



# Hair Specimen Request for Information: Summary of Public Comments

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# Hair RFI Format

- The RFI questions were divided into the following topic areas:
  - Hair specimen
  - Collection
  - Specimen preparation
  - Analytes/Cutoffs
  - Specimen validity
  - Testing

# RFI Questions

- Each topic area contained specific questions:
  - Hair specimen (3 questions)
  - Collection (4 questions)
  - Specimen preparation (4 questions)
  - Analytes/Cutoffs (4 questions)
  - Specimen validity (3 questions)
  - Testing (2 questions)

# RFI Public Comments

- 35 commenters
- 295 comments
  - 4 requests that comment period be extended
    - Comment period was extended through July 29, 2015
  - 160 in response to RFI questions
  - 63 general hair testing comments
  - 68 inappropriate/not substantial

# Hair Specimen Comments

- 55 comments on hair specimen concerned:
  - 14 - Acceptable body locations from which to collect hair
  - 13 - Alternatives when head hair is not available
  - 7 - Effect of hair treatments on drug concentration in hair
  - 21 - Reasons for hair testing

# Collection Comments

- 38 comments on collection concerned:
  - 10 - Training requirements for a collector of hair specimens
  - 6 - Acceptable protocols for the collection of hair specimen
  - 14 - Standards for hair collection including:
    - Specific instructions on how close to cut the hair specimen to the skin,
    - Determination of authenticity of the hair specimen,
    - Type of cutting instruments to use,
    - Decontamination of cutting instruments, and
    - Collection kit requirements
  - 8 Amount of hair to be collected

# Specimen Preparation Comments

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- 23 comments on Specimen Preparation concerned:
  - 4 - Analyte-specific wash and decontamination procedures
  - 6 - Protocols for hair specimen preparation
  - 3 - Criteria for acceptability of a specific wash and decontamination procedure
  - 4 - Published studies demonstrating effective wash procedure
  - 4 - Whether adjustments should be made for drug concentrations in wash fluids
  - 2 - Calculations for adjustments

# Analyte/Cutoff Comments

- 17 comments on Analytes/Cutoffs concerned:
  - 4 - Appropriate analytes to be measured in hair by the initial and confirmatory tests
  - 6 - Initial and confirmation cutoffs for analytes in hair
  - 4 - Criteria to distinguish external contamination from drug use (for each analyte/drug)
  - 3 - Metabolites or other biomarkers to confirm use and to distinguish drug use from external contamination

# Specimen Validity Comments

- 16 comments on Specimen Validity concerned:
  - 7 - Biomarkers/tests to verify authentic human hair
  - 5 - Appropriate biomarkers/tests for adulteration/substitution
  - 2 - Whether “Invalid Result” is appropriate for hair
  - 2 - Criteria to classify a specimen as “Invalid Result”

# Testing Comments

- 11 comments on Testing concerned:
  - 5 - Available testing technologies
  - 3 - Best sample for quality control/proficiency testing
  - 2 - How quality control/proficiency testing samples should be prepared
  - 1 - Best method to prepare contaminated hair samples vs. drug user hair