

## 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.**