Drug Chemists are Getting the Right Answers: Assessing Drug Analysis Error Rates in Municipal, County and Federal Laboratories

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The views expressed during this presentation are those of the authors alone and do not represent the views of the Oakland Police Department, Kern County Regional Laboratory, the Drug Enforcement Administration, the United States Department of Justice, or the United States Federal Government.

Error Rate

Addresses:

- Accuracy
- Reliability
- Validity

of methods to produce test outcomes

- Vernacular
  - How often you are wrong
- Statistical
  - Type I and Type II
  - False Positive and False Negative
- Scientific / Forensic
  - Proportion of test reports issued with the incorrect/incomplete answer
- Judicial
  - How much reliance should be placed on the results to determine trial outcome

NAS Report, 2009

- Recommendation # 3
- Quantify measurement of uncertainty
- Demonstration of validity of forensic methods
- Research into accuracy, reliability of forensic analyses
  - "Studies…should reflect actual practice on realistic case scenarios averaged across a representative sample of forensic scientists and laboratories."
- These argue for the establishment of error rate

Approach

- Assessment of Error can be accomplished in several ways:
  - Determining how often analysts correctly identify samples unknown to them, but known to the system (competency and proficiency tests; PT)
  - Using Quality Assurance (QA) data obtained from Quality Control (QC) samples to quantify agreement
  - Reanalyzing (RA) casework to assess correctness

Error Assessment

- Proficiency Test (PT)
- Quality Control (QC)
- Reanalysis (RA)

- PRO
  - Maps laboratory process
- CON
  - Unless blind, analyst aware

Error Assessment

- Proficiency Test (PT)
- Quality Control (QC)
- Reanalysis (RA)

- PRO
  - Casework reflects street samples—not pristine
  - QC removal is routine not treated different by analyst
- CON
  - Liquids/plants excluded
  - QA program ≠ entire laboratory process
  - Other errors introduced

Error Assessment

- Proficiency Test (PT)
- Quality Control (QC)
- Reanalysis (RA)
  - PRO
    - Reflective of actual street samples
  - PRO/CON
    - May (or may not) map entire laboratory process
  - CON
    - Adjudicated cases only
    - Labor intensive to rework analyses already completed

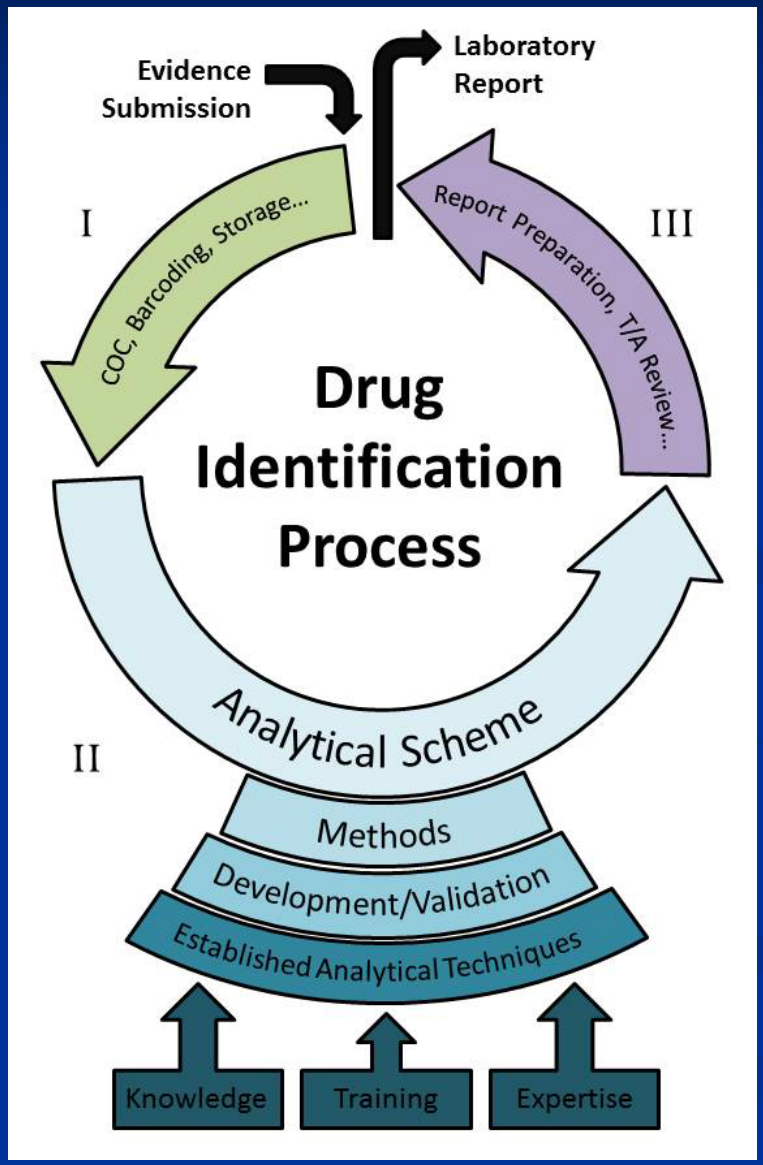
DEA System

- **Background:**
  - DEA laboratory system (8 labs; > 270 chemists)
  - Tens of thousands reports per year
- **Objective:**
  - Quantitative assessment of the reliability of the *overall* laboratory process
  - Quality of laboratory results
  - Confidence (or uncertainty) of reported identifications

DEA Laboratory Analytical Scheme:

- Requires analysts to test, at minimum:
  - Two portions
  - Two different and independent techniques
  - Use negative controls
  - Use positive controls (traceable reference materials)
- SWGDRUG Recommendations
- ASTM E2329
  - *Standard Practice for Identification of Seized Drugs*

DEA Drug Identification Process:



DEA Drug Identification Process:

- Where can errors occur?
- Phase I
  - Sample swapping, wrong barcoding, etc.
- Phase II
  - Analysis, sample swapping, contamination, etc.
- Phase III
  - Report preparation, dissemination, etc.

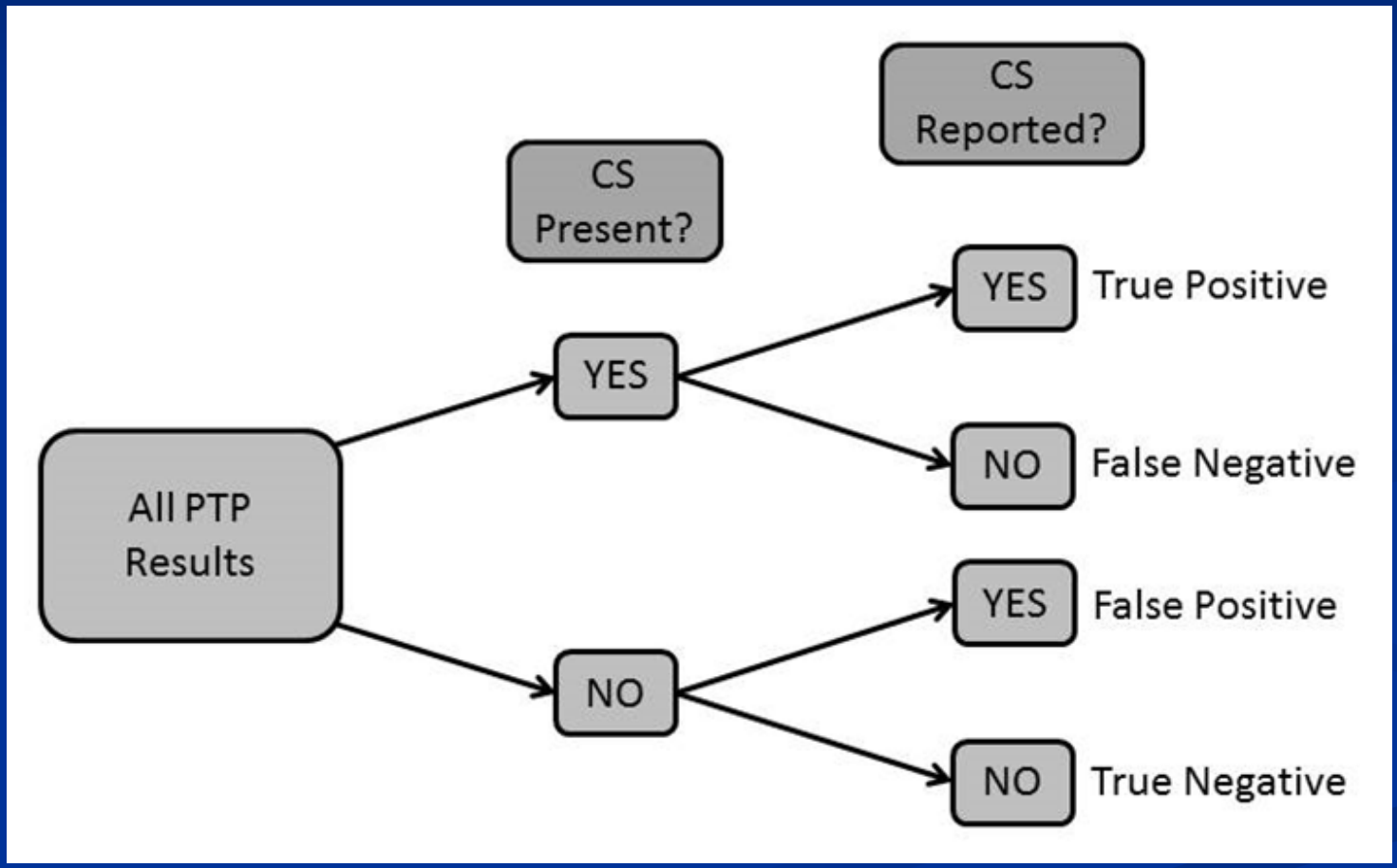
Uncertainty in Qualitative Analysis:

- Limited studies
- Past emphasis on quantitative analysis:
  - Measurement uncertainty
- References:
  - S.L.R. Ellison, *Accred. Qual. Assur.* 5 (2000) 346-348.
  - A. Pulido, I. Ruisanchez, R. Boque, F.X. Rius, *Trend Anal. Chem.* 22 (2003) 647-654.
  - B.L. Milman, *Trend Anal. Chem.* 24 (2005) 493-508.

DEA PTP Historical Data:

- 2005-2016
- 4794 test results
- 2392 inter-laboratory (24-27 PT rounds/year)
- 2058 intra-laboratory
- 216 external
- 128 blind

Classification of PT Results:



Calculating Response Rates:

$$TPR\ (\textbf{sensitivity}) = \frac{True\ Positives}{All\ Positives} = \frac{TP}{(TP + FN)}$$

$$TNR\ (\textbf{specificity}) = \frac{True\ Negatives}{All\ Negatives} = \frac{TN}{(TN + FP)}$$

$$FPR\ (\textbf{Type I error}) = \frac{False\ Positives}{All\ Negatives} = \frac{FP}{(TN + FP)} = 1 - specificity$$

$$FNR\ (\textbf{Type II error}) = \frac{False\ Negatives}{All\ Positives} = \frac{FN}{(TP + FN)} = 1 - sensitivity$$

DEA Results Matrix:

		CS Reported				
		YES	NO	Total:		
CS Present	YES	4333	4	4337	0.99907	TPR (sensitivity)
	NO	4	453	457	0.00875	FPR (type I error)
	Total:	4337	457	4794		
		0.00092	0.99124			
		FNR (type II error)	TNR (specificity)			

About the False Results:

- 4 False Positives:
  - Sample swapping
  - Low-level secondary CS reported w/o fulfilling QA and documentation requirements
  - 2 incorrect CS reported (LIMS)
- 4 False Negatives:
  - Sample swapping
  - Low concentration of target CS
  - 2 cases of low-level secondary CS

3,4-methylenedioxymethcathinone
3,4-methylenedioxy**di**methcathinone

Using Bayesian Inference:

$$P(A|B) = \frac{P(B|A) \cdot P(A)}{P(B)}$$

Confidence

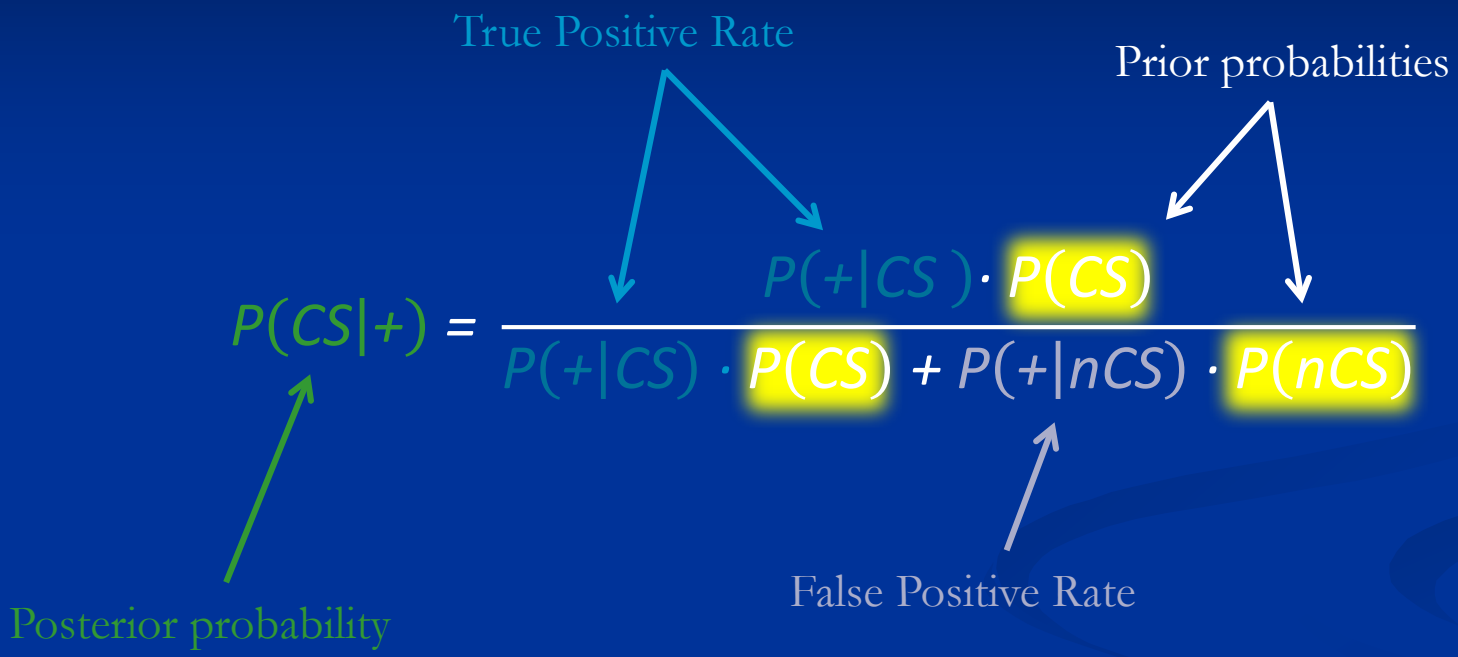
$$P(CS|+) = \frac{P(+|CS) \cdot P(CS)}{P(+)}$$

$$P(nCS|+) = \frac{P(+|nCS) \cdot P(nCS)}{P(+)}$$

Uncertainty

S.L.R. Ellison, S. Gregory, W.A. Hardcastle, *Analyst* 123 (1998) 1155-1161.

Confidence in the Positive ID:



- *Probability CS is present, given a reported result*
- *Confidence in the positive identification result*

DEA Submissions & Reports:

Year	Total	Laboratory Results		CS (%)	NCS (%)
		CS	NCS		
1994	37,115	32,779	4,336	88.32	11.68
1995	38,668	34,645	4,023	89.60	10.40
1996	43,662	38,836	4,826	88.95	11.05
1997	49,156	43,965	5,191	89.44	10.56
1998	55,946	49,919	6,027	89.23	10.77
1999	60,093	53,869	6,224	89.64	10.36
2000	64,608	57,840	6,768	89.52	10.48
2001	66,235	59,776	6,459	90.25	9.75
2002	64,504	58,065	6,439	90.02	9.98
2003	59,793	54,148	5,645	90.56	9.44
2004	56,709	50,973	5,736	89.89	10.11
Total	**596,489**	**534,815**	**61,674**	**88.2 – 90.9**	**9.0- 11.8**

Population: DEA Lab Submissions

- $P(CS) = 0.90$
- $P(nCS) = 0.10$

$$Confidence = P(CS|+) = \frac{P(+|CS) \cdot P(CS)}{P(+|CS) \cdot P(CS) + P(+|nCS) \cdot P(nCS)}$$

$$P(CS|+) = \frac{(0.99907)(0.90)}{(0.99907)(0.90) + (0.00875)(0.10)}$$

$$P(CS|+) = 0.99902 = 99.90\%$$

Population: DEA Lab Submissions

- $P(CS) = 0.90$
- $P(nCS) = 0.10$

$$Uncertainty = P(nCS|+) = \frac{P(+|nCS) \cdot P(nCS)}{P(+|nCS) \cdot P(nCS) + P(+|CS) \cdot P(CS)}$$

$$P(nCS|+) = \frac{(0.00875)(0.10)}{(0.00875)(0.10) + (0.99907)(0.90)}$$

$$P(nCS|+) = 0.00097 = 0.097\%$$

OPD Proficiency Tests

- Proficiency Test results
  - Shows that OPD analysts get the right answer
  - 20 years, averaging 2-3 analysts per year, n=87
  - All proficiency test answers submitted were correct
  - No failures occurred
- As a small population, not statistically significant
- Potential to lead to incorrect conclusion of "0% error"

OPD QA Program/QC samples

- Another treasure trove
- In 1996, ASCLD/LAB assessment, team of assessors wanted more information regarding microcrystalline testing
- OPD opted to start a QA program
  - In 2000, SWGDRUG recommendations suggested contemporaneous peer review, OPD instead elected to continue QA Program

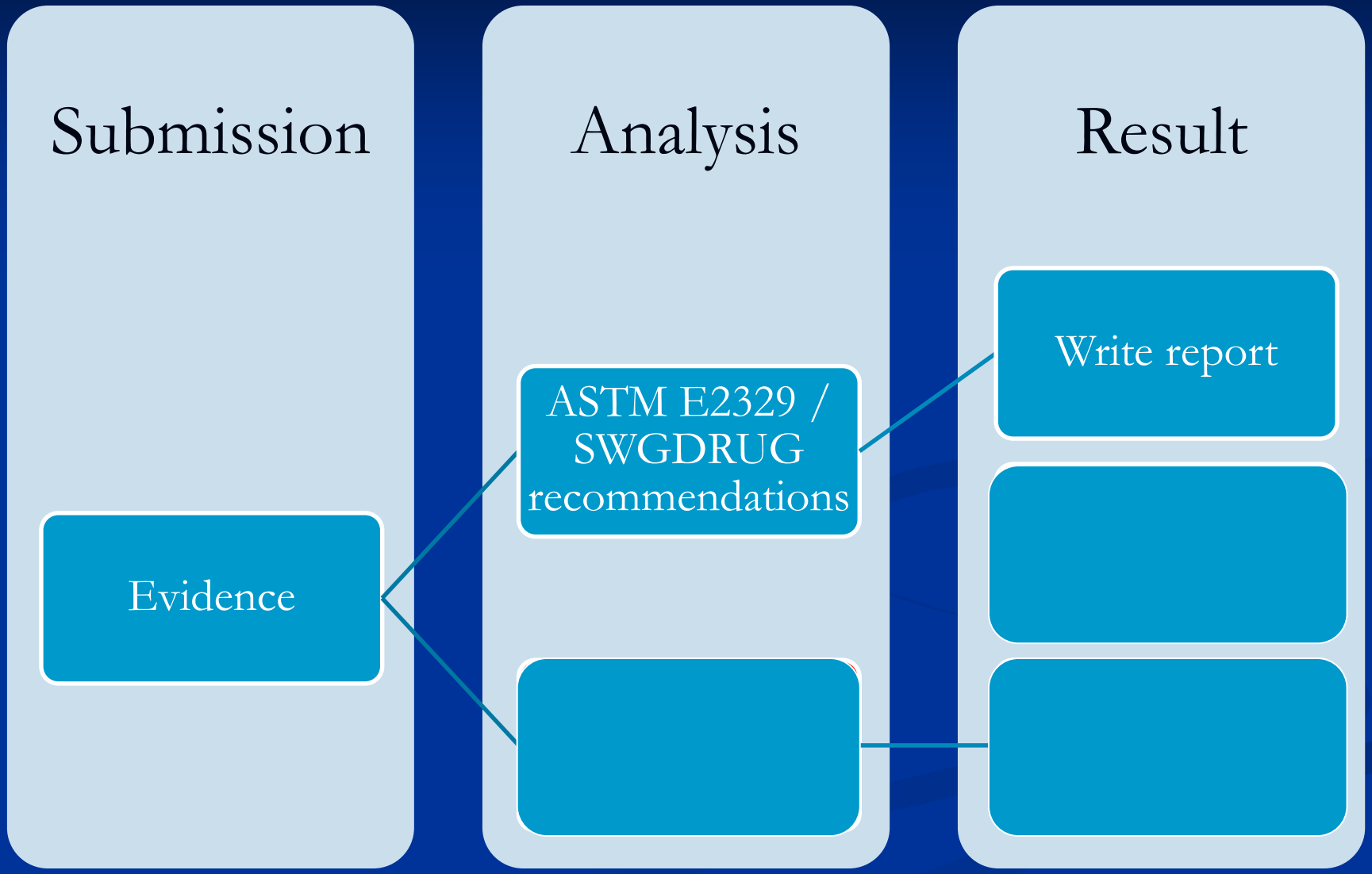
OPD QA Program/QC samples

- All powders > 0.06 g sampled and set aside
- Analyst conducts testing; sometime throughout analysis, collects QC sample into ziplock
  - No mandate to do so before or after test sample is collected
  - No mandate to ensure homogeneity
    - May not know this until after testing is complete
- Liquids and plant material excluded

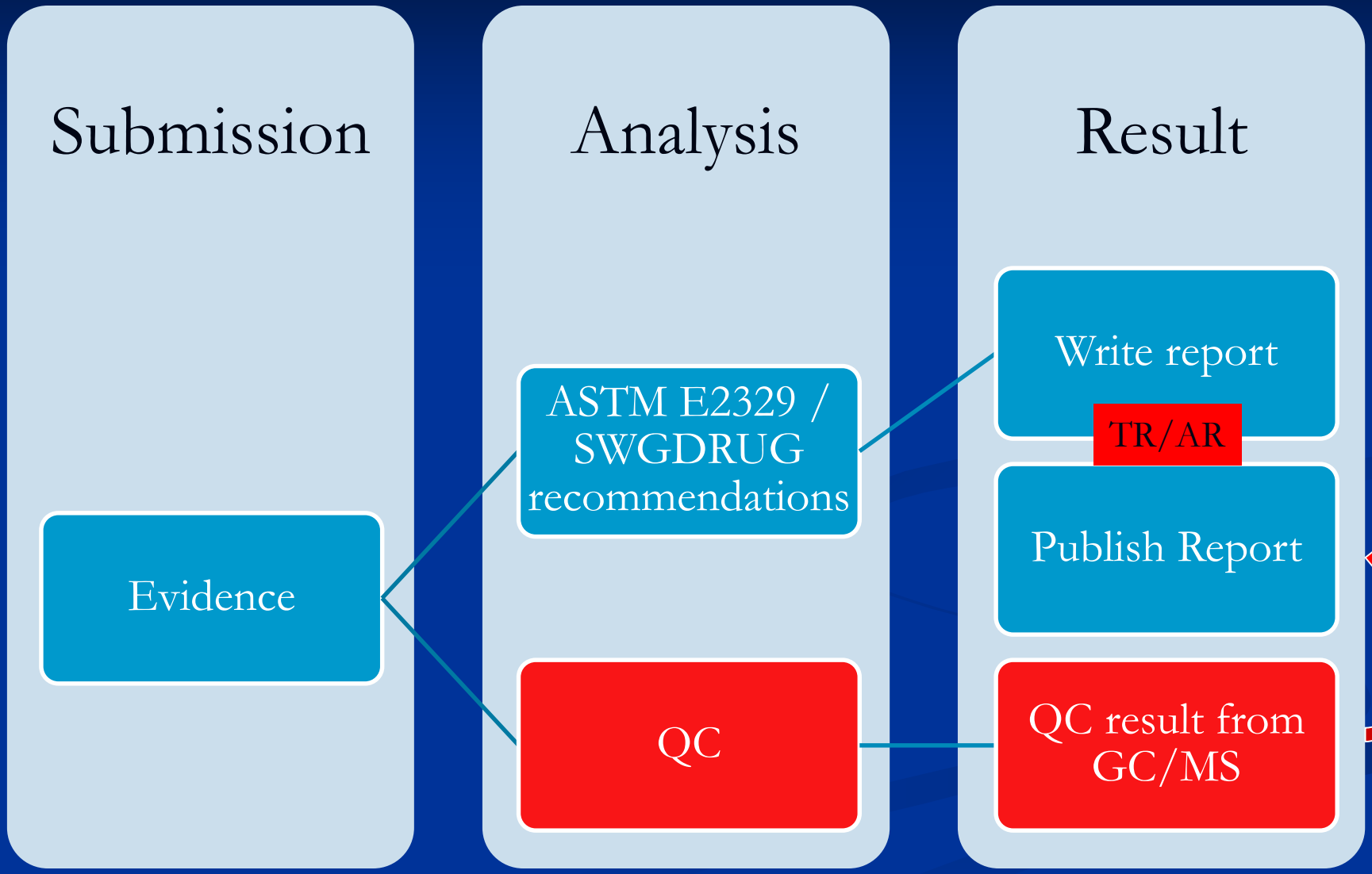
QA Program

- At least 10% QC samples randomly selected and tested
- In the first year, 1996, original analysis reconfirmed by retesting using the same method
  - If the submission had been tested by microcrystals, it was retested by microcrystals
- In the second year, 1997, the selected samples were run by GC/MS
- For 20 years from 1997 – 2016 this has continued
- 4459 samples analyzed in this time

Analysis

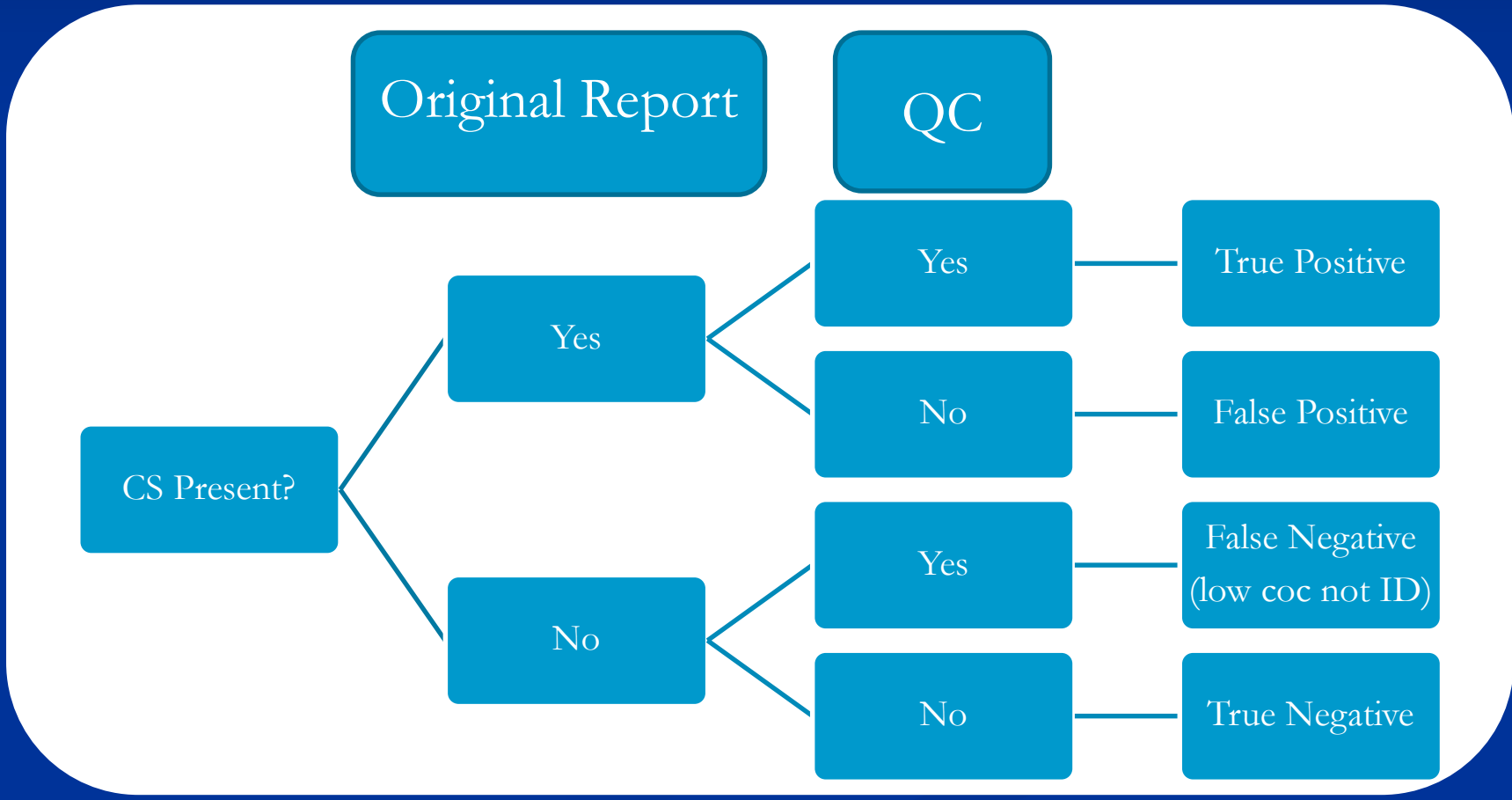

Submission
Analysis
Result
Evidence
ASTM E2329 / SWGDRUG recommendations
Write report

Analysis and QA Program



Archived Data

Classification of QC Results:



OPD Results

- 4459 QC samples
- 4445 Agreement after investigation (99.6%)
- 7 False Positives
- 7 False Negatives

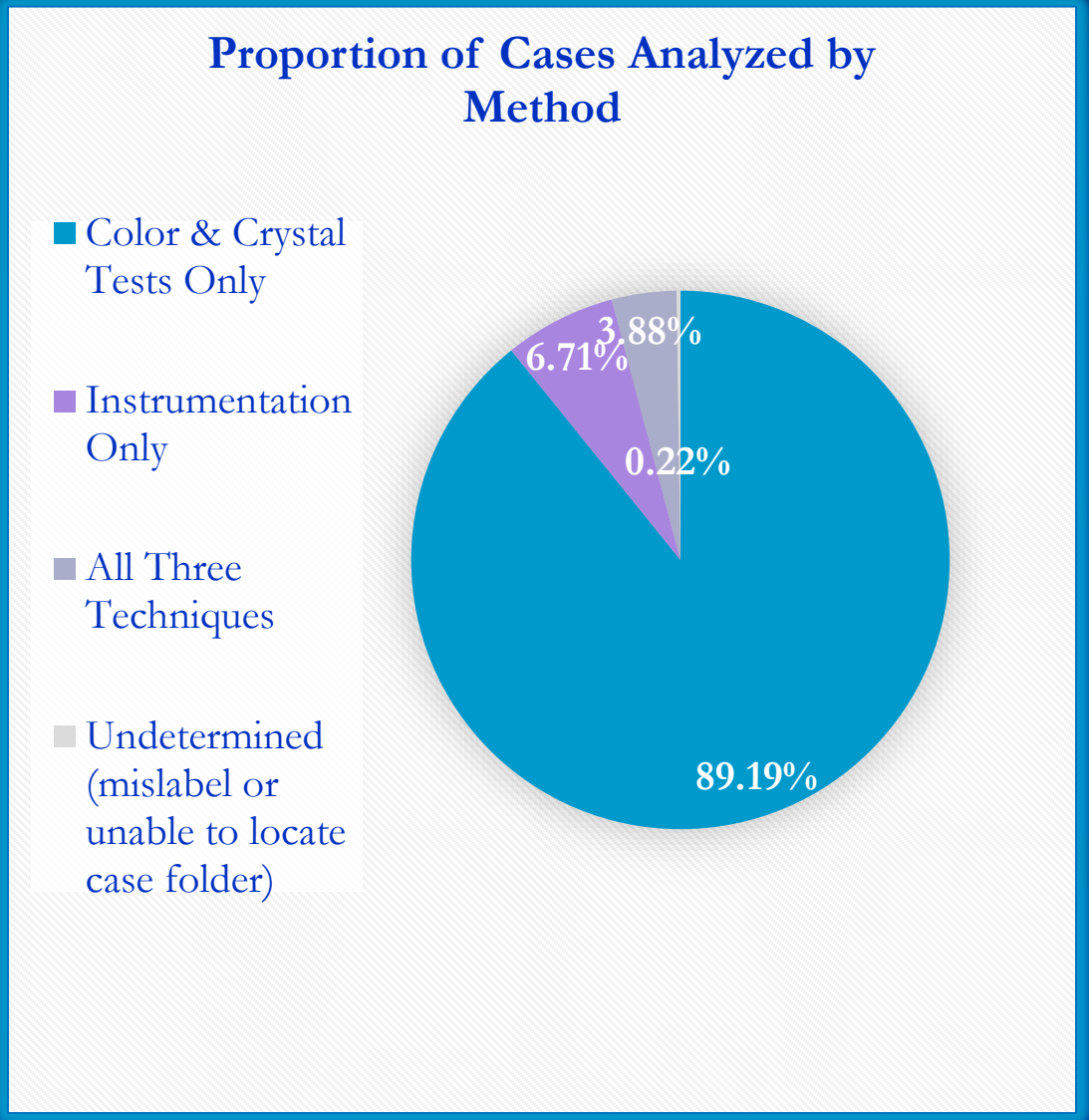
- False Positives
  - Isomer indistinguishability
  - Unexplained trace cocaine in QC, need to retest
  - 3 cases of meth+MDA where meth not observed in QC
- False Negatives
  - Isomer indistinguishability
  - 4 cases of method limitation: microcrystal and trace cocaine
  - Threshold – analyst did not call

OPD Results Matrix

		CS Present QC				
		YES	NO	Total:		
CS reported	YES	4218	7	4225	0.99834	TPR (sensitivity)
	NO	7	227	234	0.02991	FPR (type I error)
	Total:	4225	234	4459		
		0.00166	0.97009			
		FNR (type II error)	TNR (specificity)			

OPD Methods in Casework

- 4459 QC samples
- 3977 microcrystals (89.2%)
- 299 instrument (6.7%)
- 173 micro+inst (3.88%)
- 227 negative samples (5.1%)



Population: OPD Lab Submissions

- $P(CS) = 0.95$
- $P(nCS) = 0.05$

$$Confidence = P(CS|+) = \frac{P(+|CS) \cdot P(CS)}{P(+|CS) \cdot P(CS) + P(+|nCS) \cdot P(nCS)}$$

$$P(CS|+) = \frac{(0.99834)(0.95)}{(0.99834)(0.95) + (0.02991)(0.05)}$$

$$P(CS|+) = 0.99728 = 99.84\%$$

Population: OPD Lab Submissions

- $P(CS) = 0.95$
- $P(nCS) = 0.05$

$$Uncertainty = P(nCS|+) = \frac{P(+|nCS) \cdot P(nCS)}{P(+|nCS) \cdot P(nCS) + P(+|CS) \cdot P(CS)}$$

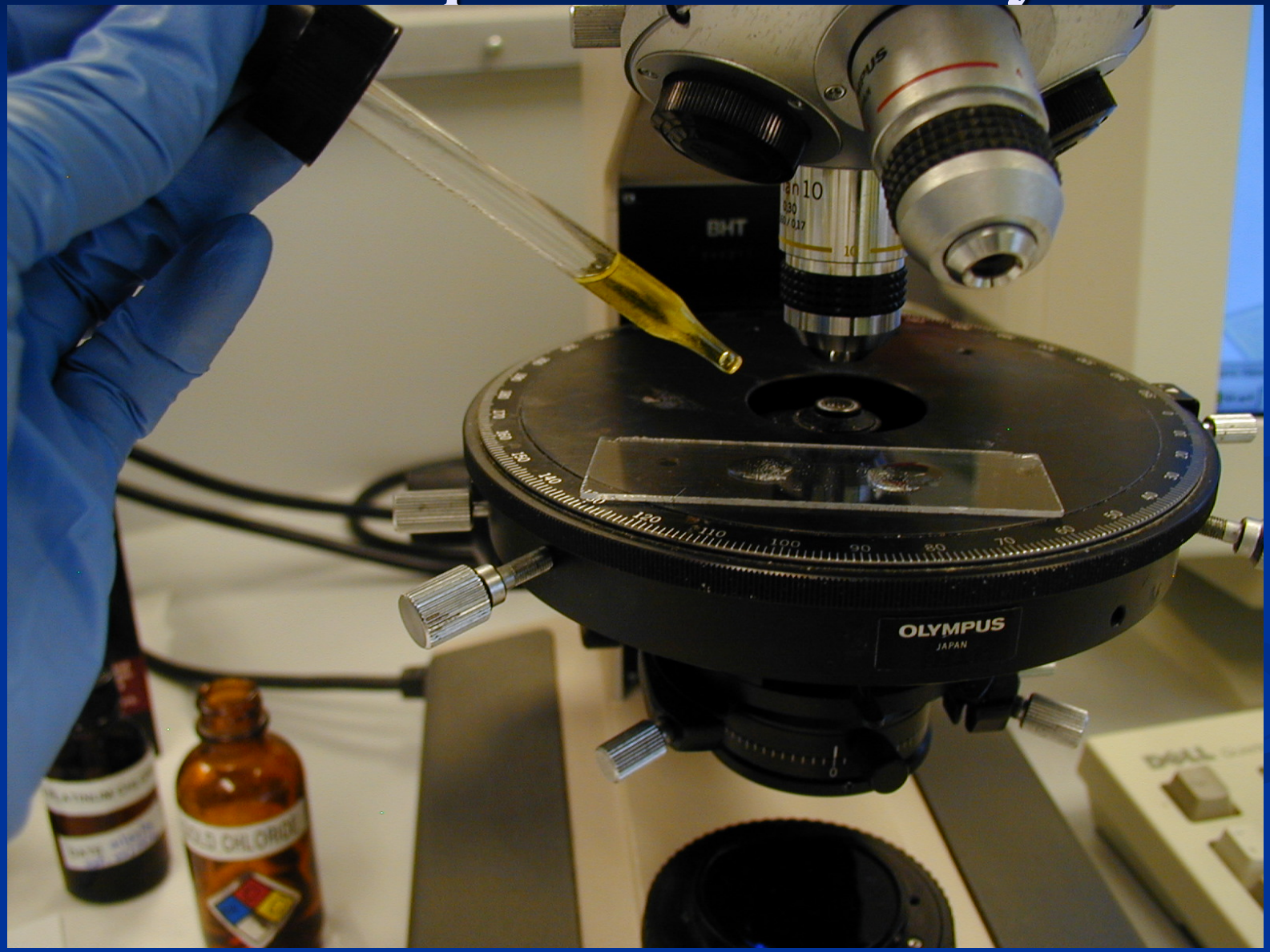
$$P(nCS|+) = \frac{(0.02991)(0.05)}{(0.02991)(0.05) + (0.99834)(0.95)}$$

$$P(nCS|+) = 0.00272 = 0.16\%$$

Microcrystalline Tests

- Positive Aspects
  - Fast
  - Cheap
  - Intuitive
  - Used in forensic science for over 100 years
- Negative Aspects
  - 'Techniquey'
  - Not good for mixtures
  - Few tests for emerging drugs; more for established ones

Microscope for Microcrystals



Methamphetamine Microcrystals

Kern Regional Crime Lab

- Two microcrystalline tests conducted
  - Cocaine base 113
  - Cocaine salt 27
  - Methamphetamine 510
  - Amphetamine 3
- GC/MS confirmation
  - Cocaine base 113
  - Cocaine salt 27
  - Methamphetamine 511
  - Amphetamine 5

653 out of 656 correctly identified = 99.5%

Conclusion

- Drug Chemists are doing an excellent job identifying controlled substances
- Error rates were effectively assessed by using:
  - PTs, QA Program/QC samples and Reanalysis
  - All demonstrated to be less than 0.5%
- This study addresses NAS Report Rec #3 by assessing error "… on realistic case scenarios averaged across a representative sample of forensic scientists and laboratories"

Acknowledgements:

- Mary Gibbons and Jennifer Mihalovich
  Oakland Police Department Crime Laboratory Manager (retired) and Acting Laboratory Manager
- Waliana Dieu and Roehl Cinco
  Current OPD Drug Chemists
- Todd Weller, Aviva Lieberman, Tana Langley, Vince Dietchman, Brian Karp, Lansing Lee, Anne Jancse, Melanie Cleland, Penny Ritter, Mary Trudell
  Former OPD Drug Chemists
- Ron Nichols
  Former OPD Drug Analysis Unit Supervisor, Developed QA program

Acknowledgements:

- Mark E. McDonald, Richard P. Meyers, Scott R. Oulton, and Nelson A. Santos
  DEA Office of Forensic Sciences
- Jason A. Bordelon, Jaclyn A. Iera, James V. Malone
  DEA Southwest Laboratory
- Jack Mario
  NY Suffolk County Crime Laboratory – retired
- Will Guthrie
  NIST

Acknowledgements:

- Tammi Noe, Dan DeFraga, Alison Kennedy, Petra Imhof, and Renee Peterson
  Management support at Kern Regional Crime Laboratory
- Jeanne Spencer, Jodi Kessler, Kelly Woolard, and Apryl Brown
  Data Collection at Kern Regional Crime Laboratory
- Jena Bowers, Petra Imhof, Robert Ekvall, Ismail Sebatan
  National University's Forensic Science Thesis Committee

Questions?

- Thank You!

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