Specimen Validity Testing (SVT) – The Rules

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Disclosure

- FSSolutions, Chalfont, PA
  - Medical Director, Recovery Management Services

Outline

- Invalid Results
- Dilute/Substituted
- Adulterated
- Split Specimens

Validity Testing (SVT)

- Definition: Validity testing is the evaluation of a specimen to determine if it is consistent with normal human urine and if the observed properties allow detection of drugs of abuse

- Currently:
  - HHS mandated since 11/1/2004
  - HHS Mandatory Guidelines issued IFR 1/23/2017
  - DOT issued NPRM 1/23/2017
  - DOT issued Final Rule 11/13/2017, effective 1/1/2018:

SVT MANDATORY FOR ALL DOT TESTING

- MRO review and split specimen testing option required for adulterated and substituted confirmed laboratory results
- MRO review but no split option for invalid results
- 40.89

Laboratories and Validity Testing I

- Lab must test each specimen for:
  - Creatinine concentration
  - Specific gravity when creatinine is less than 20 mg/dL
  - pH
  - Oxidizing agents (specific agents not specified)
- Additional SVT testing must be performed when:
  - Abnormal physical characteristics (e.g., color, odor, foaming)
  - Reactions characteristic of adulterants during testing
  - Possible unidentified interfering substance/s
- 40.91

Laboratories and Validity Testing II

- When the presence of an interfering substance or adulterant is suspected but lab unable to identify, lab must consult with the MRO to decide whether to send to another HHS-certified lab
- If new adulterant identified, labs must complete testing for drugs to the extent technically feasible and notify:
  - DOT's Office of Drug & Alcohol Policy Compliance (ODAPC)
  - HHS (Division of Workplace Programs)
- 40.91

Invalid Results

Invalid Result

- Definition - Laboratory report of a drug test for a specimen that contains:
  - An unidentified adulterant, or
  - Unknown interfering substance, or
  - Has abnormal physical characteristics, or
  - Has an endogenous substance at an abnormal concentration that prevents the lab from obtaining a valid drug test result.
- 40.3

HHS Guidance for Laboratory Invalid Comments

- Creatinine < 2 mg/dL; SG Acceptable (>1.0010 & <1.0200)
- SG ≤ 1.0010; Creatinine ≥2 mg/dL
- Abnormal pH: (lab must report value)
  - pH ≥ 4.0 & < 4.5, OR
  - pH ≥ 9.0 & < 11.0
  - Possible (Oxidant, Halogen, Aldehyde, or Surfactant) Activity
- Immunoassay Interference
- Interference with confirmation (GC/MS, LC/MS or MS/MS)
- Abnormal Physical Characteristic (Specify)
- Bottle A and Bottle B – Different Appearance
- Specimens with the Same Abnormal Color in Bottles A and B still tested. No comment to MRO

Invalid Result: MRO Actions I

- Check with the Certifying Scientist for suggestions. (HHS requires CS to call MRO in some cases)
- If invalid due to “immunoassay interference”, consider:
  - NSAIDs (tolmetin classic), quinolones, metronidazole,
  - Possible synthetic urine
- Ask lab about its ability to perform an alternative screening assay that will not cross react with these and possibly other medications.

- 40.159

Invalid Result: MRO Actions II

- If no alternate initial test available, MRO may order specimen transferred to another HHS-certified lab.
  - Sending the specimen elsewhere will be time consuming and expensive.
  - May have to confer with DER (after donor interview).
  - Client should have established policy and notify MRO at account set-up time.
- After discussion with Certifying Scientist, interview the donor.
- Verify prescription medication as required.

Invalid Result with Justification (e.g., Cipro)

- Report as “Test Cancelled” and enter under remarks:
  - “Invalid Result” and
  - “Direct observation recollection not required”
- Report to DER with reason and that no further action is required unless a negative test is required (i.e., pre-employment, follow-up, and return to duty)
- When a negative result is required, recollection is not done under direct observation.
- 40.159

40.159 (4) (iii)

- If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

40.160 (a)

- …as the MRO, you must determine if there is clinical evidence that the individual is currently an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation. In addition, if appropriate, you may also consult with the employee's physician to gather information you need to reach this determination.

40.160 (d)

- If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report this to the employer as a negative test result with written notations regarding the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.
- (1) Check “Negative” (Step 6) on the CCF.

40.160 (e)

- If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding the results of the medical examination.

MRO [pH Issue] Q&A 07/08

- When an employee has no other medical explanation for the pH in the 9.0 - 9.5 range, MROs should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.
- In doing so, MROs are authorized to consider the following:
  - The temperature conditions likely to have existed between the time of collection and transportation of the specimen to the laboratory; and
  - The length of time between the specimen collection and arrival at the laboratory.
- MRO determines time and temperature likely account for the pH value, cancel the test: take no further action.
- MRO determines that time and temperature fail to account for the pH value, cancel test: direct observation collection.

40.159

Invalid Result Without Justification I

- If adulteration is denied, report as:
- “Test cancelled” and under Remarks:
  - “Invalid Result” and
  - “Direct observation recollection required”

- Tell DER that immediate, “no-notice” observed recollection is required.
- 40.159

Invalid Result Without Justification II

- If adulteration is admitted, report as:
- “Refusal to Test” and under Remarks: “Adulterated with …” (i.e. “with a bottle donor says he purchased over the Internet.”) and
- Write and sign a statement detailing what was said.
- 40.159

Two Consecutive Invalids

- First ensure the 2nd collection was observed
  - Should be noted on CCF, but collector may need to be called
  - If not, no interview, send donor back for no-notice observed re-collection
- If 2nd collection was properly observed and:
  - Invalid for the same reason:
    - Cancel, no further action unless negative needed
    - If negative needed, examination as in 40.160
  - Invalid for different reason:
    - No interview, no-notice observed re-collection
- 40.159

MRO Report Options - (Only 4)

1. "Negative" or "Negative, dilute"
2. "Positive" or "Positive for (drug/metabolite), dilute"
3. "Test Cancelled because (give reason under Remarks)"
4. "Refusal to Test because:
   – Specimen Adulterated with (name substance identified)"
   – Specimen Substituted"

May need to combine 2 and 4

40.129

Reporting 1 Event/2 Collections 40.162

1st	2nd	MRO Report	Other?
Negative	Negative	2nd result	DNR
Negative	Non-Neg	2nd result	DNR
Non-Neg	Negative	1st result immediately	DNR
Non-Neg	Non-Neg	1st result immediately; report 2nd too	N/A

Dilute/Substituted Specimens

DOT/HHS Differences

- For DOT (Since 5/2003)
  - Two categories of Dilute
    - Creatinine > 5 and < 20 mg/dL
    - Creatinine ≥ 2 and ≤ 5 mg/dL (Hyper-dilute, Ultra-dilute, Super-dilute??)
  - Substituted definition agrees with HHS
- For HHS
  - One category of Dilute
    - Creatinine ≥ 2 and < 20 mg/dL
  - Substituted definition agrees with DOT
  - Unlike DOT, HHS requires 1 time unobserved re-collection for negative, dilute

Definitions (Both DOT and HHS)

- Dilute
  - Creatinine < 20 mg/dL but ≥ 2 AND
  - Specific Gravity > 1.0010 and < 1.0030
- Substituted
  - Creatinine < 2.0 mg/dL AND
  - Specific Gravity ≤ 1.0010 OR ≥ 1.0200

- 40.93

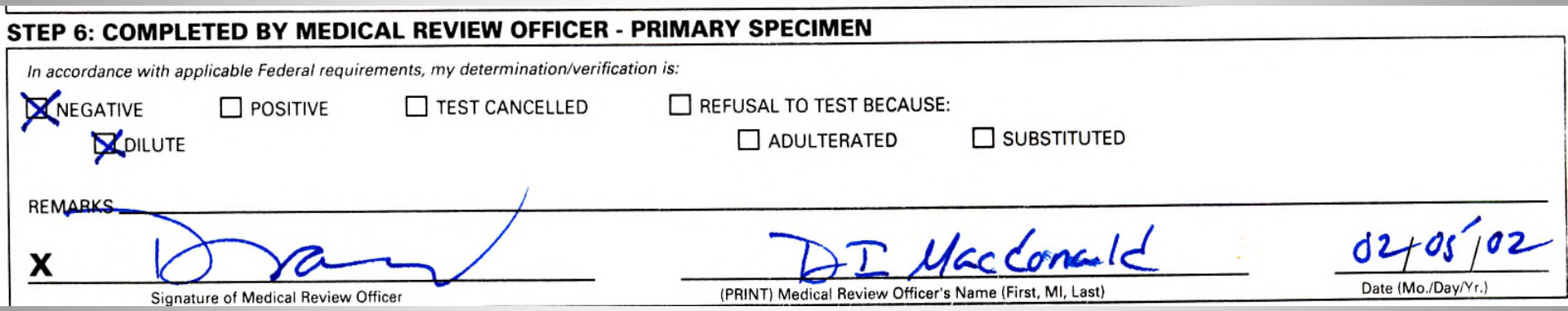
Laboratory Reports

- Dilute reported as:
  - "Negative" or "Positive for drug(s)/metabolite(s)" and
  - "Dilute"
  - Values given for creatinine and S.G.
- Substituted reported as:
  - "Substituted" with remarks
  - Values given for creatinine and S.G.
  - If creatinine below lab detection level, it will be reported as "creatinine not detected". In this case, lab must tell MRO their LOD.

- 40.97

Dilute Specimens - MRO Actions

- No donor interview required for negative dilute
- Report as “NEGATIVE” or “POSITIVE” for (drug(s) and “DILUTE”



STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

☒ NEGATIVE ☐ POSITIVE ☐ TEST CANCELLED ☐ REFUSAL TO TEST BECAUSE:

☒ DILUTE ☐ ADULTERATED ☐ SUBSTITUTED

REMARKS

X _____ Signature of Medical Review Officer

D I MacDonald (PRINT) Medical Review Officer's Name (First, MI, Last)

02/05/02 Date (Mo./Day/Yr.)

- For Negative and Dilute: Inform the employer of option to collect another specimen (not observed) but only once.
- 40.197

Creatinine/Specific Gravity - MRO Actions I

- Specimen is Substituted if
  - Creatinine < 2.0 mg/dL AND
  - S.G. ≤ 1.0010 OR ≥ 1.0200
    - MRO interview
    - Report as: “Refusal to test because Specimen Substituted”. (40.193)
    - If drug positive, report as “Refusal…, and Positive for…”

Creatinine/Specific Gravity - MRO Actions II

- Specimen is Invalid if
  - Creatinine < 2.0 and S.G. acceptable (>1.0010 AND < 1.0200)
  - Creatinine ≥ 2.0 and S.G. ≤ 1.0010
    - MRO interview
    - Report as “Test Cancelled, Invalid Specimen”
    - Advise DER observed recollection required if no legitimate medical explanation

MRO Actions: (DOT "Hyper-Dilute" Only)

- Creatinine ≥ 2.0 but ≤ 5.0 mg/dL AND
- Specific Gravity >1.0010 but < 1.0030
  - Drug positive
    - MRO interview
    - "Positive for …, dilute"
  - Drug negative
    - No MRO interview
    - Report as "Negative, dilute. Immediate observed re-collection required"

40.155

Creatinine Level <20 mg/dL

DOT & HHS dilute

2 mg/dL to <20 *and* SG >1.0010 AND <1.0030

↓

Lab reports as "Dilute" plus positive (P), or negative (N)

↓

MRO does not interview if negative.

↓

Reports as dilute plus P or N.
If DOT N and >5 employer may order 1 recollection

DOT "hyper" dilute

2 mg/dL to ≤ 5 *and* SG > 1.0010 AND <1.0030

↓

Lab reports as "Dilute" (plus P, as req) *and* gives SG and Creatinine levels

↓

If P, MRO interviews and reports as P or N "dilute"

↓

If lab N, no MRO interview, report as N "dilute" Mandatory immediate observed recollection for DOT

DOT & HHS substituted

<2 mg/dL *and* SG ≤ 1.0010 OR SG ≥ 1.0200

↓

Lab reports as "Substituted" plus P, I, *and* gives SG and Creatinine levels

↓

MRO interviews and reports as "Refusal to test – substituted specimen"

↓

Split offered and, at MRO discretion, medical evaluation

* When Specific Gravity does not match Creatinine as noted above, result is reported as invalid.

Adulterated

“Specimen Adulterated with…”

- Requires confirmed identification of:
  - A substance that is not expected to be present in human urine; or
  - A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or
  - Physical characteristics of the specimen are outside the normal expected range for human urine.
- 40.95

Adulterated Specimen Cutoffs
(HHS Mandatory Guidelines)

- pH < 4 or ≥ 11 (This is a change)
- Nitrite ≥ 500 mcg/mL
- Chromium (VI) ≥ 50 mcg/ml
- Halogen ≥ 200 mcg/mL nitrite equivalents, ≥ 50 mcg/ml Chromium VI equivalents, or ≥ LOD*
- Gluteraldehyde ≥ LOD
- Pyridine/pyridinium chlorochromate ≥ 200 mcg/mL nitrite equivalents, ≥ 50 mcg/ml Chromium VI equivalents, or ≥ LOD*
- Surfactant ≥ 100 mcg/mL
- Any other adulterant identified using different initial and confirmatory techniques on separate aliquots

*depending on test used

Adulterated Specimen Lab Reporting
(HHS Mandatory Guidelines)

- pH =(conf. test numerical value)
- Nitrite =(conf. test numerical value) mcg/ml
- Chromium (VI) =(conf. test numerical value) mcg/ml
- (Specify Halogen) present
- Glutaraldehyde =(conf. test numerical value) mcg/ml
- Pyridine =(conf. test numerical value) mcg/ml
- Surfactant present
- (Specify adulterant) present

Quantitation

- Quantitative values for adulterated, substituted, dilute and invalid (as appropriate) results must be reported by the laboratory to the MRO

  – 40.97 and HHS Mandatory Guidelines

Lab Report - Adulterated

STEP 5a: PRIMARY SPECIMEN TEST RESULTS - COMPLETED BY PRIMARY LABORATORY

☐ NEGATIVE ☐ POSITIVE for: ☐ MARIJUANA METABOLITE ☐ CODEINE ☐ AMPHETAMINE ☒ ADULTERATED
☐ DILUTE ☐ COCAINE METABOLITE ☐ MORPHINE ☐ METHAMPHETAMINE ☐ SUBSTITUTED
☐ REJECTED FOR TESTING ☐ PCP ☐ 6-ACETYLMORPHINE ☐ INVALID RESULT

REMARKS Nitrite = 1025 mcg/mL

TEST LAB (if different from above) _____

I certify that the specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

X Jane E. Smith
Signature of Certifying Scientist

Jane E. Smith
(PRINT) Certifying Scientist's Name (First, MI, Last)

12/03/09
Date (Mo/Day/Yr.)

Laboratory Reports

- Negative or Negative, dilute
- Positive or Positive, dilute with drug(s)/metabolite(s) noted
- Rejected for testing with remark(s)
- Invalid result with remark(s)
- Adulterated with remark(s)
- Substituted with remark(s) or
- Multiple results

- 40.97

Laboratory Multiple Results

- Negative and dilute
- Positive and dilute
- Positive and adulterated
- Positive and Substituted
- Positive and Invalid
- Adulterated and Invalid
- Adulterated and Substituted
- Substituted and Invalid

MRO Actions - Adulterated/Substituted I

- Follow standard verification process with donor interview, split notification, etc.
- Burden of proof on donor – must present at time of the verification interview.
- MRO may extend donor time up to 5 days. (Can they get an appointment in that time?)
- Adulteration: Must demonstrate adulterant entered specimen through physiological means.
- Substitution: Must demonstrate that he or she can produce urine meeting criteria through physiological means.
- 40.145

MRO Actions - Adulterated/Substituted II

- If you believe medical explanation may be reasonable:
- Donor must be directed to obtain evaluation by a licensed physician within 5 days who is:
  - Acceptable to MRO but chosen by the worker, perhaps with MRO assistance
  - Expert in the issues (i.e., nephrologist)
- Worker is responsible for arranging, conducting, and/or paying for any studies

- 40.145

MRO Actions - Adulterated/Substituted III

- If expert physician used, MRO must
  - Provide guidance on what is expected
  - Explain test results and consequences
- Referral physician:
  - May conduct additional tests (if on urine, testing must be in HHS-certified lab)
  - Must make written recommendation to MRO
- MRO has final decision
- 40.145

Legitimate Medical Explanations

- Diagnosis of a medical condition by itself is not enough.
- Must have methodically valid demonstration of physiologic ability to produce urine with characteristics noted.
- 40.145

MRO Report Options - (Only 4)

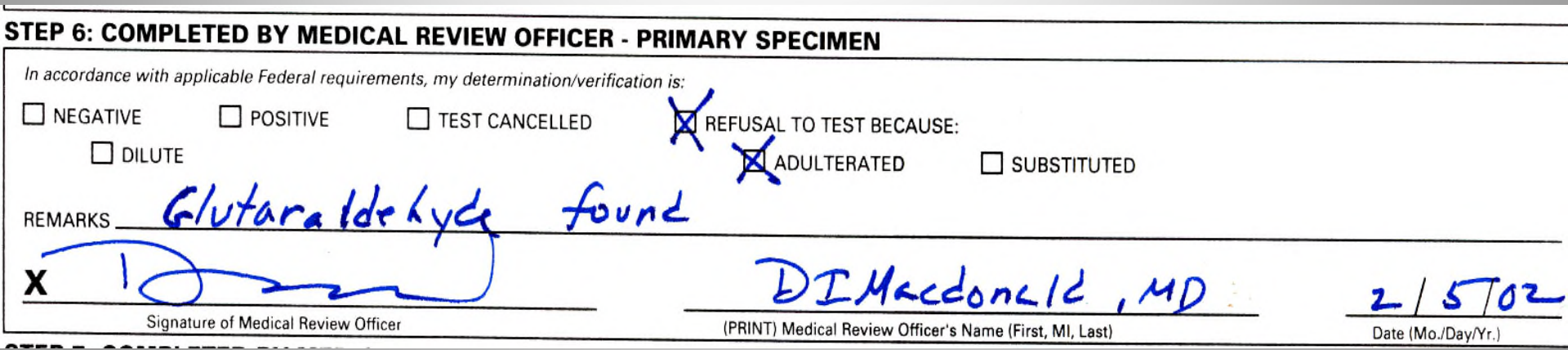
1. “Negative” or “Negative, dilute”
2. “Positive” or “Positive for (drug/metabolite), dilute”
3. “Test Cancelled because (give reason under Remarks)”
4. “Refusal to Test because:
   - Specimen Substituted”
   - Specimen Adulterated with (name substance identified)”

May need to combine 2 and 4

40.129

MRO Reports - Adulterated/Substituted

- Check REFUSAL TO TEST and either
- ADULTERATED or SUBSTITUTED.
  - If adulterated, name adulterant on remarks line.
- Sign form, print name, and date (MRO may not delegate this step).



STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

☐ NEGATIVE ☐ POSITIVE ☐ TEST CANCELLED ☒ REFUSAL TO TEST BECAUSE:

☐ DILUTE ☒ ADULTERATED ☐ SUBSTITUTED

REMARKS Glutaraldehyde found

X [signature] — Signature of Medical Review Officer

D I MacDonald, MD — (PRINT) Medical Review Officer's Name (First, MI, Last)

2/5/02 — Date (Mo./Day/Yr.)

MRO Reports - Adulterated/Substituted

- If legitimate medical explanation:
  - Cancel test and report to DER.
  - Inform ODAPC in writing why you think that.
- If no legitimate medical explanation:
  - Report as “Refusal to test because specimen adulterated with…” or
  - “Refusal to test because specimen substituted.”

- 40.145

Refusal to Test Applies to a Donor Who Refuses to:

- Appear for test within reasonable period of time
  - Be careful if pre-employment
- Remain at testing site until process is complete.
  - Employee may leave with legitimate reason prior to their selection of collection container. (40.193 Rev).
- Provide a required specimen.
- Permit direct observation when required.

- 40.191

Refusal to Test Applies to a Donor Who Refuses to:

- Provide sufficient specimen without legitimate medical explanation.
- Cooperate with any part of the testing process.
- Take a second test directed by employer or collector.
- Undergo medical examination for insufficient specimen volume protocol.
- Has a verified adulterated or substituted report.

- 40.191

Refusal to Test Report

- Immediate notification of DER is required.

- 40.191

Split Specimens (Bottle ‘B’)

Split Specimens

- Mandatory for all HHS/DOT collections.
- 45 ml collection (30 ml primary, 15 ml split).
- Collected in single specimen container and poured into A and B bottles by collector (in presence of donor).
- In non-DOT programs without split specimens, reanalysis may (in some states, must) be done on an aliquot of the single specimen.

- 40.171

Split Specimen - Laboratory Actions

- If Bottle A is non-negative, Bottle B is kept frozen for 1 year.
- If Bottle B is unavailable or unacceptable:
  - Lab analyzes Bottle A, even if no B.
  - If only Bottle B has required volume, re-designate and test as Bottle A.
  - Lab does not inform MRO of Bottle B deficiency unless split is requested.
  - If and when split is requested, lab will inform MRO of the deficiency, and the MRO verified result will be “Test Cancelled, because Split Unavailable”
  - 40.175

Allowed Retesting

- **Bottle B Reconfirmation Testing**
  - May only be ordered by the employee through the MRO
    - To Reconfirm Bottle A Positive/Adulterated/Substituted Results
    - 72 hour rule; MRO may extend.

- **Bottle A Reanalysis**
  - May only be ordered by:
    - A Federal Agency as part of a legal or administrative proceeding
    - The MRO for additional testing when Bottle A is invalid or requires THC-V or d/l chiral separation
    - The employee through the MRO when Bottle B fails to reconfirm and is substituted or adulterated (i.e., Bottle A is tested for the adulterant)
    - HHS (e.g., investigating a possible deficiency at an HHS-certified laboratory)

Lab A Actions When Split Analysis is Ordered

- Send following items to Lab B:
  - Original Bottle B with intact seal.
  - Copy of MRO's written request.
  - Copy of Copy 1 of CCF which identifies drug(s)/metabolite(s) or the validity criteria for which Lab B is to test.
- Do not send employee name (not a fatal flaw if it happens).

- 40.175

Testing Splits for Drugs

- Confirmatory testing only.
- Analysis of split is for presence of drug at laboratory's limit of detection (LOD) or limit of quantitation (LOQ).
  - No requirement for ≥ 100 ng/mL Amp to reconfirm Methamphetamine
- Testing at LOQ not cut-off levels because:
  - Plastic bottles may adsorb analytes over time.
  - Adulterants may affect drug recovery.
  - Bacteria may affect levels.
- 40.177

Failure to Reconfirm for Drug(s)/Metabolite(s)

- If Lab B fails to reconfirm drug(s) reported by Lab A:
  - Lab B performs validity tests.
  - If Lab B is unable to identify reason for failure to confirm, they may send specimen to another HHS-certified lab that will conduct another reconfirmation test (HHS requires discussion with the MRO to decide whether testing at a third laboratory would be useful).
- 40.177

Testing Splits for Adulterated/Substituted

- Same levels and criteria as primary analysis.
- Only the test(s) needed to confirm the Bottle A results
- This is different from testing split for drug(s), which only need to find presence of drug(s) at or above the LOD or LOQ.

- 40.179 and 181

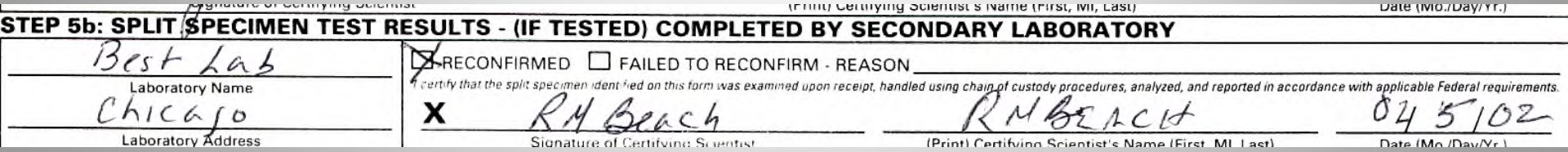
Split Specimen Reports

- Reconfirmed
- Failed to reconfirm with reason

Lab Report: Split Reconfirmed

- Report can go only to the MRO.
- Laboratory name and address entered.
- Reported as “RECONFIRMED”.
- Certifying scientist to enter name and sign and date form.

- 40.187



(Print) Certifying Scientist's Name (First, MI, Last) Date (Mo./Day/Yr.)

STEP 5b: SPLIT SPECIMEN TEST RESULTS - (IF TESTED) COMPLETED BY SECONDARY LABORATORY

Best Lab
Laboratory Name

Chicago
Laboratory Address

☒ RECONFIRMED ☐ FAILED TO RECONFIRM - REASON _____

I certify that the split specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

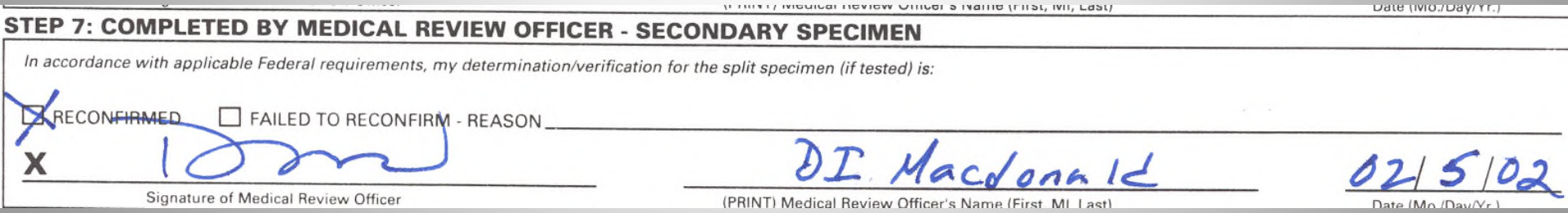
X RM Beach
Signature of Certifying Scientist

RM BEACH
(Print) Certifying Scientist's Name (First, MI, Last)

04 5 02
Date (Mo./Day/Yr.)

"Split Reconfirmed" MRO Action - Drugs

- Report as "RECONFIRMED", and
- Under "Remarks" give drug(s) and
- Inform worker and DER of result.



STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SECONDARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification for the split specimen (if tested) is:

☒ RECONFIRMED ☐ FAILED TO RECONFIRM - REASON

X [signature] — Signature of Medical Review Officer

D I Macdonald — (PRINT) Medical Review Officer's Name (First, MI, Last)

02/5/02 — Date (Mo./Day/Yr.)

“Split Reconfirmed” MRO Action Adulterated or Substituted

- Report “RECONFIRMED” and
- Under “Remarks” say Adulterated with …, or Substituted
- Constitutes “Refusal to Test”.
- Inform worker and DER of result.

- 40.187

Possible Lab Reports - Split Specimens

- Reconfirmed.
- Failed to reconfirm with reason:
  - Drug(s)/metabolite(s) not detected.
  - Adulterant (or Substitution) Criteria not met.
  - Specimen not available for testing (or QNS).
  - Specimen Results Invalid.
  - Adulterated with ……

- 40.183,5,7

Fails to Reconfirm I

- If the split is a valid specimen that fails to reconfirm drug(s)/metabolite(s) or adulterated/substituted:
- **MRO must:**
  - Notify DER and worker of result and that both tests are cancelled and no re-collection is required unless a negative is needed, and
  - Report case to ODAPC

- 40.187

Fails to Reconfirm II

- If the split fails to reconfirm because:
  - Specimen Unavailable for Testing (or QNS).
  - Specimen Results Invalid.
- **MRO must:**
  - Notify DER and employee of result that both tests are cancelled and
  - Order immediate no notice observed recollection, and
  - Report case to ODAPC.

- 40.187

Notify ODAPC

- On Split analysis when Lab ‘B’ reports:
  - “Drug(s)/metabolite(s) not detected” or
  - “Adulteration/Substitution Criteria not met” or
  - “Specimen unavailable for testing (or QNS)” or
  - “Specimen results invalid” or
  - Specimen adulterated or substituted, but reversed by MRO based on reanalysis of Bottle A.

- 40.187

Mandatory Recollection

- Order immediate, “no-notice”, observed recollection when specimen is reported as:
  - Split Specimen unavailable for testing (or QNS).
  - Split Specimen failed to reconfirm and was invalid.
  - Split Specimen failed to reconfirm substituted result AND Creatinine ≥ 2.0 and ≤ 5 with SG <1.003
- 40.187