CERTIFICATION OF RESULTS

Inspector Instructions:

- Sampling of certifying review of analytical and forensic records

FDT.05849 Results Certification **Phase II**

The laboratory retains a record of review of each step of the certification process.

NOTE: The review must include the following elements for screening and confirmatory testing:

1. *Chain-of-custody documents*
2. *Results of standards or calibrators*
3. *Results of quality controls*
4. *Identifications of specimens tested in each batch*
5. *Testing sequence of calibrators, controls, and unknowns*
6. *Results of specimens*
7. *Identity of analyst(s) performing the test*

FDT.05850 Certifying Review **Phase II**

The laboratory retains records of the certifying review that include the identification of the reviewer and the date of the review.

INSPECTION OF RECORDS

Inspector Instructions:

- Sampling of laboratory records using the following guidelines:
  - At least 20% of batches originating from the time between the last on-site inspection and 60 days prior to the current inspection
  - At least one batch for each drug in each matrix
  - Review of batches before and after proficiency testing failures to assess systematic analytical problems
- Sampling of external and internal chain-of-custody records for completeness (includes specimen disposition)

FDT.05862 Chain-of-Custody Documents **Phase II**

The external and internal chain-of-custody records are available, and properly completed.

FDT.05874 Screening/Confirmatory Tests **Phase II**

The data from all screening and confirmatory tests are available.

NOTE: The data must include:
1. *Results of standards or calibrators*
2. *Results of controls*
3. *Results of donor specimens tested*
4. *Laboratory identification and sequence of specimens tested*
5. *Evidence of any repeat injections, reanalysis, secondary screening, or rescreening*
6. *Identity of the individual(s) performing and reviewing the tests*
7. *Evidence of potential carryover review*
8. *Evidence of review of the completed data by a certifying official*
9. *Evidence of comparison of initial and confirmatory testing to ensure consistent results*

FDT.05886 Records **Phase II**

The records permit valid review of the data.

REPORTING OF RESULTS

Inspector Instructions:

READ	• Sampling of reporting policies and procedures (includes telephone and electronic reporting) • Sampling of test reports as applicable (printed, FAX with record of transmission to a "secure or confidential FAX", remotely printed, computer access)
ASK	• How do you ensure confidentiality of donor reports? • How does your laboratory differentiate non-forensic drug testing from forensic drug testing services?
DISCOVER	• Examine the laboratory's reporting system. Ensure that the process provides appropriate, accurate and confidential reporting.

FDT.05900 Result Reporting **Phase II**

The laboratory follows written procedures for the reporting of results to clients or their representatives.

NOTE: These procedures require that a forensic drug test report must include the following:
1. *Date of specimen collection (when given)*
2. *Date of specimen receipt by the laboratory*
3. *Donor and client identification information*
4. *Laboratory's unique specimen identification information*
5. *Specimen matrix tested and, if hair, site of collection*
6. *Drugs analyzed as part of the forensic drug test*
7. *Cutoff values per drug for both screening and confirmation tests*
8. *Positive and/or negative results*
9. *Date of report*