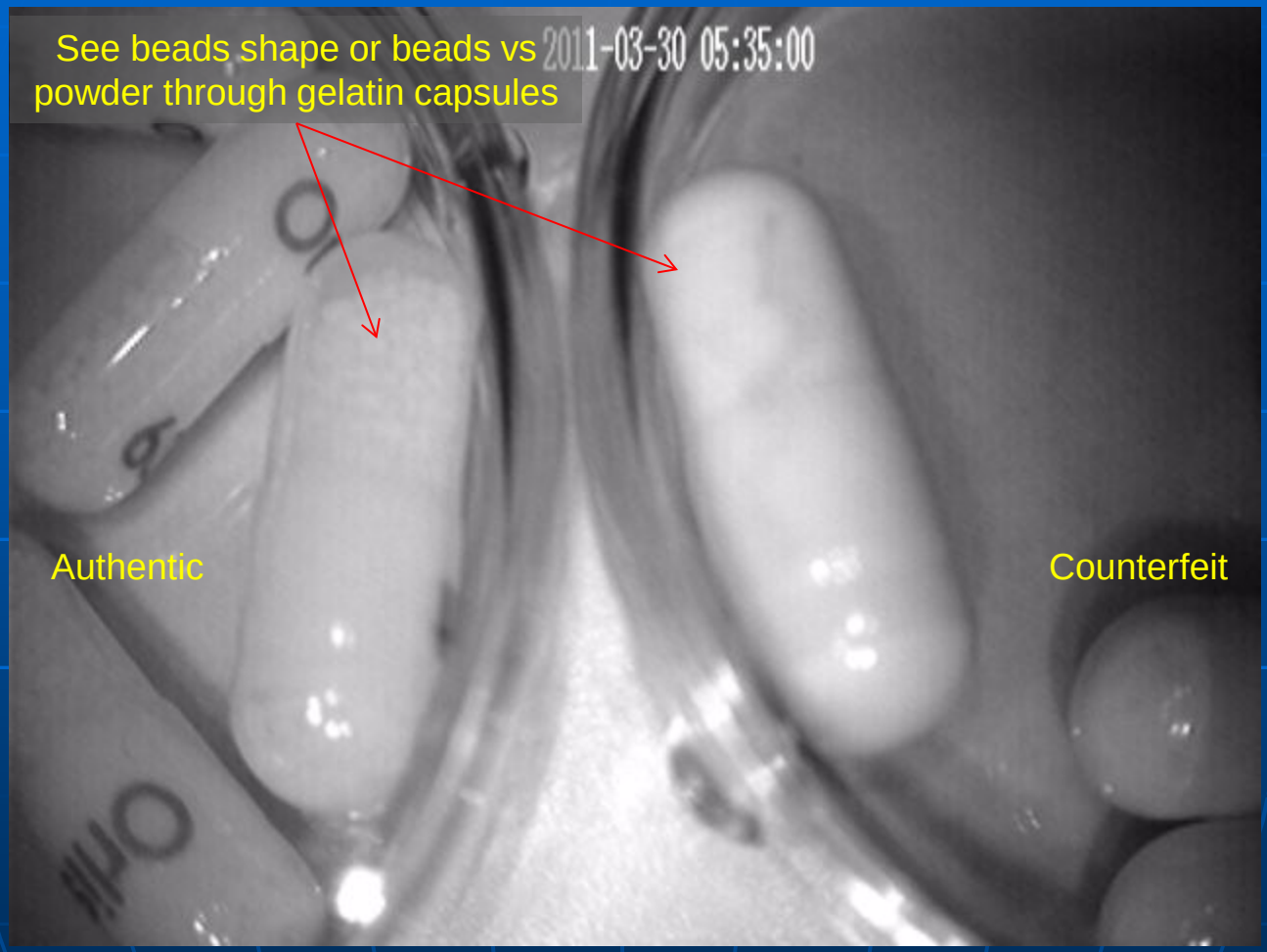
CD3 Infrared Imaging of capsules

(Use of visible range imaging on capsules)

CDx captured infrared image using the 750nm cut-off filter

CD3 Infrared Imaging of capsules

(Use of visible range imaging on capsules)



CDx captured infrared image using the 750nm cut-off filter

Infrared Imaging of Sunglasses

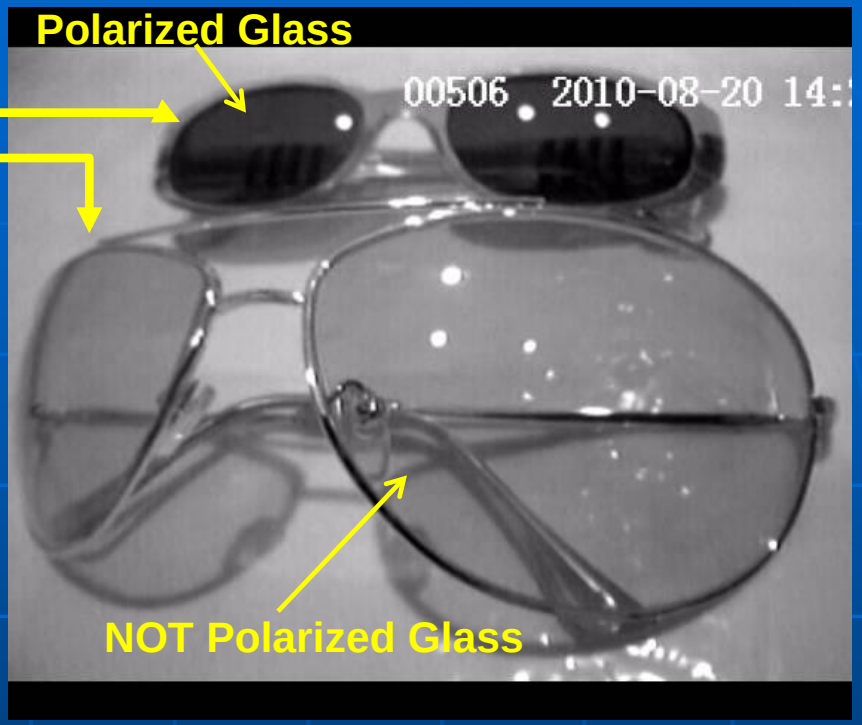
(Use of IR visible range through "polarized" glass)

Actual Case

"Polarized" Glasses

Sun glasses under white light

Sun glasses under IR

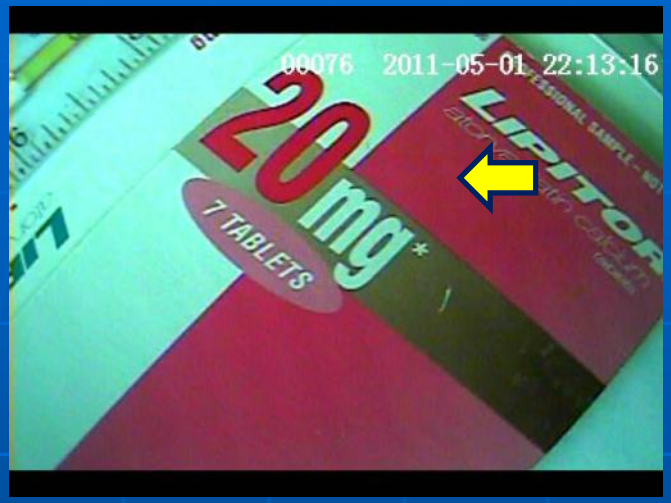


Note: beads vs powder seen through gelatin capsules

Making Covert Markers using Infrared Imaging

(Use of IR visible range on inks)

Marking w/ IR inks



White Light

UV-Vis Imaging

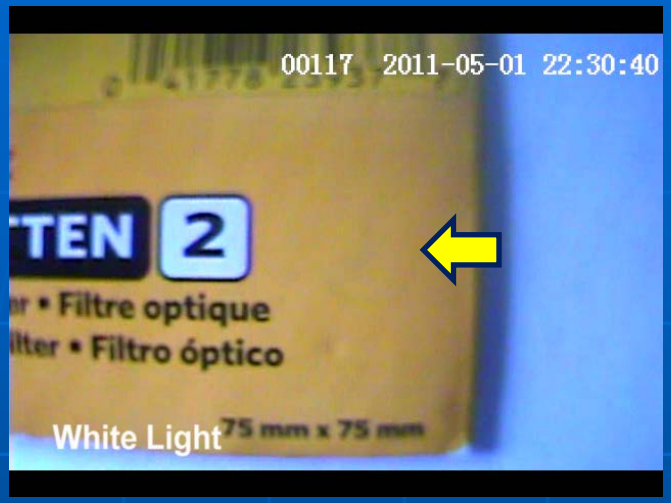
IR Imaging

Note: covert marking not visible in white light or using UV light source

Making Covert Markers using Infrared Imaging

(Use of IR visible range on inks)

Marking w/ IR inks



White Light

UV-Vis Imaging

IR Imaging

Note: covert marking not visible in white light or using UV light source

CDx Imaging of capsules

(Use of visible range imaging on capsules)

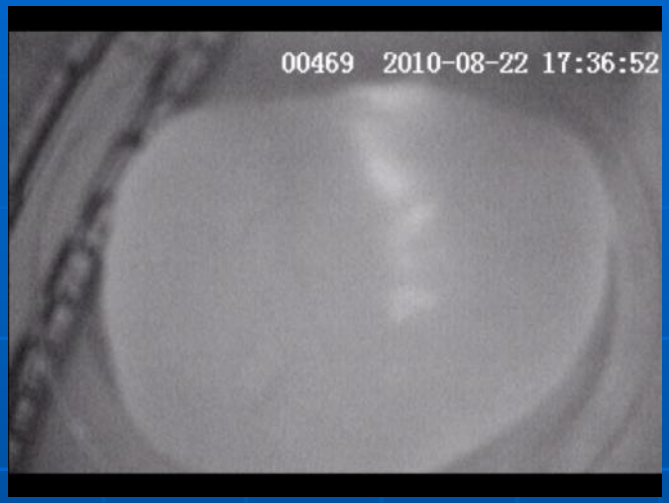
Actual Case

Finding Rat Poison using Infrared Imaging

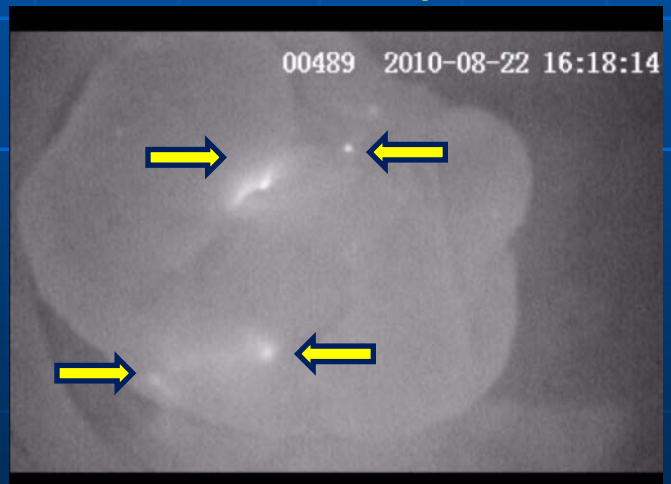
(Use of visible range of IR fluorescent inks)

Rodenticide Pellets in Cookie White Dough – Tampering

No rodenticide pellets



IR Imaging – rodenticide pellets squeezed in the dough



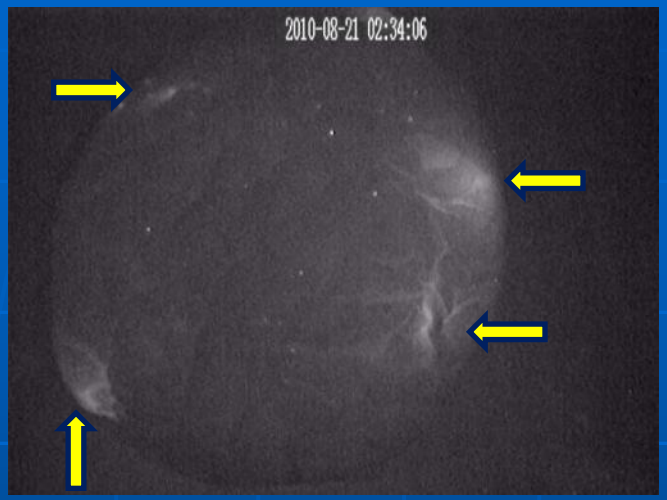
IR Imaging – rolled and worked dough

Note: when the dough is mixed or worked the pellets IR fluorescent dye gets mixed in the dough hence more fluorecence

Finding Rat Poison using Infrared Imaging

(Use of visible range of IR fluorescent inks)

Rodenticide Pellets in Cookie Wheat Dough – Tampering



IR Imaging – rodenticide pellets squeezed in the dough

IR Imaging – rolled and worked dough

Note: when the dough is mixed or worked the pellets IR fluorescent dye gets mixed in the dough hence more fluorecence

Infrared Imaging Dark Liquids

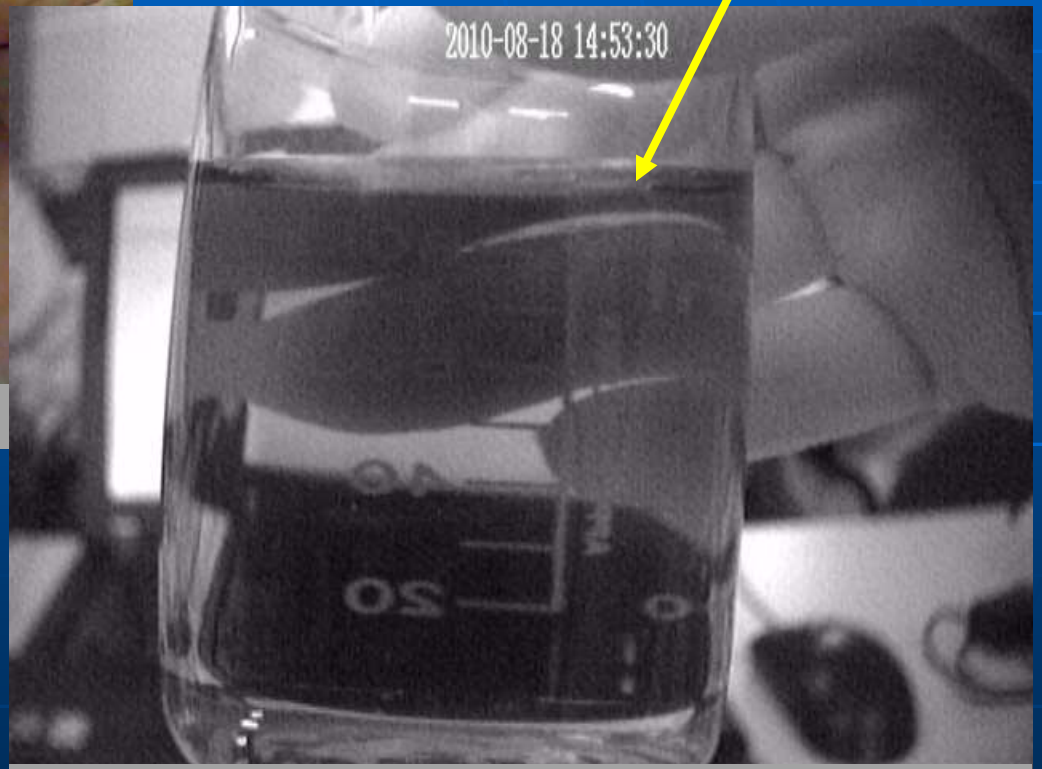
(Imaging of IR visible range through plastic or glass bottles)

Foreign Objects – Tampering

Note: light in the back to help see through dark liquid while in white light mode

Dark colored soft drink viewed in white light

Note: you can easily see fingers of beaker holder through dark soft drink liquid



Dark colored soft drink viewed in IR Mode

Note: one can easily see through very dark beverages like looking through water

Infrared Imaging Dark Liquids

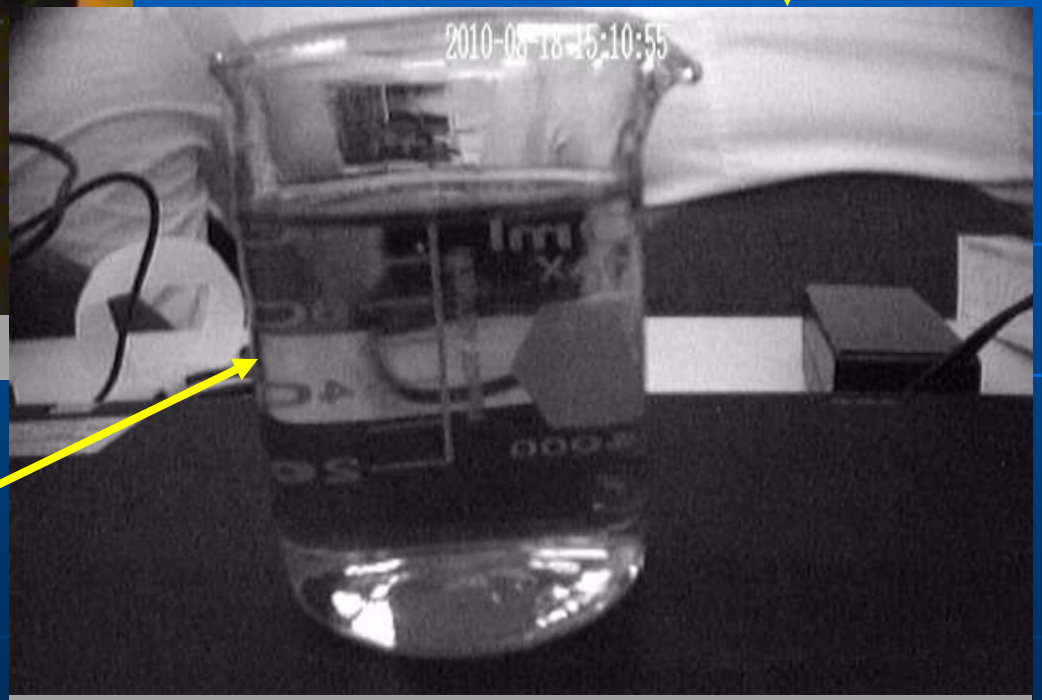
(Imaging of IR visible range through plastic or glass bottles)

Foreign Objects – Tampering

Note: light in the back to help see through dark liquid while in white light mode

Also note the dark trainee shirt how it changes in IR Mode; you can see the shirt stitching pattern and that pants are differrent color than the top.

Dark colored soft drink



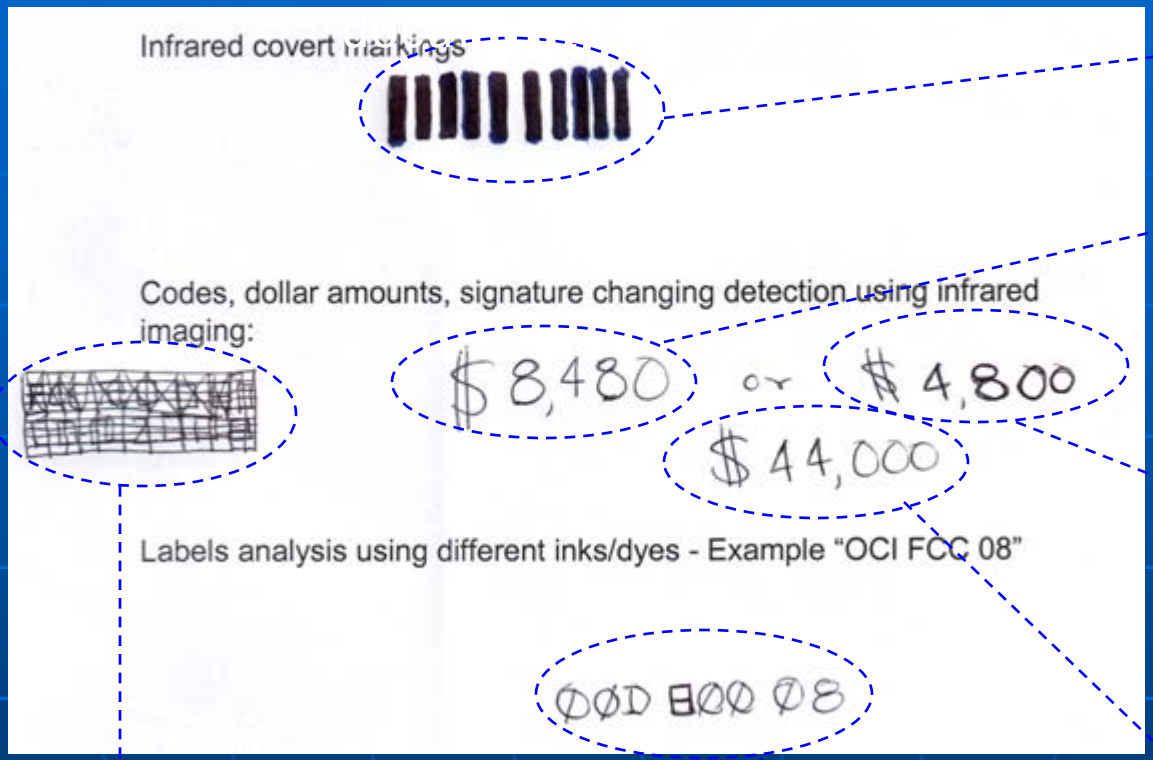
Dark colored soft drink viewed in IR Mode

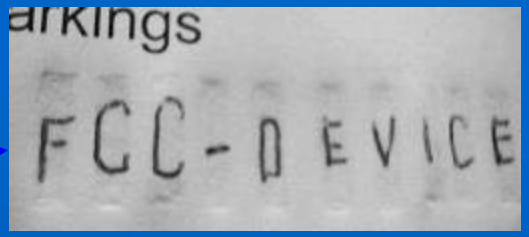
Note: you can easily see through beaker through dark soft drink liquid

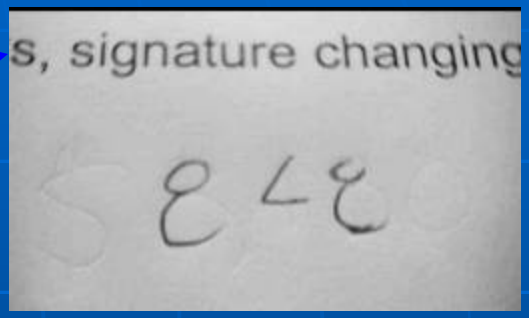
Note: you can easily see through very dark beverages like looking through water; also see the top of person is different than bottom

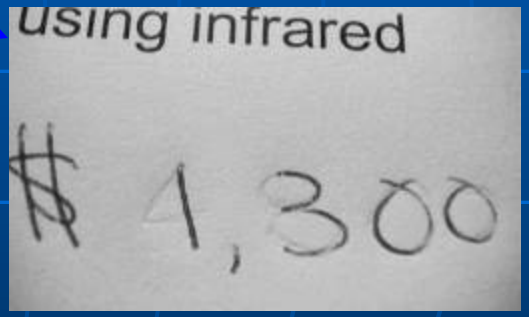
CDx Infrared imaging of inks (pigments/dyes)

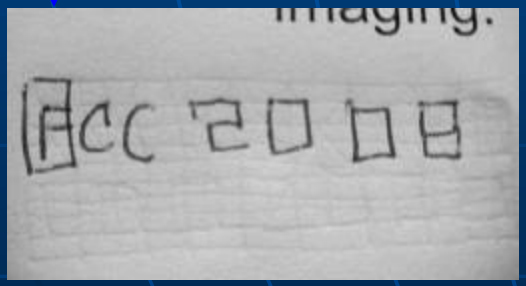
Codes changing, covert marking of packaging,

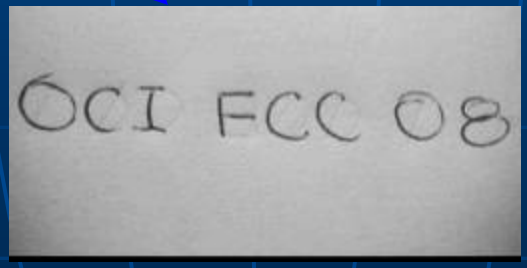


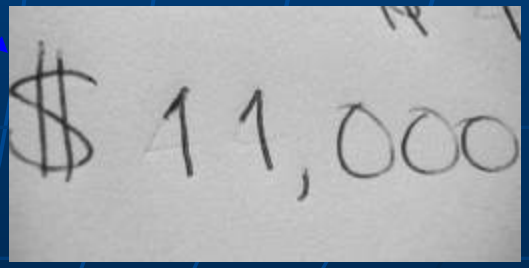












CDx Infrared imaging of inks (pigments/dyes) on packages
Captured infrared images of actual counterfeit versus authentic toothpaste packaging

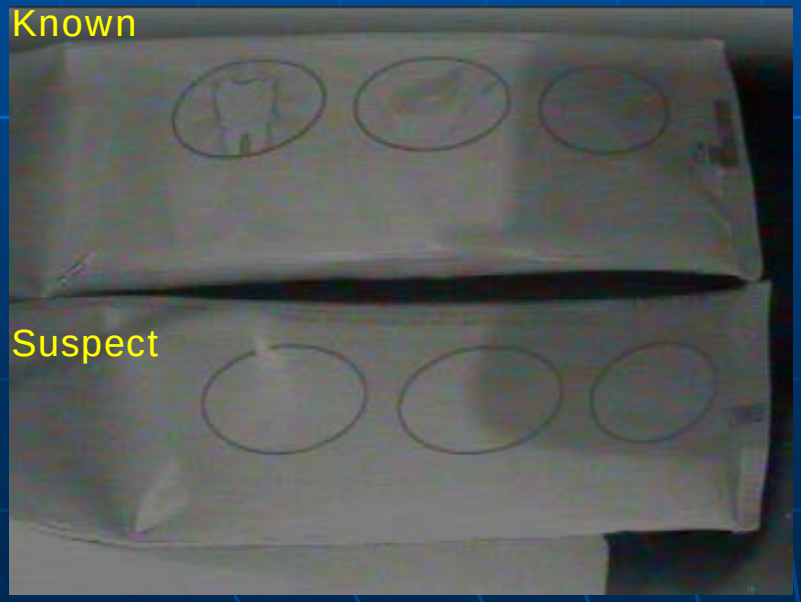
Known

Suspect

Suspect

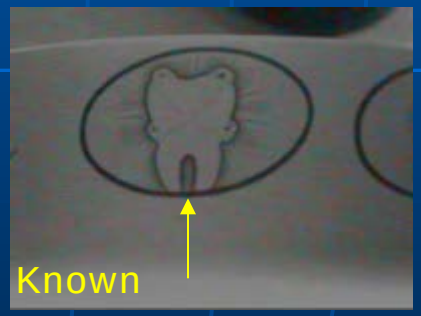
Known

Known

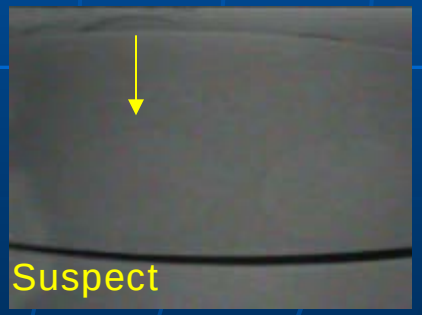


Suspect

Known

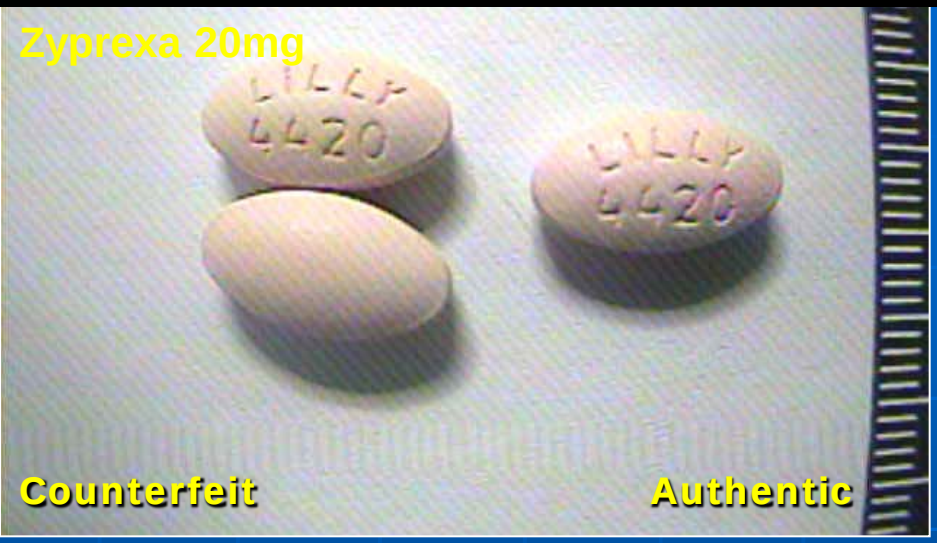


Suspect



CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)



Note: large sample was analyzed quickly

CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)

Note: large sample was analyzed quickly

CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)

Note: large sample was analyzed quickly

CD3 Real Time Scan

Actual imaging performed by trained FDA investigators / CSOs

White light image

Counterfeit Viagra

CDx V1 illumination

All Counterfeit Viagra

CDx V1 illumination

Counterfeit Xanax

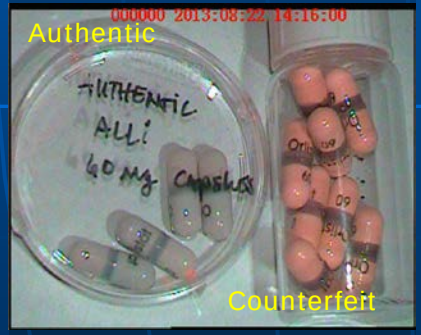
CDx V2 illumination

Counterfeit Xanax

White light image

Counterfeit Alli

CDx UV4 illumination

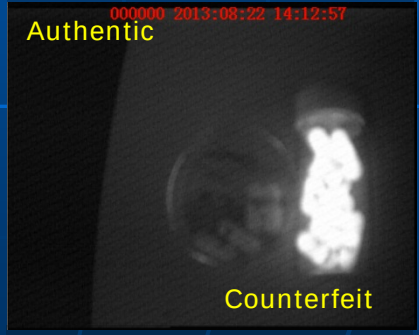


Counterfeit Alli

IR Mode no illumination

Counterfeit Alli

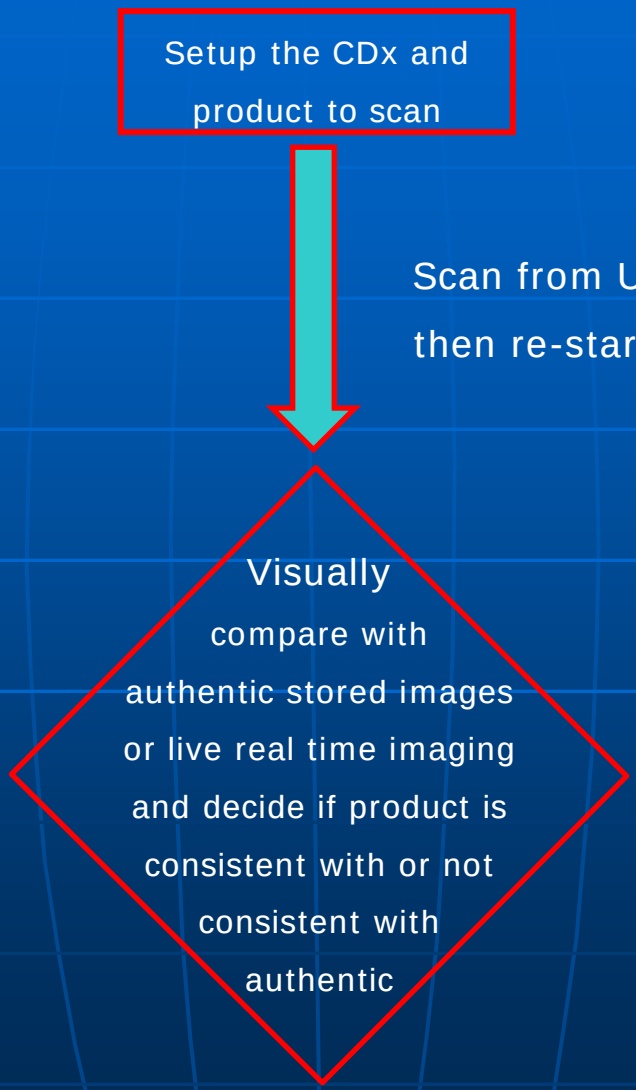
IR Mode V3 illumination



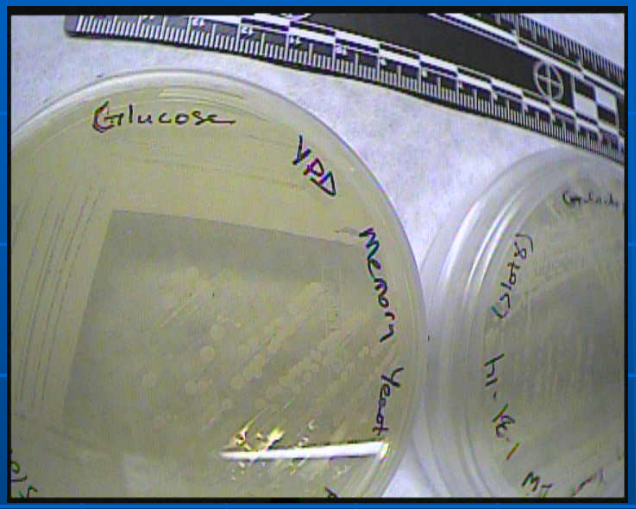
Counterfeit Alli

Note: once counterfeit is detected by the visual appearance examination of many is tremendously faster than many techniques

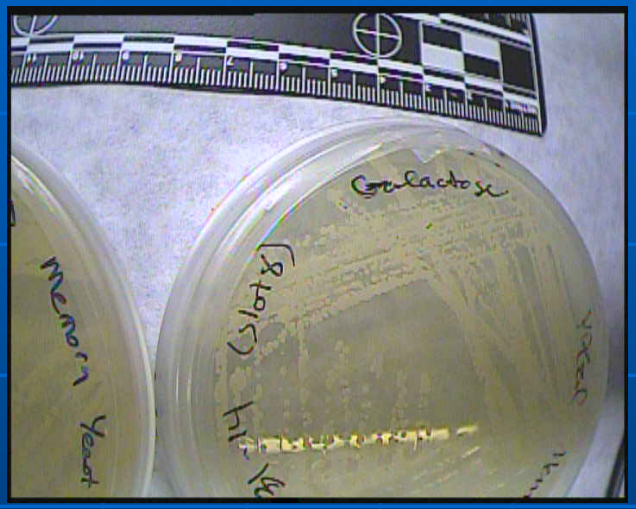
CDx “real-time” basic scan flowchart



Examination of Fluorescent Protein using the FDA/FCC CDx

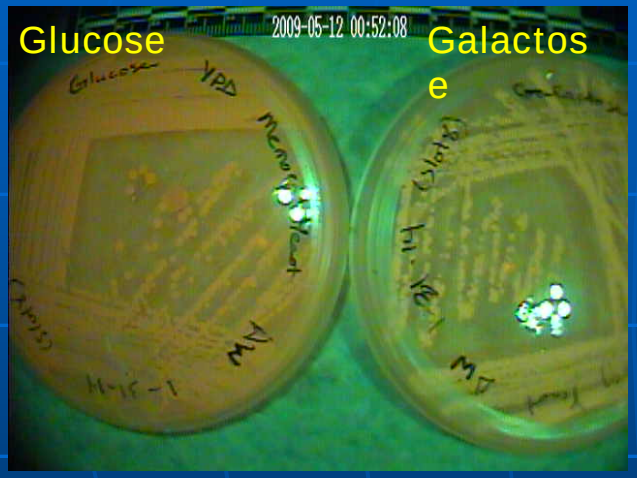


Glucose sugar source plate



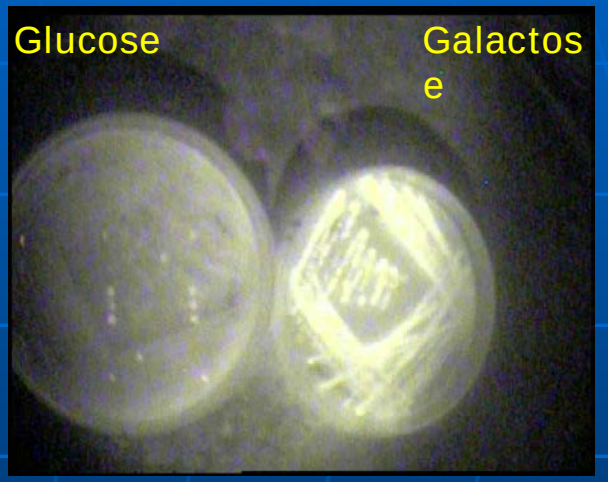
Galactose sugar source plate

Examination of Fluorescent Protein using the FDA/FCC CDx



Wavelength 1 – Y-Filter

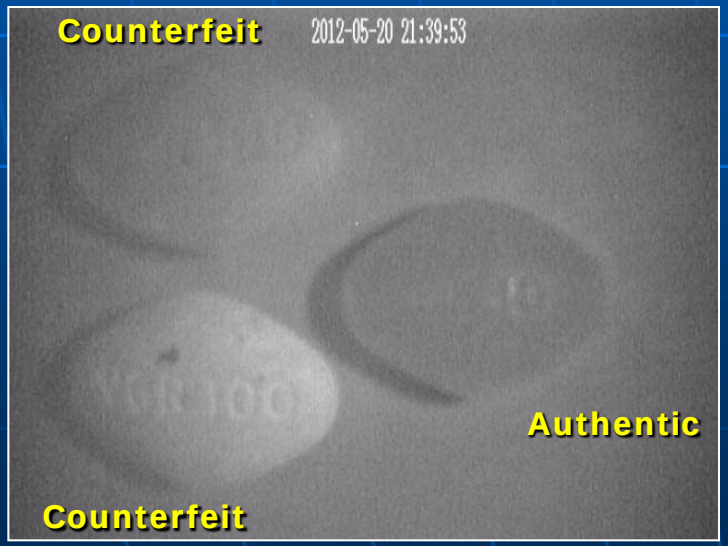
Wavelength 2 – Y-Filter

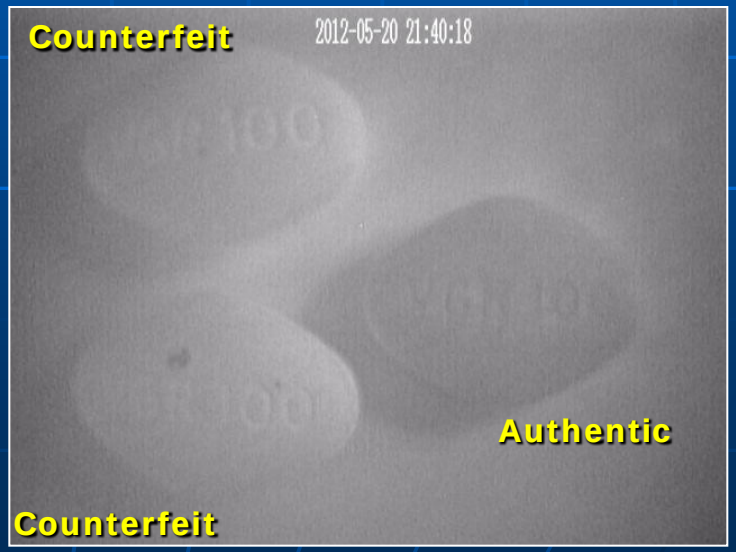


Wavelength 2 – O-Filter

CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)

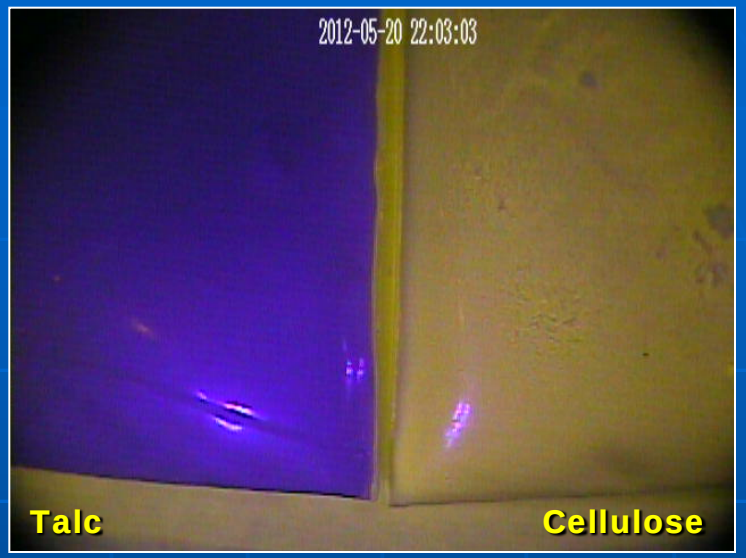




Note: large sample was analyzed quickly

CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)



Note: large sample was analyzed quickly

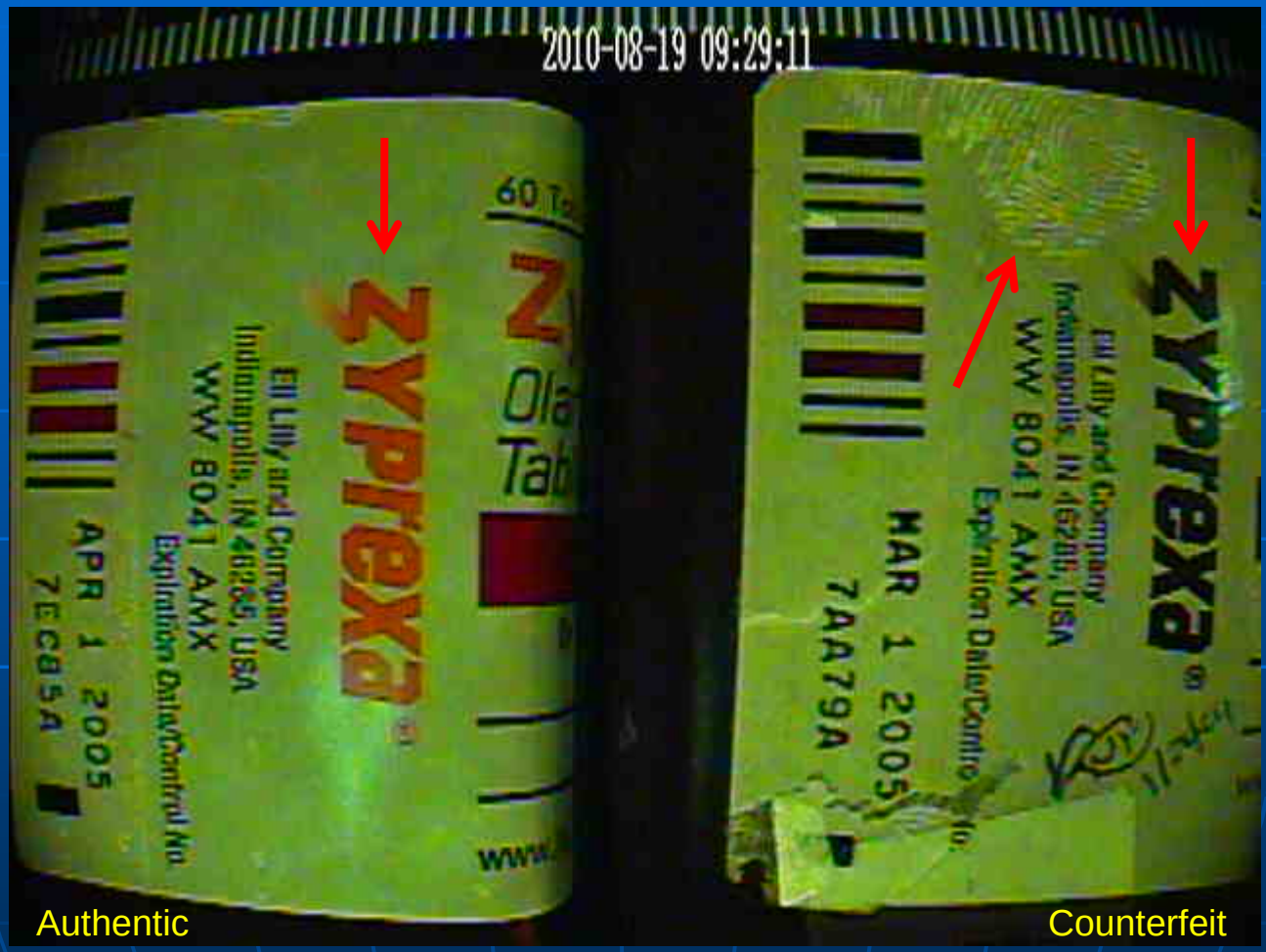
CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)

Note: large sample was analyzed quickly

CDx Latent Fingerprints Detection

(also bottle washing detection)



CDx on Antimalarial Drugs Packaging - Covert markings

Counterfeit

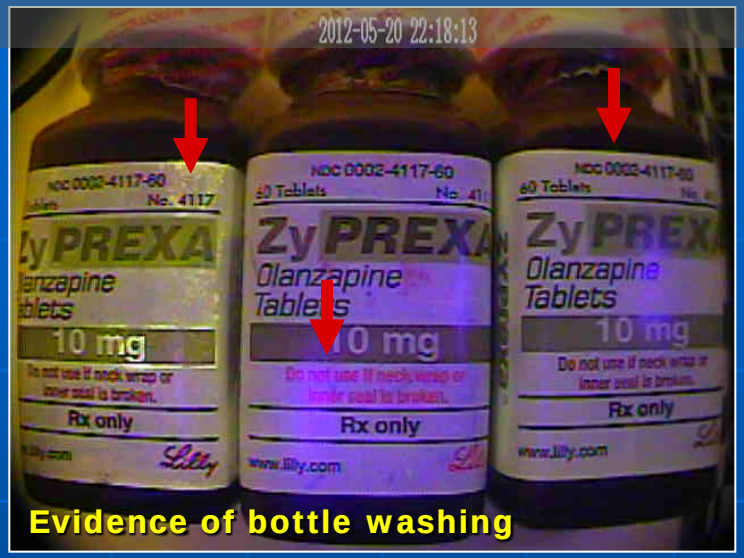
Authentic

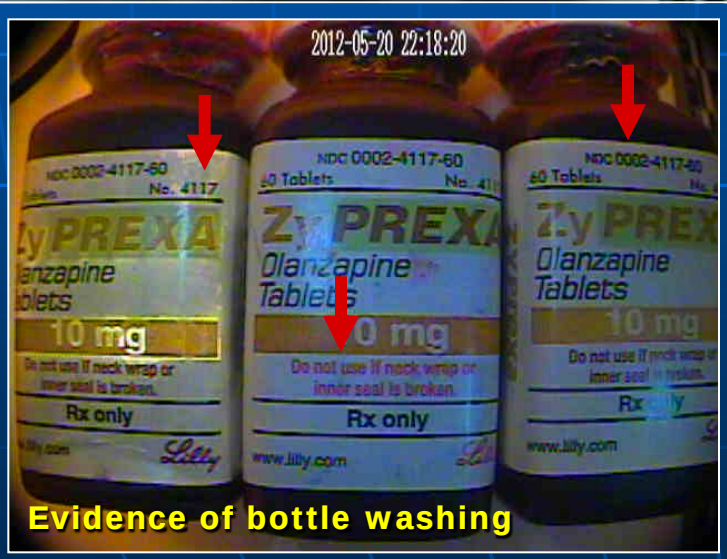
Counterfeit

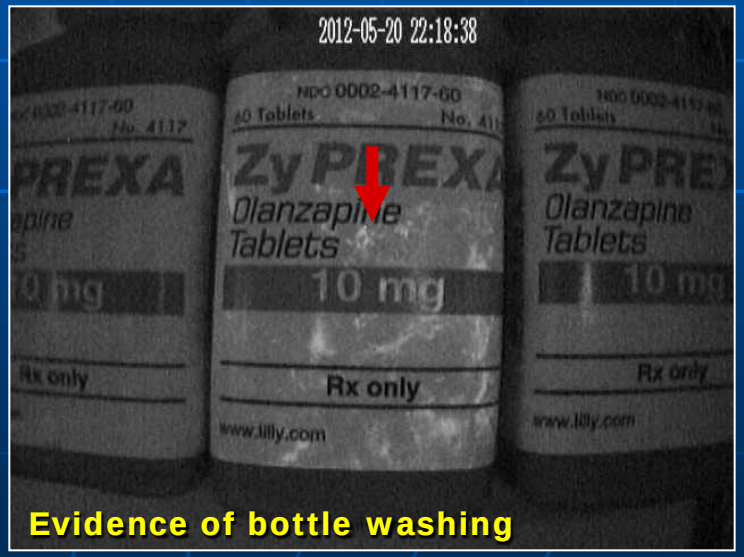
Authentic

CD3 Real Time Scan

Actual Cases (captured images of actual counterfeit versus authentic finished dosages)





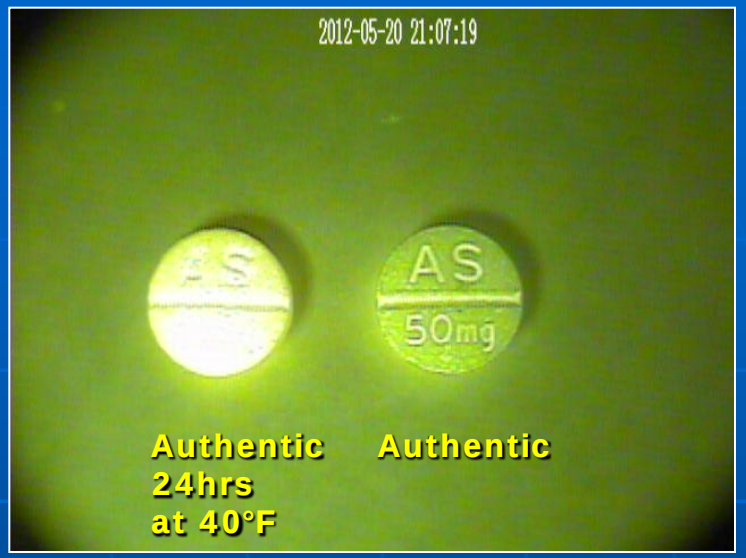


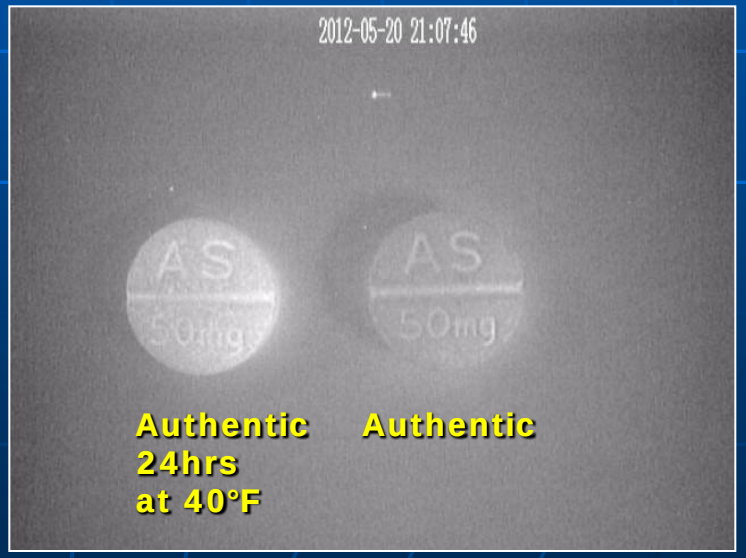
Note: large sample was analyzed quickly

CD3 Real Time Scan

Lab Study

(captured images of authentic at high temperatures)

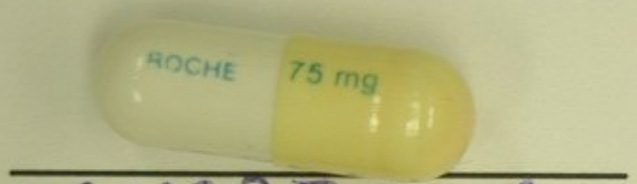




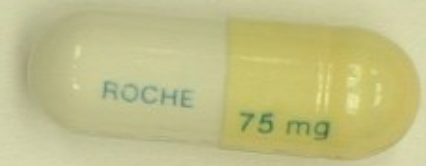
Note: large sample was analyzed quickly

ALS
Imaging
FCC
08-2007

Tamiflu



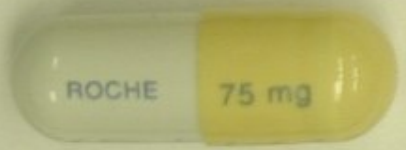
SUSPECT 1



SUSPECT 2

SUSPECT 3

SUSPECT 4



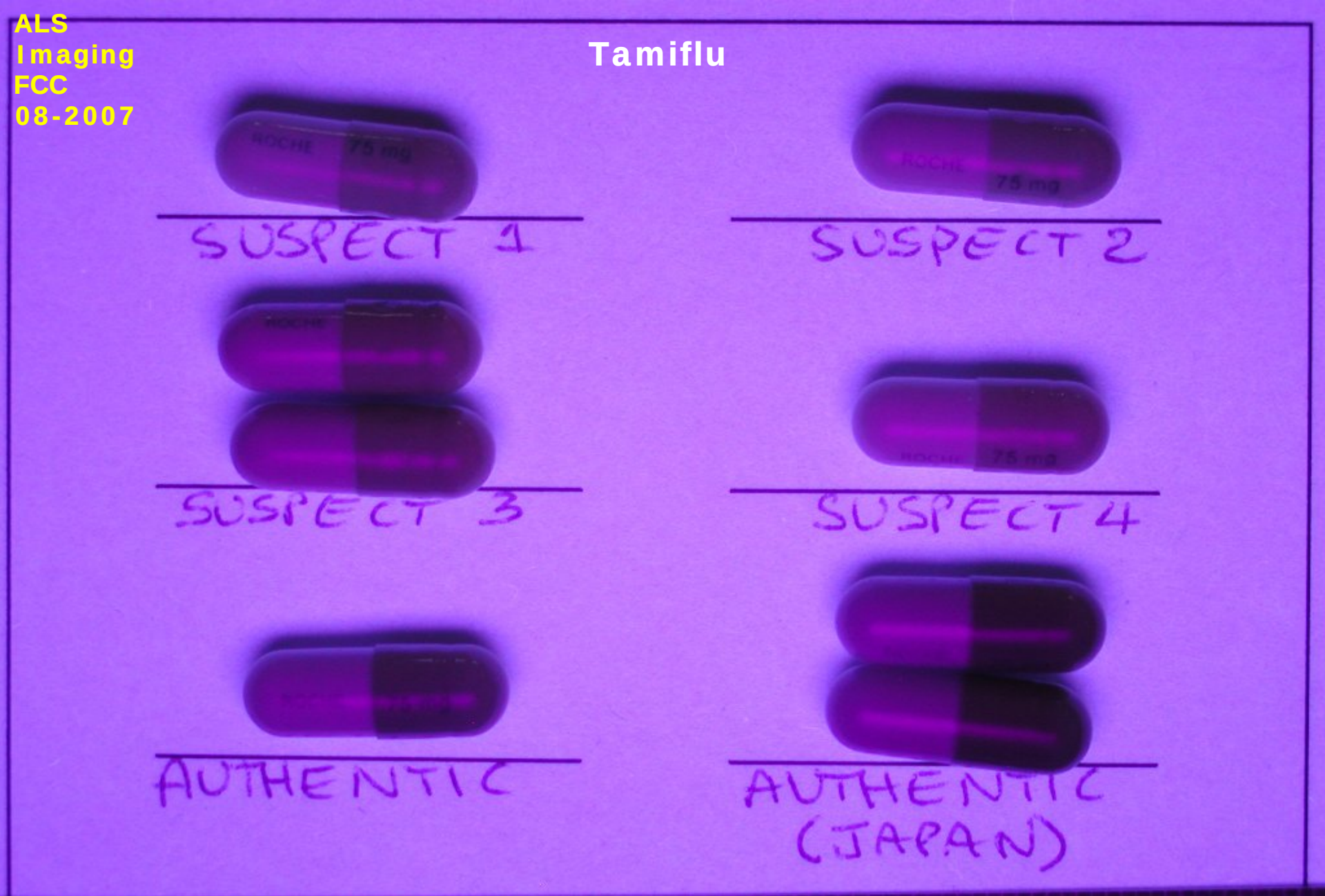
AUTHENTIC

AUTHENTIC
(JAPAN)

Ambient Lighting

ALS
Imaging
FCC
08-2007

Tamiflu



Black Light – hard to notice differences

ALS
Imaging
FCC
08-2007

Tamiflu

F1-UV4

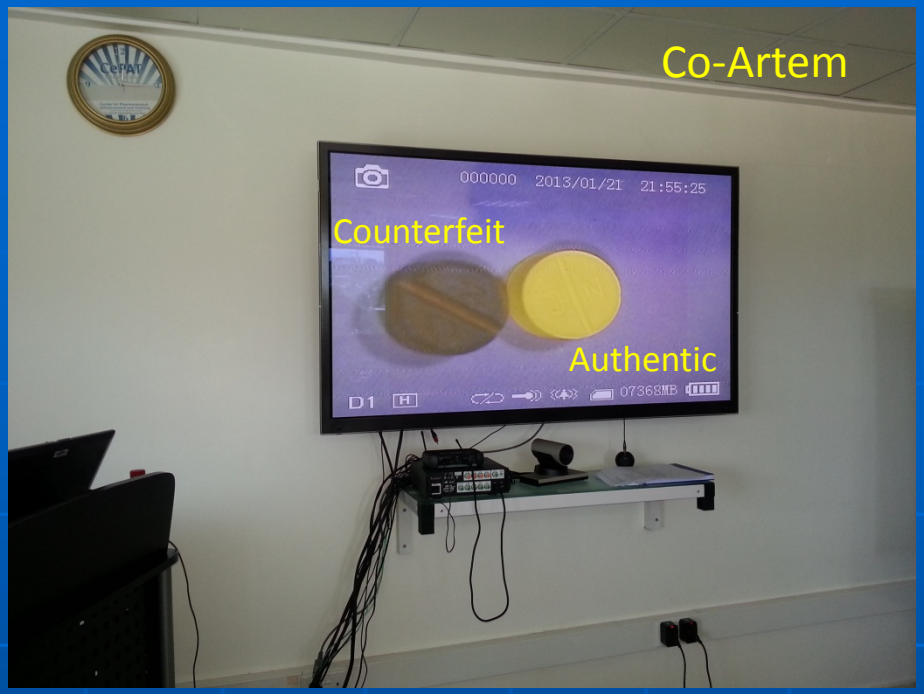
ALS
Imaging
FCC
08-2007

Tamiflu

F2-V2


Viremox
Counterfeit
Authentic


500 mg
Janssen


Co-Artem
000000 2013/01/21 21:55:25
Counterfeit
Authentic
D1
07368MB


000000 2013/01/21 21:55:44
D1
07368MB

Counterfeit Detection Device Version 3

USFDA Forensic Chemistry Center
Cincinnati, Ohio 45237

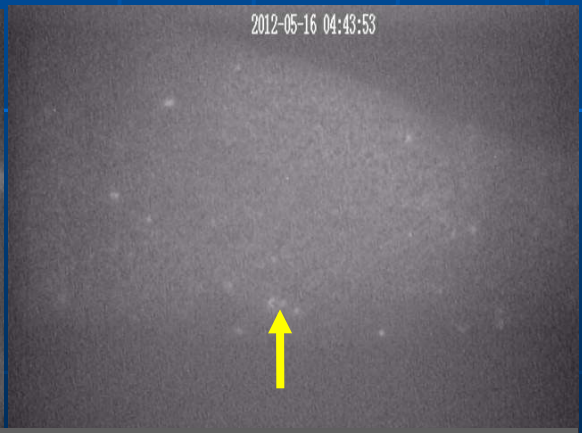
White powder undistinguishable particles with un-aided eye

CD3 Powder Scans For Dr. Mantai Mesmer- 09/28/2012

(Question: Is it sugar only?)

Suspect white powder – undistinguishable particle difference with un-aided eye

UV-Vis Mode: shows particles but harder to visualize as unique



IR Mode: shows particles difference and better separation

Note: CD3 w/ shade using plain white paper as background (not UV fluorescent if available)

CD3 Powder Scans For Dr. Mantai Mesmer- 09/28/2012

(Control Sugar for comparison with Suspect powder)

Control Sugar

UV-Vis Mode: shows particles with many shades of color but uniformly similar

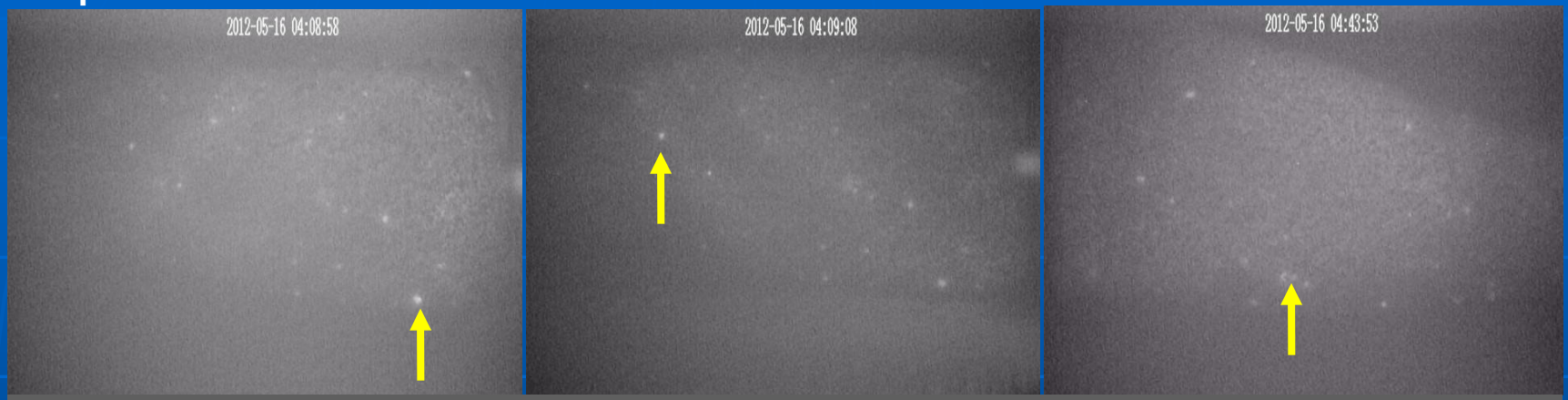
IR Mode: shows no particle difference / separation

Note: CD3 w/ shade using plain white paper as background (not UV fluorescent if available)

CD3 Powder Scans For Dr. Mantai Mesmer- 09/28/2012

(Suspect white powder vs Control Sugar)

Suspect Powder



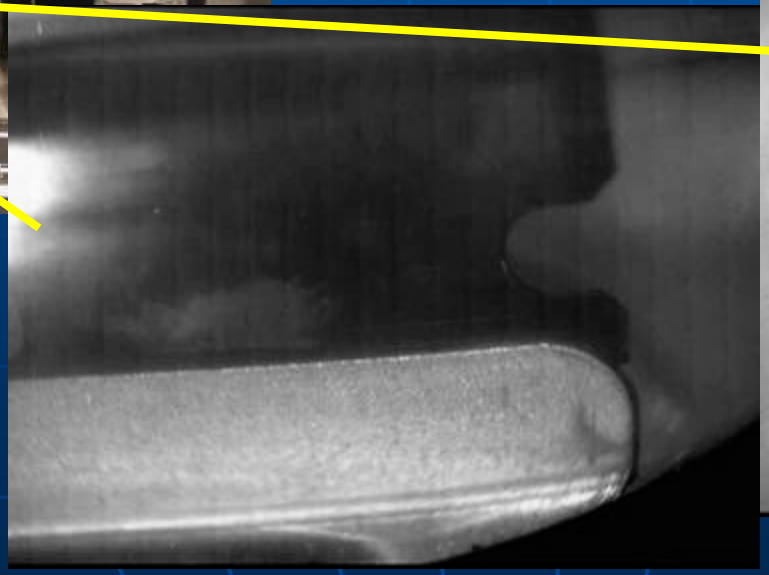
IR Mode: shows difference in particles; multiple brighter white particles

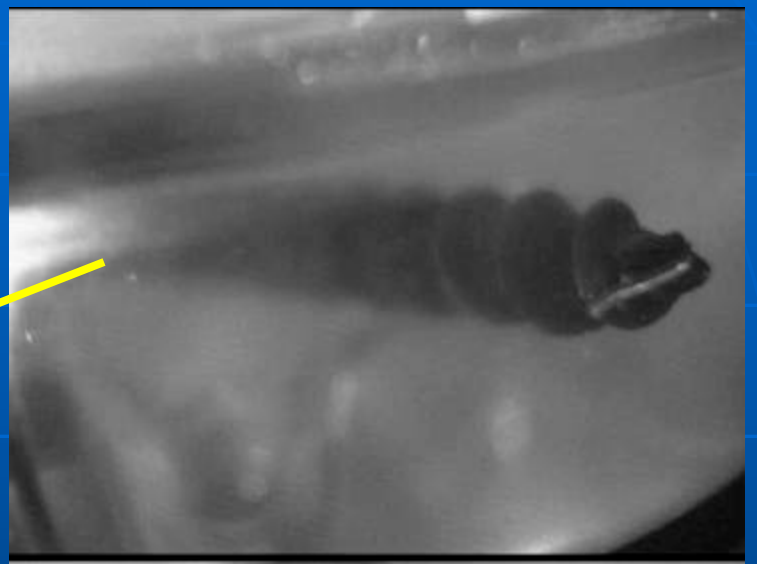
Control Sugar

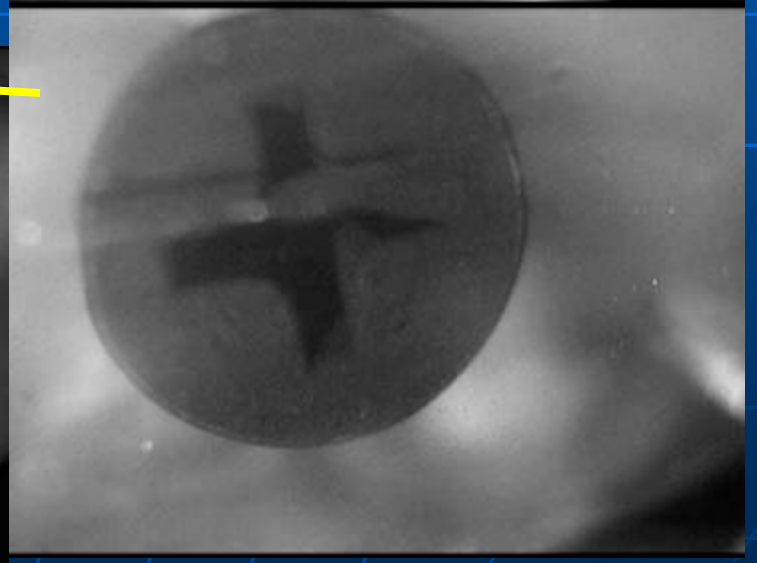
IR Mode: shows no particle difference

Note: CD3 w/ shade using plain white paper as background (not UV fluorescent if available)

CDx Infrared imaging of liquids / product tampering
Captured images of foreign objects that can be seen in very dark beverages as though looking through water



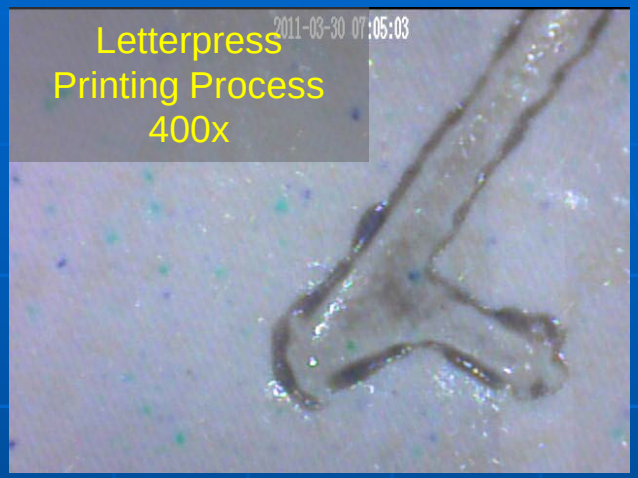


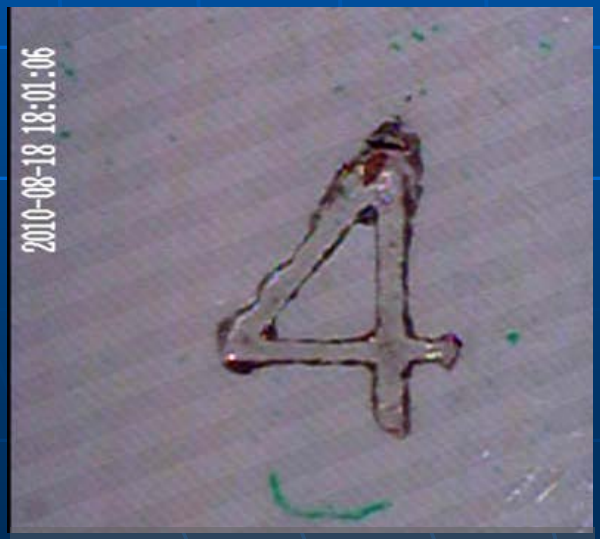


Print Process Examination and Determination Examples

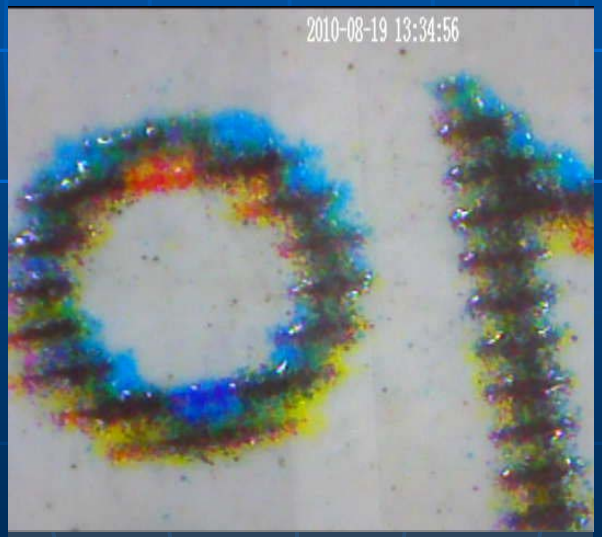
CD3 Digital Microscope **45x – 400x** Magnifications

CD3 Device with Loaded Microscopic Image Library





Letterpress Printing Process
100x



Electrographic Printing Process
100x

Flexographic Printing Process
100x

CD3 In-use On-site Analysis by LOS-DO Imports

CD3 List of Applications
(UV-Vis-IR imaging)

Current Applications – Others are up to the curious and intuitive user

1. Label copying, alterations, version substitutions, etc.
2. Covert/Hidden security features in printing technology
3. Pharmaceutical excipients
4. Tablet core and coating (90+ product library of finished dosage)
5. Tablet homogeneity/blending
6. Capsule shells and content (see library of finished dosage)
7. Pharmaceutical product diversion
8. Veterinary liquid meds
9. Dark colored liquids (i.e. soft drinks, grape juice or jelly, etc.)
10. Cosmetic product (i.e. makeup blushes and powders, chap stick, etc.)
11. Document fraud (i.e. date or signature changing, etc.)
12. ID cards counterfeiting
13. Fingerprints
14. Adhesives differences
15. Tobacco packaging and paper
16. Rat poison in dough
17. Sunglasses polarized / UV
18. Crime scene investigation tool
19. Preliminary scans conducted but not fully tested yet:
    1. olive oil
    2. juices
    3. jewelry/gems
    4. Clothing
20. Other unknowns not tested yet?

Note: other unknown applications are the possibility of the user

Notes

- Technology and methods are to be considered proprietary.
- Results generated using CD3 and print examination are considered preliminary.
- To be considered is that not all methods and techniques will work for everything.

Benefits of CDx

- Real-time, low cost, portable tool
- Trained CD3 users do not require a scientific or technical background
- Portability makes deployment manageable for FDA regional offices, international mail facilities, and other remote locations
- FDA intends to make continuous improvements to the device