FORENSIC SCIENCE ERROR MANAGEMENT

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Errors in a DNA Testing Laboratory

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Topics to Discuss

- Errors that occurred
  - 1988-2005 Cellmark Diagnostics/Orchid Cellmark
  - Private DNA testing laboratory in Germantown, MD
- What we did regarding the error
  - Assessment
  - Resolution
  - Prevention
- Strategic planning for errors
- Management Culture and Support

Errors that Occurred
ALL Human Errors

- Case-Specific Errors
  - PCR Negative Control and/or Sample Contamination
  - Errors in Report
- General Laboratory
  - "Proficiency Test" Errors
  - Errors in Population Databases
  - Dishonest Scientist

Negative Control/Sample Contamination (PCR)

- Contamination with detectable amounts of *Human* DNA
- "Errors" that are expected based on the technology used
  - Due to the sensitivity of the assay
    - More sensitive, more risk of error
  - Negative controls are required
- Contamination in reagents used, plastic ware/ disposables, sample and liquid handling errors

Negative Control/Sample Contamination (PCR)

- Detect results in negative controls, mixture in expected single-source sample
- Re-test to see where introduced (e.g., re-run, re-amplify)
- Re-extract, if necessary, using another portion of the sample
  - Report re-tested results
  - Retain all records in the case file, contamination records, QA/QC documentation

Prevention

- Training critical
  - Evidence and liquid handling techniques
    - Organization of bench set-up
  - Wear PPO, limit talking, changing gloves
- Small volumes of reagents in use at a time
- Procedures with fewer manipulations
- (Robotics, pre-screen or treat plastic ware)

Typographical Errors

- Errors that were missed at technical and administrative review
  - Found after report issued
- Issued an amended report
- Corrected in testimony if caught during pre-trial preparation or testimony

- Careful technical and administrative review
  - Can implement checklists and/or automated reporting

Error in Conclusion of Report

- Misaligned the data for the suspect and victim on the table of results in the report
  - All data and in the case file were fine; testing performed correctly
- Reported incorrect conclusions
  - Inclusion of the suspect instead of the victim
- Missed by analyst and technical reviewer
- Also missed by expert hired by the defense to review our data, casefile and report

Error in Conclusion of Report

- Additional error by me when reviewing for court testimony
- Caught the mistake in court during an admissibility hearing
- Immediately orally corrected the report in court
- Issued amended report the following business day and sent to the court

"Proficiency Test" Errors

- 1988-90
  - 2 tests issued by CACLD
  - RFLP testing done
  - 50 samples – all treated as possibly containing sperm
    - 3 extracts made/sample so 150 total extracts to evaluate
  - 1 mistake on each test

"Proficiency Test" Errors – First Error

- Label on tube got smudged – number misread
- Two different samples got combined as one sample
  - Incorrect results reported
- Corrective action – Changes to laboratory SOPs
  - Double label tubes
  - Witnessing step for all samples, tubes and transfers
  - Used different pens for labeling tubes

"Proficiency Test" Errors – Second Error

- Contamination of a DNA extract having little or no DNA with a DNA extract from an adjacent tube that had a high amount of DNA
  - Reported incorrect results/conclusion for the contaminated sample
- Corrective action – Changes to laboratory SOPs
  - All tubes closed at all times, except 2 tubes open for transfer
  - Separate high DNA samples from low DNA samples
  - Increased awareness regarding possible means of contamination

Errors in Population Databases

- Occurred in both the RFLP and DQ/PM databases
  - Data from a small number of individuals put into the "wrong" database
- Corrected the data in the databases
- Verified very minor effect on statistical frequencies calculated for profiles
- Updated statistics for all cases sent out on discovery and in preparation for court testimony
  - Issued an amended report with documentation regarding the error discovered in the databases

Dishonest Scientist – The Error

- Found to be substitution of negative profiles in case and data files for negative controls that needed to be re-run due electrophoretic issues that prevented the assessment of the negative control
  - PCR using STR analysis
- Discovered during technical review of the data

Dishonest Scientist – Actions Taken by the Lab

- Suspended analyst from case work immediately
- Controlled access to case files, computers and data files
- Reviewed all of her cases and data files to determine if a one-time or repeated event
  - Determined to have occurred in many cases
  - Only negative controls and allelic ladders affected
  - Tabulated cases
- Notified ASCLD/LAB and provided regular updates of the process

Dishonest Scientist – Actions Taken by the Lab

- Notified all clients - phone calls and letter
- Re-ran all negative controls that were available
  - No contamination detected in any controls
- Repeated testing at no charge
  - No discrepancies in the data were found
  - Suggests only negative control data were manipulated

Dishonest Scientist – Actions Taken by the Lab

- Implemented SOP changes
  - Random verification of electronic data for sample manipulation
  - Required printout of primer peak for all negative controls in the case file (in response to issues in other labs with negative controls)

Strategic Planning

- Had annual strategic planning meetings for all management and supervisors
- Assessed Strengths, Weaknesses, Risks and Threats
- Considered risk/threat of rogue scientist and possible errors

Important to know that
ERRORS WILL HAPPEN

Management Culture and Support

- Culture is Critical
  - Attitudes and work ethic of management and laboratory staff are very important
  - Encourage reporting and correcting of all errors
  - Involve staff in correcting errors, making improvements
  - Non-punative
  - Quality FIRST!!
    - Reduced repeat rate, improved TAT

Policy for Disclosure of ALL Errors

- All case-specific documentation kept in original case file
- All records kept by QA/QC manager
  - Available for review, audits, discovery
- All documentation provided on discovery
- All information disclosed to client & attorney (especially during pre-trial preparation)
- Testified to all errors in court

Summary

- Expect mistakes and plan for them
- Look for mistakes - is your assessment adequate?
- View mistakes as an opportunity rather than a failure
- Correct mistakes – document & retain
- Put corrective actions in place for the lab
- Learn from mistakes → make improvements
- Be open about all mistakes → share with all staff and others
- Provide on discovery, testify in court honestly and completely

Food for Thought…

Thomas J. Watson, the founder of IBM:

"If you want to increase your success rate, double your failure rate."

"How could we learn a better way of doing things, if we had never made mistakes?"

— Lailab Gifty Akita

THANK YOU!!!

- Dr. Robin Cotton, Laboratory Director, TL
- Mark Stolorow, Director of Operations
- All analysts, QC/QA managers, supervisors/ managers at Cellmark Diagnostic - Germantown