

**FORENSIC TOXICOLOGY LABORATORY
OFFICE OF CHIEF MEDICAL EXAMINER
CITY OF NEW YORK**

PROFICIENCY TESTING

PRINCIPLE

Laboratories may participate, by mandate or by choice, in external proficiency testing programs. Expected results for proficiency test specimens are unknown to anyone in the laboratory. The results are known only to the providing external agency and are revealed to the laboratory as a monitor of the laboratory's performance, as an aid for laboratory improvement and/or a condition of licensure. Proficiency testing programs also provide the opportunity to compare the laboratory performance with the mean and range of results obtained by other laboratories. Target values may be assigned by selected reference laboratories based on the weighed-in amounts or by a consensus of the participating laboratories. Programs of greatest value are those where the sample matrix and analytes are representative of the laboratory's stated mission.

Effective January 1, 2010, all ABFT accredited laboratories are required to subscribe to both the FTC (Toxicology) and the T-series proficiency tests of the College of American Pathologists (CAP). Laboratories are required to complete all challenges for the FTC set for which the laboratory has established, validated methods. All of the laboratory's usual screening and confirmation tests need to be completed for the T-series, plus those quantitative challenges for which the laboratory has routine methods. Results must be returned to CAP within the reporting period. In addition, laboratories must subscribe to the CAP AL1 Whole Blood Alcohol program or comparable program(s) with an equivalent number of challenges for ethanol and related volatiles.

This laboratory currently participates in the following proficiency testing programs:

Supplier/Sponsor	Description	Year Commenced	Challenges
CAT	Proficiency Testing	1987	2/year
CAP	Whole blood alcohol	1988	3/year
CAP	Serum alcohol	1988	3/year
CAP	Urine Toxicology (UT-series)	1988	3/year
CAP	Toxicology (T-series)	1991	3/year
CAP	Forensic Toxicology - Criminalistics (FTC – series)	2007	2/year
New York State DOH	Blood and urine alcohol	1993	1/year/analyst

STATE OF NEW YORK, DEPARTMENT OF HEALTH, VEHICLE AND TRAFFIC ALCOHOL ANALYST CERTIFICATION

Criteria for acceptable performance

All analysts are required to participate in the program. The performance standard of the program requires that results be within $\pm 7.5\%$ of the gravimetric assignment (g ethanol/ dL of whole blood) for concentrations equal to or greater than 0.10% or within ± 0.008 g/dL of the gravimetric assignment (g ethanol/ dL of whole blood) for concentrations less than 0.10%.

Four samples are provided to each analyst and at least three of these must meet the performance standard of the program. Analysts who meet the score of 75% or higher are issued the *Blood and Urine Alcohol Analyst Permit* by the State of New York, Department of Health. The permit is valid for a period of one year. Analysts who have been issued this permit are considered qualified to perform alcohol testing in areas of post mortem as well as human performance forensic toxicology.

Corrective action

Corrective action is required for all unsatisfactory results. Corrective action is determined based on the type of error (i.e. analytical, transcription, procedural).

An investigation of the analytical error(s) is required for scores less than 75%. Corrective action will include, at a minimum, repeat analysis of samples under observation by a certified analyst. Corrective action may also include preparation of new calibrators, preparation of new controls or a complete re-validation of the analytical procedure.

A report of this investigation and corrective action taken is provided to NYS DOH which will then issue another set of four proficiency samples, whenever necessary.

AACP/CAP WHOLE BLOOD ALCOHOL/ETHYLENE GLYCOL/VOLATILES SURVEY

Criteria for acceptable performance

The American Association for Clinical Chemistry/College of American Pathologists (AACP/CAP) evaluates results based upon a range of acceptability. The range is determined using a target value and a limit. The target value is usually the mean of all methods and the range of acceptability is either $\pm 20\%$ of target or 0-9 mg/dL for ethanol free specimens.

This laboratory considers the range of acceptability for volatiles to be $\pm 10\%$ of target or within ± 1 SD of participant mean (0-9 mg/dL for ethanol free specimens).

The range of acceptability for ethylene glycol is $\pm 20\%$ of target or within ± 2 SD of participant mean.

Corrective action

Corrective action is required for all unsatisfactory results. Corrective action is determined based on the type of error (i.e., analytical, transcription, procedural).

Corrective action for analytical errors will include, at a minimum, repeat analysis of samples under observation by an analyst holding a *Blood and Urine Alcohol Analyst Permit* by the State of New York, Department of Health.

Corrective action may also include preparation of new calibrators, preparation of new controls, a complete re-validation of the analytical procedure, and repeat analysis of case work which may have been affected.

AACC/CAP SERUM ALCOHOL/ETHYLENE GLYCOL/VOLATILES SURVEY

Criteria for acceptable performance

The American Association for Clinical Chemistry/College of American Pathologists (AACP/CAP) evaluates results based upon a range of acceptability. The range is determined using a target value and a limit. The target value is usually the mean of all methods and the range of acceptability is either $\pm 20\%$ of target or 0-9 mg/dL for ethanol free specimens.

This laboratory considers the range of acceptability for volatile compounds to be $\pm 10\%$ of target or within ± 1 SD of the participant mean (0-9 mg/dL for ethanol free specimens).

The range of acceptability for ethylene glycol is $\pm 20\%$ of target or within ± 2 SD of participant mean.

Corrective action

Corrective action is required for all unsatisfactory results. Corrective action is determined based on the type of error (i.e., analytical, transcription, procedural).

Corrective action for analytical errors will include, at a minimum, repeat analysis of samples under observation by an analyst holding a *Blood and Urine Alcohol Analyst Permit* by the State of New York, Department of Health.

Corrective action may also include preparation of new calibrators, preparation of new controls, a complete re-validation of the analytical procedure, and repeat analysis of case work which may have been affected.

CAP URINE TOXICOLOGY SURVEY (UT SERIES)

Criteria for acceptable performance

Only false positive results are considered unacceptable in the College of American Pathologists (CAP) UT series. Participants are marked incorrect if they report a drug present when it is not. They are not marked incorrect if they do not report a drug present. False positives are marked incorrect whereas false negatives are not marked incorrect. Quantitative results are not required.

Corrective action

Corrective action is required for all false positive results. Corrective action is determined based on the type of error (i.e., analytical, transcription, procedural).

Corrective action for analytical errors will include, at a minimum, repeat analysis of relevant samples, to exclude the possibility of a random error (e.g. sampling error). Corrective action may also include preparation of new calibrators, preparation of new controls, a complete re-validation of the analytical procedure and repeat analysis of case work which may have been affected.

Corrective action may be required for some false negative results. False negative results for analytes which are included in the laboratory's list of routinely tested analytes or analytes detectable in the routine initial screen will require corrective action, as per above. Corrective action is not required for false negative results of analytes not included in the routine initial screen or for analytes tested by special request only. However, if in-house methodology exists for such analytes, analysis will be performed upon review of the PT results and same acceptance criteria will be applied as for the routinely tested analytes.

Uncontrolled Copy

CAP TOXICOLOGY SURVEY (T SERIES)

Criteria for acceptable performance

Only false positive results are considered unacceptable in the College of American Pathologists (CAP) T series. Participants are marked incorrect if they report a drug present when it is not. They are not marked incorrect if they do not report a drug present. False positives are marked incorrect whereas false negatives are not marked incorrect. Acceptable performance for ethanol is the same as described under serum and whole blood CAP surveys. Acceptable performance for other analytes, where practical, is based on the following: at least 80% of the challenges should be within ± 2 SD of participant mean or within $\pm 20\%$ of weighed-in target and remaining challenges should be within ± 3 SD of participant mean or within $\pm 30\%$ of weighed in target.

Corrective action

Corrective action is required for all false positive results. Corrective action is determined based on the type of error (i.e., analytical, transcription, procedural).

Corrective action for analytical errors will include, at a minimum, repeat analysis of relevant samples, to exclude the possibility of a random error (e.g. sampling error). Corrective action may also include preparation of new calibrators, preparation of new controls, a complete re-validation of the analytical procedure, and repeat analysis of case work which may have been affected.

Corrective action may be required for some false negative results. False negative results for analytes which are included in the laboratory's list of routinely tested analytes or analytes detectable in the routine initial screen will require corrective action, as per above. Corrective action is not required for false negative results of analytes not included in the routine initial screen or for analytes tested by special request only, however, if in-house methodology exists for such analytes, analysis will be performed upon review of the PT results and same acceptance criteria will be applied as for the routinely tested analytes.

CALIFORNIA ASSOCIATION OF TOXICOLOGISTS (CAT) PROFICIENCY TESTING

The objective of the CAT biannual survey is to present analytical toxicologists with physiological samples containing drugs which in many cases will challenge the performance of conventional methodologies. The survey samples may contain drugs of abuse, volatiles, commonly prescribed drugs, as well as rarely prescribed drugs, "designer drugs" or drugs which are not available in the USA. Urine, whole blood or serum matrixes are utilized.

Criteria for acceptable performance

The performance of three reference laboratories is used to establish a benchmark of performance. CAT does not set any specific criteria for acceptable performance. The acceptance criteria which follow apply for this laboratory.

Acceptable performance for ethanol is same as described under serum and whole blood CAP surveys. Acceptable performance for other analytes, where practical, is based on the following:

at least 80% of the challenges should be within ± 2 SD of participant mean or within $\pm 20\%$ of weighed-in target and remaining challenges should be within ± 3 SD of participant mean or within $\pm 30\%$ of weighed in target.

Corrective action

Corrective action is required for all false positive results. Corrective action is determined based on the type of error (i.e., analytical, transcription, procedural).

Corrective action for analytical errors will include, at a minimum, repeat analysis of relevant samples, to exclude the possibility of a random error (e.g., sampling error). Corrective action may also include preparation of new calibrators, preparation of new controls, a complete re-validation of the analytical procedure, and repeat analysis of case work which may have been affected.

Corrective action may be required for some false negative results. False negative results for analytes which are included in the laboratory's list of routinely tested analytes or analytes detectable in the routine initial screen will require corrective action, as per above. Corrective action is not required for false negative results of analytes not included in the routine initial screen or for analytes tested by special request only, however, if in-house methodology exists for such analytes, analysis will be performed upon review of the PT results and same acceptance criteria will be applied as for the routinely tested analytes.

Results of proficiency tests are reviewed by the Laboratory Director and the QA/QC supervisor upon receipt of summaries from providers. Results are discussed with laboratory personnel during the regular weekly meetings.

CAP FORENSIC TOXICOLOGY CRIMINALISTICS SURVEY (FTC Series)

Criteria for acceptable performance

Only false positive results are considered unacceptable in the College of American Pathologists (CAP) FTC series. Participants are marked incorrect if they report a drug present when it is not. They are not marked incorrect if they do not report a drug present. False positives are marked incorrect whereas false negatives are not marked incorrect. Acceptable performance for ethanol is the same as described under serum and whole blood CAP surveys. Acceptable performance for other analytes, where practical, is based on the following: at least 80% of the challenges should be within ± 2 SD of participant mean or within $\pm 20\%$ of weighed-in target and remaining challenges should be within ± 3 SD of participant mean or within $\pm 30\%$ of weighed in target.

Corrective action

Corrective action is required for all false positive results. Corrective action is determined based on the type of error (i.e., analytical, transcription, procedural).

Corrective action for analytical errors will include, at a minimum, repeat analysis of relevant samples, to exclude the possibility of a random error (e.g. sampling error). Corrective action may also include preparation of new calibrators, preparation of new controls, a complete re-

validation of the analytical procedure, and repeat analysis of case work which may have been affected.

Corrective action may be required for some false negative results. False negative results for analytes which are included in the laboratory's list of routinely tested analytes or analytes detectable in the routine initial screen will require corrective action, as per above. Corrective action is not required for false negative results of analytes not included in the routine initial screen or for analytes tested by special request only, however, if in-house methodology exists for such analytes, analysis will be performed upon review of the PT results and same acceptance criteria will be applied as for the routinely tested analytes.

Please refer also to the Guidelines for Performing Corrective Action for Deviations in Proficiency Test Results distributed by the ABFT Accreditation Committee, December 1, 2012.

Uncontrolled Copy