Urine Specimen Collection Guidelines

For

Indiana Union Construction Substance Abuse Trust (IUCSAT)

Developed by Midwest Toxicology Services, Inc.
603 E Washington St, Suite 200
Indianapolis, IN 46204
317/262-2200 FAX 317/262-2222
www.midwesttoxicology.com

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Urine Specimen Collection Guidelines for IUCSAT

These guidelines apply only to participants in the **IUCSAT** substance abuse program and those individuals who conduct urine specimen collections for the **IUCSAT** program. The term "employee" is used throughout this document and has the same meaning as "donor" as used on the Custody and Control Form (CCF).

INTRODUCTION

The procedures for collection of urine are very specific and must be followed whenever a urine specimen collection is performed. These procedures, including use of a non-regulated Custody and Control Form (CCF), apply only to **IUCSAT** testing. While these collection and testing procedures are based on DOT collection guidelines, no collections or testing for **IUCSAT** shall be conducted with Federal CCFs nor implied that the testing is being conducted under DOT authority.

The collector has a major role in the success of the **IUCSAT** drug testing program. The collector is the one individual in the testing process with whom all employees have direct, face-to-face contact. Without the collector assuring the integrity of the specimen and collection process, the test itself may lose validity. Without the collector's sensitivity to an employee's privacy, the entire testing program may be subject to criticism. It is imperative that collectors fully understand and follow these procedures. These guidelines, together with assistance from the **IUCSAT** program administrator, will provide collectors with the information needed in the performance of their collection duties.

The information in this document addresses normal collection procedures and some of the more common problems or situations encountered. Problems or situations not specifically addressed by this document will be resolved by the governing board of this program.

Midwest Toxicology Services, Inc. is the third party administrator (TPA) for this program:

603 E Washington St, Suite 200
Indianapolis, IN 46204
317/262-2200 or 800/358-8450
FAX 317/262-2222

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SECTION 1. COLLECTOR

A collector is a trained person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the urine specimen provided by those employees, and who initiates and completes the non-regulated Drug Testing Custody and Control Form (CCF).

Any individual, who has received training described within this document (see Appendix A) for conducting the required collection procedure, may serve as a collector except in the following situations:

1. The immediate supervisor of a particular employee may not act as the collector when that employee is tested, unless no other collector is available. (The immediate supervisor may act as a monitor or observer (same gender) if there is no alternate method at the collection site to conduct a monitored or observed collection.);
2. A participant in the **IUCSAT** program should not be a collector, an observer, or a monitor for co-participants. This is to preclude any potential appearance of collusion or impropriety;
3. An individual working for an HHS-certified drug testing laboratory (e.g., as a technician or accessioner) may not act as a collector if that individual can link the employee with the specimen drug test result or laboratory report; and,

4. The employee may not be the collector of his or her own urine specimen.

A collector should have appropriate identification, which includes the collector's name and the name of the Collection facility or clinic. The collector is required to provide his or her identification if requested by the employee. There is no requirement for the collector to have a picture I.D. or to provide his or her driver's license with an address or telephone number. Also, the collector is not required to provide any certification or other documentation to the employee documenting the collector's training. However, the collector must provide this documentation on request to **IUCSAT** representatives, participating contractors, or the third party administrator of this program (Midwest Toxicology Services).

SECTION 2. COLLECTION SITE

A collection site is a place (permanent or temporary) selected by the third party administrator where employees present themselves for the purpose of providing a urine specimen for a **IUCSAT** required drug test.

The collection site must allow the donor to have privacy while providing the specimen.

The first, and preferred, type of facility for this purpose is a single toilet room, having full-length privacy door. The second type of facility for urination is a multistall restroom with partial length doors. If a multistall restroom is used, the collector must secure all sources of water and other substances that can be used to adulterate a specimen (i.e. soap dispenser) and place bluing agent in all toilets or secure the toilets to prevent access.

A collection site must have:

1. A source of water for washing hands that, if practical, is external to the restroom where urination occurs. If the only source of water available is inside the restroom, the employee may wash his or her hands, and then the collector must secure (e.g., use tamper-evident tape, cut off the water supply) the water source before the collection takes place. If water is not available at the collection site, the collector may provide moist towelettes outside the restroom.
2. A suitable clean surface for the collector to use as a work area and for completing the required paper work.

All collection sites must meet the following security requirements by having:

1. Procedures or restrictions to prevent unauthorized access to the site during the collection;
2. Procedures to prevent the employee or anyone else from gaining unauthorized access to the collection materials/supplies. The collector must also ensure that the employee does not have access to items that could be used to adulterate or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water);
3. Procedures to ensure that all authorized persons are under the supervision of a collector or appropriate site personnel at all times when permitted into the site; and,
4. Procedures to provide for the secure handling and storage of specimens.

SECTION 3. COLLECTION SUPPLIES

The following items must be available at the collection site in order to conduct proper collections:

1. A collection kit that contains the collection cup, two bottles, and a plastic bag that bottles and CCF will be placed in after collection is completed. The kit shall be provided by the testing laboratory.
2. Non-regulated Drug Testing Custody and Control Forms (CCF).
3. Bluing (coloring) agent to add to the toilet bowl/water tank to prevent an employee from diluting the specimen.
4. Single use disposable gloves are recommended for use by collectors while handling specimens.
5. The collector should have available tamper-evident tape for securing faucets, toilet tank tops, and other appropriate areas, and signs, when necessary, that can be posted to prevent entry into collection areas.

SECTION 4. DRUG TESTING CUSTODY AND CONTROL FORM

The Drug Testing Custody and Control Form must be used to document every urine collection required by the **IUCSAT** drug testing program.

A typical CCF will consist of the following four copies:

Copy 1.	Original (Laboratory Copy) – accompanies the specimen to laboratory
Copy 2.	Collector Copy - retained by the collector
Copy 3.	MRO/Employer Copy - sent to the MRO
Copy 4.	Donor (Employee) Copy - given to the employee

The following steps describe how a non-regulated CCF from Kroll Laboratory should be filled out. A sample of what the Kroll CCF looks like can be found in Appendix D. Other CCFs should have similar fields of data and the collector should complete it as appropriate.

Step 1. This step is completed by the collector prior to the employee providing a urine specimen.

- The employer and MRO names, addresses, and telephone and fax numbers may be preprinted or handwritten.
    - **Note:** It is acceptable to modify a CCF under the direction of the TPA.
- The collector enters the employee's name and social security number or employee's ID number after verifying the employee's identity.
    - **Note:** The collector cannot require the employee to provide their social security number. The employee can choose to use their drug card ID number or driver's license number instead of their social security number.
- The collector also marks the appropriate box to indicate the reason for the test. (Note: Do not write in any numbers in part E. Test Code unless directed by the TPA.)

Step 2. This step is completed by the collector after receiving the specimen from the employee and observing the temperature of the specimen.

- This step requires the collector to mark the appropriate box to indicate if the temperature of the specimen was within the required temperature range.
- This step also requires the collector to indicate whether it is a split specimen or single specimen collection, and to indicate if it was an observed collection.
- **Note: This program prefers to have split specimen collections but a single specimen can be accepted by the collector.**

Step 3. This step instructs the collector to seal and date the specimen bottles and have the employee initial the bottle seals after placing them on the bottles.

Step 4. The collector enters the information required for the collection site (this information may also be preprinted).

- The collector's telephone number is critical, since the laboratory or the MRO may need to contact the collector if they have questions related to a collection.
- In this step, the collector must print their full name and sign the form to certify that the specimen was collected, labeled, sealed, and released for shipment to the laboratory.
    - Note: The collector must not sign the CCF until Step 5 has been completed.
- The collector is also required to note the time of the collection and the date of collection.
- This step also includes a "remarks" line which is used by the collector to add notes for the laboratory and/or MRO about the collection.
    - Note: the collector is NOT permitted to note any prescription/medication information on the CCF.

Step 5. This step is completed by the employee (listed as donor on the CCF) and the collector.

- It is preferable that the collector print the employee's name, date of birth, daytime and evening telephone numbers, and date of collection.
- The employee reads the certification statement and signs the form.
- After the employee completes this portion of the CCF, the collector reviews it to ensure that all the required information was provided.

The right side of the CCF is reserved for the tamper-evident specimen bottle seals/labels. There usually are two seals/labels (i.e., one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen if one is collected) to accommodate collecting split specimens.

- Each seal/label must have the same preprinted specimen identification number that appears at the top of the CCF.
- Each seal/label must also have a place for the collector to annotate the date of the collection and a place for the employee to initial each seal/label after it is placed on the specimen bottle.
    - Note: The seals/labels have a place for the collector's signature but it is not required that the collector sign the seals/labels.
- If a split collection is not conducted, the "B" seal/label should be discarded.

SECTION 5. EMPLOYEE IDENTIFICATION

The employee must provide appropriate identification to the collector upon arrival at the collection site. Acceptable forms of identification include:

1. A photo identification (e.g., drivers license, employee badge issued by the employer, any other picture identification issued by a Federal, state, or local government agency, or program ID drug card), or
2. Identification by an employer representative.

Unacceptable forms of identification include:

1. Identification by a co-worker,
2. Use of a single non-photo identification card (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card), or
3. Faxed or photocopies of identification document.

Note: The collection should not proceed until positive identification is obtained. Depending on reason for testing, the collector is authorized to direct the employee to leave and come back with a valid piece of identification. If assistance is needed, please contact the TPA.

SECTION 6. COLLECTION PROCEDURES

The collector must do the following before each collection to deter potential tampering, adulteration, alteration, or substitution of the specimens:

1. Secure any water sources or otherwise make them unavailable to employees (e.g., turn off water inlet, tape handles to prevent opening faucets);
2. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;
3. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;
4. Inspect the site to ensure that no foreign or unauthorized substances are present;
5. Ensure that undetected access (e.g., through a door not in your view) is not possible;
6. Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and
7. Recheck items (1) through (6) following each collection to ensure the site's continued integrity.

To avoid distraction that could compromise security, the collector is limited to conducting a collection for only one employee at a time. However, during the time period that an employee is consuming fluids (shy bladder), the collector may conduct a collection for another employee. In this case, the employee with the shy bladder must be properly monitored (see Section 7).

When a specific time for an employee's test has been scheduled (i.e. reasonable suspicion, post-accident, follow-up, or immediate random tests) and the employee does not appear at the collection site by the specified time, the collector must notify the TPA as soon as possible – this could be deemed a refusal to test.

The following steps describe a typical urine collection:

1. The collector prepares the collection site to collect urine specimens. All collection supplies must be available, the area properly secured, water sources secured, and bluing (coloring) agent placed in all toilets as specified in Sections 2 and 3 of these guidelines.

2. The collector begins the collection without delay after the employee arrives at the collection site. Do not wait because the employee is not ready or states he or she is unable to urinate. In most cases, employees who state they cannot provide a specimen will, in fact, provide sufficient quantity to complete the testing process. (If an alcohol breath test is also scheduled, the alcohol test should be conducted first, if practicable.)

3. The collector requests the employee to present an acceptable form of identification.

4. The collector explains the basic collection procedures to the employee. The collection facility may have these instructions posted, available in a handout format, or refer to the back side of the CCF.

5. The collector ensures that the required information is provided at the top of the CCF (the laboratory name and address and a pre-printed specimen ID number which matches the ID number on the specimen bottle seals). If the information is not already preprinted, the collector enters the required information in Step 1 of the CCF (usually employee name, SSN or ID number, and reason for test). Note: The collector cannot require the employee to provide their social security number. The employee can choose to use their drug card ID number or driver's license number instead of their social security number.

6. The collector asks the employee to remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.) and to leave any briefcase, purse, or other personal belongings he or she is carrying with the outer clothing. The employee may retain his or her wallet.

> **Note:** Work boots or cowboy boots do not have to be removed unless the collector has a reason to suspect that the employee has something in them, which may be used to adulterate or substitute a specimen. When an employee is asked to remove his or her hat or head covering, and refuses to do so based on religious practice, the collector may exempt the employee from removal of the head covering, unless the collector has an observable indicator that the employee is attempting to hide inside the head covering adulterants or other substances which may be used in an attempt to adulterate or substitute a specimen.

7. The collector directs the employee to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee places the items back into the pockets and the collection procedure continues. If the employee refuses to empty his or her pockets, this is considered a refusal to cooperate in the testing process.

> **Note:** If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, this will be considered a refusal to test. If the item appears

to be inadvertently brought to the collection site, secure the item and continue with the normal collection procedure. For example, a bottle of eye drops may have been brought inadvertently and would have to be secured by the collector and the collection would proceed. However, a bottle of liquid or urine would suggest intent to tamper with the specimen and a refusal to test will be issued. Items, such as suspected urine, plastic bags with fluid in them, artificial or mechanical objects for providing substituted urine, etc., should be fully described in an attached memorandum for record, copies of which should be sent to the MRO.

8. The collector instructs the employee to wash and dry his or her hands, under the collector's observation, and informs the employee not to wash his or her hands again until after the employee provides the specimen to the collector. The employee must not be allowed any further access to water or other materials that could be used to put into the specimen. If the employee refuses to wash his or her hands – after being directed to do so – this is a refusal to test.

9. The collector opens the collection kit under direct observation of the employee and gives the employee the collection container.

Note: Ensure the employee takes only the collection container into the room used for urination. The sealed specimen bottles remain with the collector.

10. The collector directs the employee to go into the room used for urination, provide a specimen of at least 45 mL, not to flush the toilet, and return with the specimen as soon as possible after completing the void. (In many restrooms, a toilet tank into which bluing agent may be placed is not accessible to the collector. When the employee flushes the toilet, he or she can use the clear (un-blued) water to potentially dilute the specimen. Inadvertently flushing the toilet does not automatically require any corrective action by the collector or a recollection. However, to guard against this action, the collector may want to place a card with instructions not to flush by the toilet handle or tape or otherwise secure the handle with tamper-evident tape.) The collector may set a reasonable time limit for the employee to be inside the bathroom and this time frame should be explained to the employee.

Note: The collector may explain to the employee that the temperature of the specimen is a critical factor and that the employee should bring the specimen to the collector as soon as possible after urination. The collector can inform the employee that if it is longer than 4 minutes from the time the employee urinates into the container and the collector takes the specimen temperature, the potential exists that the specimen may be out of range and an observed collection may be required.

Note: The collector should pay close attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen. If the collector detects such conduct, and the employee has already provided a specimen, the specimen will be placed in front of the employee and the collector will explain why the specimen is unacceptable and ask if there are any questions before discarding the specimen. The collector will immediately begin a new collection under direct

observation using a new kit. The collector then provides an appropriate comment on the "Remarks" line in Step 4 on the CCF and marks the “Observed” box in Step 2 of the CCF.

11. After the employee gives the specimen to the collector, the collector must:
- check the temperature of the specimen,
    - The temperature must be checked as soon as the employee presents the specimen, but no later than four minutes after the employee comes out of the restroom.
    - The acceptable temperature range is 32°-38°C/ 90°-100°F.
    - Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container.
    - If the temperature is within the acceptable range, the "Yes" box is marked in Step 2 on the CCF and the collector proceeds with the normal collection procedure.
    - If the temperature is out of range, the collector must:
        - Note the time of collection and whether the temperature was below or above the acceptable range on the “Remarks” line.
        - Explain to the employee that:
            - the specimen is not acceptable,
            - the specimen will be discarded,
            - the employee will be required to provide another specimen under direct observation, and
            - if the employee leaves the collection site before providing another specimen it will be deemed a refusal to test.
        - Ask if the employee has any questions.
        - Collector should discard the unacceptable specimen and proceed with a direct observed collection as described in Section 8 Directly Observed Collection.
    - **Note:** There is no requirement to take the employee’s body temperature if the specimen temperature is out of range. If the collector suspects that the temperature strip was not activated, the collector should pour the urine specimen into another collection container with a temperature strip or into a specimen bottle which has a temperature strip attached or attach a new temperature strip to the collection container if one is available, and use this method to determine the specimen temperature. Collectors should <u>not</u> introduce any other object (e.g., litmus paper, testing strips, etc.) into the specimen in the collection container or the bottles.
- check the specimen volume, and
    - It is preferred that 45 ml be collected but the collector can accept as little as 30 ml (a single specimen collection can be accepted). A minimum of 30 ml must be present to fill bottle A (primary specimen bottle). Call TPA if unsure.
    - If the volume is sufficient, the collector checks the box on the CCF (Step 2) indicating whether the collection was a split (yes) or not (no).
    - If the volume is insufficient, follow directions provided in Section 7 Shy Bladder Procedures.
- inspect the specimen for adulteration or substitution.
    - Inspect the specimen for unusual color, presence of foreign objects or material, odor, or other signs of tampering or adulteration (ex. a specimen with no odor, no

bubbles/foam, and tiny black flecks is commonly observed with a specimen that is carried into the collection site).

- If the specimen appears normal, the collector should proceed with normal collection procedures.
- If it is apparent from this inspection that the employee has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach), a second collection using direct observation procedures must be conducted immediately. The collection must:
  - Note the time of collection and describe the characteristics of the specimen which made it unacceptable on the "Remarks" line.
  - Explain to the employee that:
    - the specimen is not acceptable,
    - the specimen will be discarded,
    - they will be required to provide another specimen under direct observation, and
    - if they leave the collection site before providing another specimen it will be deemed a refusal to test.
  - Ask if the employee has any questions at this point.
  - Collector should discard the unacceptable specimen and proceed with a direct observed collection as described in Section 8 Directly Observed Collection.

12. After the employee hands the collection container to the collector, the collector unwraps or opens the specimen bottles.

Note: Both the collector and employee will maintain visual contact of the specimen to the greatest extent possible until the labels/seals are placed over the specimen bottle caps/lids. If practical, the collector may permit the employee to wash his or her hands right after the employee gives the collection container to the collector (and the collector checks the temperature), provided the employee and the collector can still maintain visual control of the specimen collection container.

Note: The following are considered refusals to test:

- The employee admits to the collector that he or she adulterated or substituted their specimen.
- The employee behaves in a confrontational way that disrupts the collection process.

In either of these refusal situations, the collector discards any specimen the employee provided previously and notifies the MRO and TPA as soon as possible.

13. The collector then pours at least 30 mL of urine from the collection container into a specimen bottle and places the lid/cap on the bottle. This will be the primary specimen or "A" bottle. The collector, not the employee, then pours the remaining amount (ideally 15 ml) into a second bottle and places the lid/cap on the bottle. This will be the "B" bottle used for the split specimen. If only a single collection is possible, the collector may discard the second bottle.

Note: The collector should <u>not</u> fill the primary or split specimen bottle up to the cap because a completely full bottle is more likely to leak in transit. Additionally, when a split specimen

bottle is full and subsequently frozen, it may cause the bottle material to crack and then leak during transit as the specimen thaws.

14. The collector must then remove the tamper-evident seals from the CCF and place them on each bottle, ensuring that the seal labeled as "A" is placed on the primary bottle with at least 30 mL of urine and that the seal labeled as "B" is placed on the other bottle, if applicable. The seal must be centered over the lid/cap and down the sides of the bottle to ensure that the lid/cap cannot be removed without destroying the seal. The collector writes the date on the seals. The employee is then requested to initial the seals. The employee must be present to observe the sealing of the specimen bottles. If the employee fails or refuses to initial the seals, the collector must note this in the "Remarks" line of the CCF and complete the collection process; this is not considered a refusal to test.

Note: The collector must not ask the employee to initial the labels/seals while they are still attached to the CCF; they must be initialed after they are placed on the bottles. The collector should also inform the employee to use care during the initialing process to avoid damaging the labels/seals.
Note: Occasionally, the tamper-evident label/seal provided with the CCF will not properly adhere to the specimen bottle because of environmental conditions (e.g., moisture, temperature, specimen bottle material) or may be damaged or broken during the collection process. When this occurs, the collector should use the following corrective procedures:
(a) If either seal is broken while being removed from the chain of custody form or during the application of the seal on the bottles, the collector should transfer the information to a new CCF and use the seals from the second form.
(b) The seals from the second CCF should be placed perpendicular to the original seals to avoid obscuring information on the original seals and must be initialed by the employee (both sets of employee initials should match). The collector should draw a line through the Specimen ID number and bar code (if present) on the original seals to ensure that the laboratory does not use that number for reporting the results.
(c) The collector should ensure that all copies of the original (first) chain of custody form are destroyed or disposed of properly (e.g., shredded, torn into pieces).

15. Step 5 of the CCF is completed next. This portion of the CCF is completed by the employee (listed as donor on the CCF) and the collector. It is preferable that the collector print the employee's name, date of birth, daytime and evening telephone numbers, and date of collection. The employee reads the certification statement and signs the form. After the employee completes this portion of the CCF, the collector reviews it to ensure that all the required information was provided.

Note: If the employee refuses to sign the form, the collector must make a notation on the "Remarks" line to that effect and complete the collection. This does not constitute a refusal to test.

16. The collector completes the collector's portion of the chain of custody on the CCF (Step 4) by printing his or her name, recording the date and time of the collection, and signing where indicated.

17. The collector then ensures that all copies of the CCF are legible and complete. The collector removes the employee copy of the CCF and gives it to the employee.

> **Note:** At this time, the collector can suggest that the employee list any prescription and over-the-counter medications he or she may be taking on the employee's copy (Copy 4) of the CCF, but not on any other copy. This information may help the employee remember what medications he or she may have taken if a positive result is reported by the laboratory to the MRO.

18. The collector places the specimen bottles and Copy 1 of the CCF inside the appropriate pouches of the leak-resistant plastic bag, and seals both pouches. If the employee has not had the opportunity to wash his or her hands, they may do so now. The collector then informs the employee that he or she may leave the collection site.

19. Any urine specimen left over in the collection container after both specimen bottles have been appropriately filled and sealed should be discarded at this time, if the collector has not already done so.

20. The collector places the sealed plastic bag in an appropriate shipping container designed to minimize the possibility of damage during shipment. More than one sealed plastic bag can be placed into a single shipping container if there are multiple collections.

21. The collector then sends Copy 3 of the CCF to the MRO. The collector must fax or otherwise transmit this copy to the MRO within 24 hours or during the next business day and keep Copy 2 for at least 30 days.

22. The collector or collection site must ensure that each specimen collected is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

23. If the specimen will not be shipped immediately, the collector is responsible for ensuring its integrity and security. Specimens in plastic bags, which have not been placed into shipping containers or which are awaiting a laboratory courier, must be kept in a secure location. The specimens need not be under lock and key, however, procedures must exist that would ensure specimens cannot be subject to tampering.

The collection process is now complete.

SECTION 7. SHY BLADDER PROCEDURES

The term "shy bladder" refers to a situation when the employee does not provide a sufficient amount of urine for a required drug test. If an employee tells the collector, upon arrival at the collection site, that he or she cannot provide a specimen, the collector must still begin the collection procedure regardless of the reason given. The collector should tell the employee that most individuals can provide 45 mL of urine, even when they think they cannot urinate, and

direct the employee to make the attempt to provide the specimen.

At the point in the collection procedure where the collector and employee unwrap/open a collection container, the collector does the following:

1. The collector requests the employee to go into the rest room and try to provide a specimen.
2. If the employee provided an initial insufficient specimen, the collector discards the insufficient specimen. The collector then annotates in the "Remarks" line the time when the employee provided the insufficient specimen. This is the time when the "shy bladder" collection process starts.

   Note: If the insufficient specimen is also out of temperature range (assuming there was sufficient specimen to activate the temperature strip) or shows evidence of adulteration or tampering, the collector immediately initiates another collection under direct observation.
3. The collector explains to the employee the process for a shy bladder collection and instructs the employee to drink up to 40 ounces of fluids, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first.
   - It is <u>not a refusal</u> to test if the employee <u>declines</u> to drink although the collector should explain to the employee that not drinking sufficient fluids may result in the employee's inability to provide a sufficient specimen within the required time frame and would require a medical evaluation in the event no specimen was provided if the employee chooses to do one.
   - Under <u>no</u> circumstances can a collector "combine" urine collected from separate voids to create one specimen of sufficient volume.
4. If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is completed, the collector must discontinue the collection and note the fact on the "Remarks" line of the CCF. This is a refusal to test.
5. If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, the collector must discontinue the collection and note the fact on the "Remarks" line of the CCF.

   Note: The collector should maintain a record in the "Remarks" line on the CCF or other documentation form (see appendix E) provided by the TPA, of the time of each attempt, whether there was any specimen provided or the quantity of specimen provided, and the amount of fluids that the employee was given to drink. During the waiting time, the employee must be monitored by the collector (the one conducting the collection or another collector at the site) or by another responsible collection site staff member or an IUCSAT representative. The collector must specifically tell the employee that he or she is not permitted to leave the collection site and if they do so, that it will be considered a refusal to test.
6. If an employee has a "shy bladder" situation and the collection site closes before the three hour time allowance is up this will not be a refusal to test. The employee will be given another opportunity to complete the collection without penalty provided they complete the collection the next business day.

7. The collector then sends a copy of the CCF to the MRO. This is done even if the employee did not provide any specimen in order to notify the MRO. The collector must send or fax these copies to the MRO within 24 hours or the next business day.

SECTION 8. DIRECTLY OBSERVED COLLECTION

A directly observed collection procedure is the same as a routine collection procedure with the additional requirement that an observer physically watches the employee urinate into the collection container. The observer must be the same gender as the employee; there are no exceptions to this requirement.

An observed collection is required when:

1. The TPA directs the collector (or collection site) to conduct a collection under direct observation.
   Note: A directly observed collection is required when:
   1. The laboratory reports an invalid specimen and the MRO reports that there was not an adequate medical explanation for the result.
   2. Because a request to retest a portion of the original specimen could not be performed (e.g., inadequate volume).
   3. The MRO reports a negative-dilute result with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL.`
2. The collector observed materials brought to the collection site or the employee's conduct clearly indicated an attempt to tamper with a specimen.
3. The temperature on the original specimen was out of range or the specimen appeared to have been tampered with.

   Note: The collector may serve as the observer when the collector is the same gender as the employee. If not, the collector must call upon another individual (who is the same gender as the employee) to act as the observer. The collector must verbally instruct the observer as to the procedures the observer must follow and specifically inform the observer not to take the specimen from the employee, but have the employee bring it to the collector. It is recommended that the collector have a short written outline of the procedures to be used for an observed collection, review these procedures with the observer, and provide a copy of the written procedures to the observer, if the observer requests it.

An observed collection is conducted in the following manner:

1. The collector must explain to the employee why a directly observed collection is being conducted. If the directly observed collection is requested by the TPA/MRO, the collector may state the reason (if known) or may only state that the TPA/MRO requested a directly observed collection.
2. There is no need for the collector to use a new CCF for the directly observed collection if the collector initiates a direct observe.
3. The collector then checks the "Observed, (Enter Remark)" box and enters the reason in the "Remarks" line and the name of the observer if it is someone other than the collector.

4. The collector, if the same gender as the employee, or the same gender observer enters the restroom or facility where urination occurs with the employee.
   - The observer must request the employee to raise and lower clothing to show the observer that the employee does not have a prosthetic device.
   - After the observer has determined that the employee does not have such a device, the observer may permit the employee to return clothing to its proper position and then conduct the observed collection.
   - Note: There are several basic types of devices employees could "wear." Examples:
     1. A plastic tube connected to a bottle containing heated urine.
     2. A plastic tube attached to a battery-heated plastic bag.
     3. A device that has replaced the plastic tube with very realistic prosthetic genitalia designed to match the employee's skin tone.
5. The observer must watch the employee urinate into the collection container. Specifically, the observer must personally and directly watch the urine go from the employee's body into the collection container (use of mirrors or video cameras is not permitted).
   Note: With respect to direct observation collections, the following situations are considered refusals to test:
   - The employee declines to allow a directly observed collection.
   - The employee fails to follow the observer's instructions to raise and lower their clothing to permit the observer to determine if the employee has a prosthetic or other device that could be used to interfere with the collection process.
   - The employee possesses or wears a prosthetic or other device that could be used to interfere with the collection process.

   In either of these situations, the collector discards any specimen the employee provided previously and notifies the TPA/MRO as soon as possible.
6. After the employee has completed urinating into the collection container, the employee and observer leave the enclosed toilet stall/restroom and the employee hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the employee hands the container to the collector. If the observer is the collector, the collector may receive the collection container from the employee while they are both in the enclosed toilet stall/restroom.
7. If the collector learns that a directly observed collection <u>should</u> have taken place, but was not, the collector must contact the TPA to determine if the employee must be directed to return for an immediate recollection under direct observation.

SECTION 9. MONITORED COLLECTIONS

A monitored collection is one that is conducted under less than completely private conditions, utilizing a multi-stall restroom. If there is no practicable work place outside of the restroom, the collector may set up an area within the multi-stall restroom to be used as a work area and for finalizing the required paper work. (A collection which is <u>not</u> monitored may also be conducted in a multi-stall restroom, provided that the collector secures all of the stalls (bluing agent, etc.), secures all water sources and other potential sources of adulterants (soap dispensers) in the restroom, and posts signs or otherwise secures the restroom from entry by unauthorized personnel.)

A monitored collection is conducted in the following manner:

1. The collector must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.
2. The monitor must be the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.
3. If someone other than the collector is to monitor the collection procedure (i.e., the collector is not a medical professional), the collector must verbally instruct that person to use the following procedures (if the collector is the monitor, the collector must also follow these procedures):
   (a) A monitor stands outside the stall and does not watch the employee urinate. If the monitor hears sounds or makes other observations indicating an attempt to tamper with a specimen by the employee, there must be an additional collection conducted under direct observation.
   (b) A monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.
4. When someone besides the collector has acted as the monitor, the collector must note that person's name in the "Remarks" line of the CCF (Step 2).
5. If the employee declines to permit a required collection to be monitored, it is a refusal to test.

SECTION 10. PROBLEM COLLECTIONS

CATHETERIZATION.

If an employee needs medical attention (e.g., an injured employee in an emergency medical facility who is required to have a post-accident test), treatment takes priority and should not be delayed to collect a specimen. If an employee is catheterized as part of a medical procedure (following an accident), once the employee's medical condition is stabilized and the employee can give his or her consent to the collection (e.g., understand that a collection is required, can sign the CCF), a urine specimen should be obtained from that employee. Procedures similar to those listed below may be used when an external urine bag is involved. A urine specimen must not be collected, by catheterization or other means, from an unconscious or conscious employee to conduct a drug test. However, an employee who normally voids through intermittent or self-catheterization is required to provide a specimen in that manner if he or she is required to produce a specimen for a program test. If able to, the employee may provide the specimen directly from the catheter into the collection container in the privacy of a restroom. If an employee, who normally voids through self-catheterization, declines to do so, this would constitute a refusal to test.

EXTERNAL URINE BAG.

The following procedures should be used in the collection of a urine specimen from an employee who has a medical condition requiring an indwelling catheter or excretion of urine into an external bag. The urine specimen should be a freshly voided specimen. For an employee with an indwelling catheter they may urinate directly into a collection container. In the case of an employee with an external bag, the employee should be asked to empty his or her bag in the

privacy of a bathroom, show the empty bag to the collector, and then drink sufficient fluids at the collection site to provide 45 mL of urine, which can be subsequently poured by the employee from the bag into a collection container in the privacy of a bathroom. In this case, the temperature of the specimen would not be a critical factor. The collector should be keenly aware of the potential embarrassment that this type of collection can cause the employee and should conduct the collection with appropriate decorum.

SECTION 11. CORRECTING COLLECTION PROBLEMS

When an HHS certified laboratory receives specimen bottles and the associated CCF, it checks to see if the specimen ID number on the specimen bottle labels/seals matches the number on the CCF, that the specimen bottle seals are intact, that there is sufficient specimen volume, and that the CCF has been properly completed by the collector. If there is any discrepancy and/or error of omission (i.e., the collector did not sign the chain of custody), the laboratory will contact the collector to determine if the discrepancy and/or missing information can be recovered. That is, the collector can provide a written memorandum attesting to the fact that he or she inadvertently forgot to properly document the CCF.

> **Note:** Once contacted by the laboratory or the MRO, the collector should immediately provide a statement or memorandum to recover the discrepancy and/or error of omission. Laboratories will usually retain these specimens for a minimum of 5 business days before they may be discarded; therefore, it is critical that the collector respond immediately to the laboratory's request for corrective action.

The collector has the responsibility of trying to successfully complete a collection procedure for each employee.

1. If, during or shortly after the collection process, the collector becomes aware of any event that prevents the completion of a valid test or collection (e.g., a procedural or paperwork error), the collector must try to correct the problem promptly, if doing so is practicable. The collector may initiate another collection as part of this effort.

2. If the problem resulted from the omission of required information, the collector must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. The collector must supply this information on the same business day on which he or she is notified of the problem, transmitting it by fax.

3. The collector must maintain a copy of the written and dated documentation of correction with the appropriate CCF. The collector must also mark the CCF in such a way (e.g., stamp noting correction, written notation) that it would be obvious on the face of the CCF that the corrected (missing) information was supplied.

APPENDIX A - TRAINING REQUIREMENTS FOR COLLECTORS

To be permitted to act as a collector in this drug testing program, you must meet the following requirements:

1. Basic information. You must be knowledgeable about the collection procedures described in the guide which are patterned after DOT but do contain some differences.
2. Qualification training. You must receive qualification training which provides instruction on the following subjects:
    a. All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;
    b. "Problem" collections (e.g., situations like "shy bladder" and attempts to tamper with a specimen);
    c. How to correct problems in collections; and
    d. The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate;
3. Proficiency Demonstration. Following your completion of qualification training under paragraph 2. above, you must demonstrate proficiency in collections.
    a. Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee. This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by --
        i. Regularly conducting drug test collections for a period of at least a year;
        ii. Conducting collector training under this guideline for a year; or
        iii. Successfully completing a "train the trainer" course.
4. Documentation. You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to the program representatives and to the TPA who is using or negotiating to use your services.

APPENDIX B – QUESTIONS AND ANSWERS

If you have questions, please contact the TPA (third party administrator):

MIDWEST TOXICOLOGY SERVICES, INC.
603 E. Washington Street, Suite 200
Indianapolis, IN 46204
317.262.2200 Phone
800.358.8450 Toll Free
317.262.2222 Fax

APPENDIX C – LIST OF PROCEDURES THAT DEVIATE FROM DOT COLLECTION PROTOCOL

1. A DOT chain of custody is not utilized.

2. The collector's training requirements are modified as described in Appendix A. Error correction training and refresher training are not necessarily required as outlined in DOT regulations but are encouraged.

3. The collector is directed to contact the TPA concerning any questions or problems instead of the employee's employer since many times the employee is testing when they are not on-duty or may not be employed at the time of testing.

4. The chain of custody (CCF) will not be in the same format as a DOT chain of custody (i.e. the information that must be recorded on the chain of custody may be arranged differently on the non-regulated chain of custody).

5. The DER name and telephone number is NOT required on the CCF.

6. When the collector directs the employee to empty their pockets and finds an item that appears to have been brought to the collection site with the intent of adulterating or substituting a specimen, this will be considered a refusal to test and the collector does not need to proceed with a direct observation.

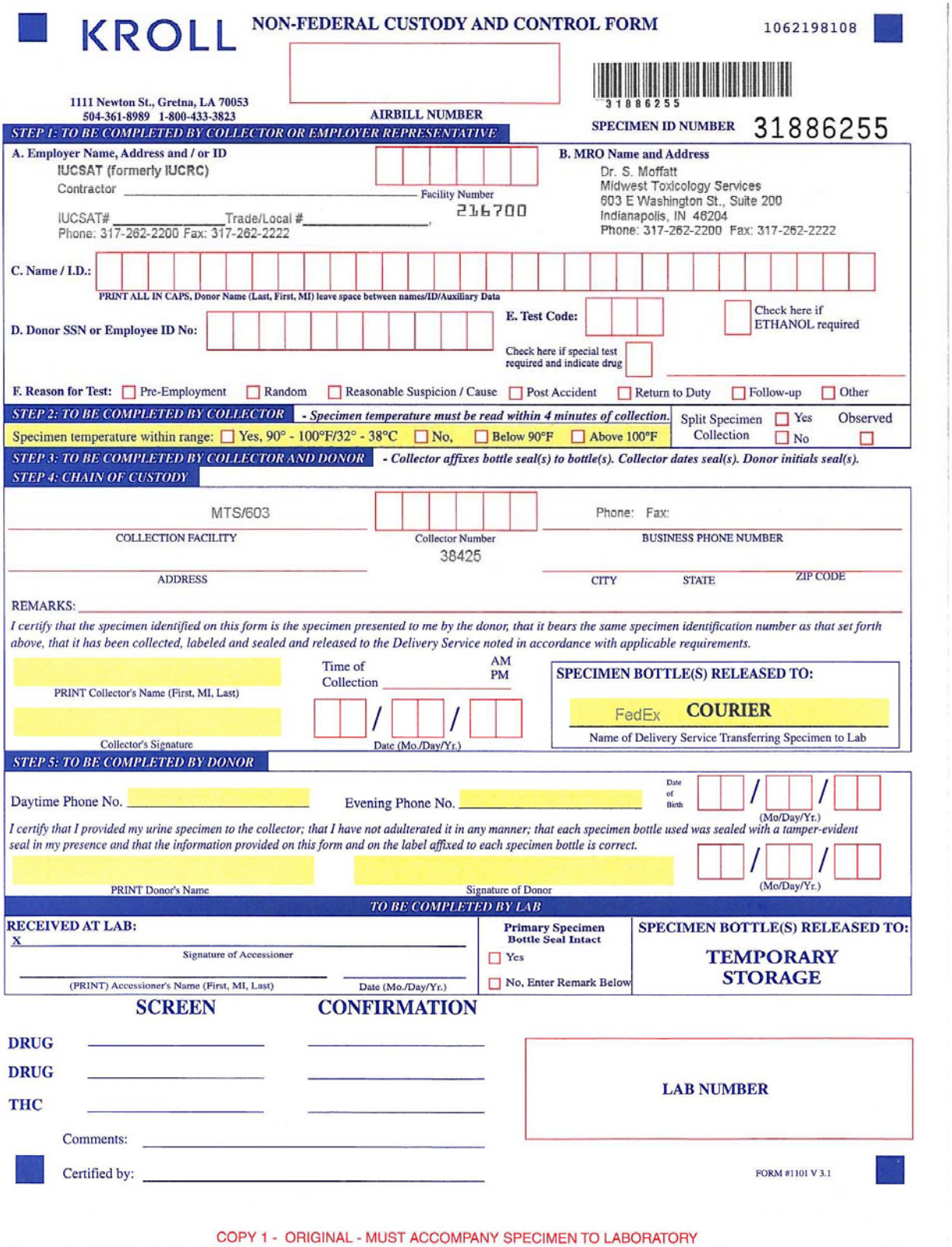
7. The employee does not need to select the collection kit.

8. The collector can accept a minimum of 30 mL and complete the collection as a single specimen collection.

9. If the employee provides an unacceptable specimen, the unacceptable specimen will be discarded and the collector will continue to use the same CCF to complete a direct observed collection.

10. In a direct observation, the employee will not be required to turn around when the observer is checking for prosthetic devices. The employee will need to remove enough clothing for the observer to be satisfied that the employee isn't wearing a prosthetic device or items used to carry in a "clean" specimen.

APPENDIX D – SAMPLE KROLL CHAIN OF CUSTODY FORM (CCF)



KROLL

NON-FEDERAL CUSTODY AND CONTROL FORM

1062198108

1111 Newton St., Gretna, LA 70053
504-361-8989 1-800-433-3823

AIRBILL NUMBER

31886255

SPECIMEN ID NUMBER 31886255

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and / or ID
IUCSAT (formerly IUCRC)
Contractor
Facility Number 216700
IUCSAT# Trade/Local #
Phone: 317-262-2200 Fax: 317-262-2222

B. MRO Name and Address
Dr. S. Moffatt
Midwest Toxicology Services
603 E Washington St., Suite 200
Indianapolis, IN 46204
Phone: 317-262-2200 Fax: 317-262-2222

C. Name / I.D.:
PRINT ALL IN CAPS, Donor Name (Last, First, MI) leave space between names/ID/Auxiliary Data

D. Donor SSN or Employee ID No:

E. Test Code:

Check here if ETHANOL required

Check here if special test required and indicate drug

F. Reason for Test: Pre-Employment Random Reasonable Suspicion / Cause Post Accident Return to Duty Follow-up Other

STEP 2: TO BE COMPLETED BY COLLECTOR - *Specimen temperature must be read within 4 minutes of collection.*

Specimen temperature within range: Yes, 90° - 100°F/32° - 38°C No, Below 90°F Above 100°F

Split Specimen Collection Yes No Observed

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - *Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).*

STEP 4: CHAIN OF CUSTODY

MTS/603
COLLECTION FACILITY

Collector Number 38425

Phone: Fax:
BUSINESS PHONE NUMBER

ADDRESS

CITY STATE ZIP CODE

REMARKS:

I certify that the specimen identified on this form is the specimen presented to me by the donor, that it bears the same specimen identification number as that set forth above, that it has been collected, labeled and sealed and released to the Delivery Service noted in accordance with applicable requirements.

PRINT Collector's Name (First, MI, Last)

Collector's Signature

Time of Collection AM PM

Date (Mo./Day/Yr.)

SPECIMEN BOTTLE(S) RELEASED TO:

FedEx COURIER

Name of Delivery Service Transferring Specimen to Lab

STEP 5: TO BE COMPLETED BY DONOR

Daytime Phone No.

Evening Phone No.

Date of Birth (Mo/Day/Yr.)

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

PRINT Donor's Name

Signature of Donor

(Mo/Day/Yr.)

TO BE COMPLETED BY LAB

RECEIVED AT LAB:
X
Signature of Accessioner

(PRINT) Accessioner's Name (First, MI, Last)

Date (Mo./Day/Yr.)

Primary Specimen Bottle Seal Intact
Yes
No, Enter Remark Below

SPECIMEN BOTTLE(S) RELEASED TO:
TEMPORARY STORAGE

	SCREEN	CONFIRMATION
DRUG		
DRUG		
THC		

LAB NUMBER

Comments:

Certified by:

FORM #1101 V 3.1

COPY 1 - ORIGINAL - MUST ACCOMPANY SPECIMEN TO LABORATORY

APPENDIX E – SHY BLADDER FORM – IUCSAT PROGRAM

Date: _____ **Donor Name:** _____

CCF Number:_____

Shy bladder time interval **began at:** Time of initial collection: _____a.m. p.m.
Shy bladder time allowance **ends three (3) hours after time of initial collection noted above.**

Instruct the donor to not drink any fluids except fluids that can be documented on this log. A collector or a DER must monitor the donor during the waiting period until a sufficient specimen is provided. All fluids provided and collection attempts made **after the initial attempt** must be documented.

Documentation of Fluids Given:

Amount of Fluid (oz.)	**Time** Provided

Documentation of attempts to provide specimen

Attempts (after initial attempt)	Time of Attempt	**# of mL provided**
1st		
2nd		
3rd		
4th		

Final Disposition of this shy bladder – check all appropriate responses:

- ☐ Donor provided a sufficient specimen
- ☐ Donor did not provide a sufficient specimen. Donor was informed that the collection is discontinued.
- ☐ TPA/MRO was notified of this situation and, if applicable, donor was provided with medical evaluation referral form.
- ☐ This form was attached to the Collector Copy of the chain of custody
- ☐ A copy of this form was sent with the MRO Copy of the chain of custody.

Other notes/remarks:_____

_____

_____

Collector: _____ _____
Printed Name Signature

APPENDIX F – PROBLEM DOCUMENTATION FORM – IUCSAT PROGRAM
Fax completed form to: 317-262-2222

This form is to be used for collection issues noted below for collections performed for the IUCSAT program. Please fill in donor's name, ID# and check all applicable issues, have donor and collector sign as designated.

Donor Name: _____ **ID or last 4 SS#:** _____

I, the undersigned donor, certify that the following procedures have been explained to me:

☐ **Unacceptable specimen provided – direct observed required.**
- A same gender collector will immediately collect a second specimen under direct observation.
- I have been informed that my unacceptable specimen will be discarded and not sent to the laboratory.
- I have been instructed not to leave the testing site. And if I leave before a second collection is completed it will be considered a **"REFUSAL**" to test.

Describe Issue:_____

☐ **Shy Bladder – Inadequate Specimen Volume – I understand my first specimen was not of sufficient volume to be accepted. I have been advised that:**
- I will be allowed to drink up to 40 ounces of fluids over a three hour period.
- I have been instructed not to leave the testing site. If I leave before the testing process is completed this will be considered a **"REFUSAL**" to test.

☐ **Specimen Temperature Out of Range – I understand my first specimen was not within acceptable temperature range (90 – 100 degrees). I have been advised that:**
- A same gender collector will immediately collect a second specimen under direct observation.
- I have been informed that my unacceptable temperature specimen will be discarded and not sent to the laboratory.
- I have been instructed not to leave the testing site. And if I leave before a second collection is completed it will be considered a **"REFUSAL**" to test.

☐ **Refusal to Test – I understand that one or more of the following occurred during the testing process which has resulted in a refusal to test:**
- ❑ A prosthetic or other device used to interfere with the collection process was detected.
- ❑ I refused to complete a 2nd collection under direct observation as required by collector.
- ❑ I admitted to the collector that I adulterated or substituted the specimen.

Other pertinent information or explanation:_____

_____

_____ _____ _____ _____
Donor Name/Signature Date Collector Name/Signature Date

☐ Donor was offered opportunity to read and sign this form, but refused to do so.

****Collector Instructions**: Fax the following items to Midwest Toxicology at **317/262-2222**
- MRO copy of CCF (custody & control form) - Document issues in "remarks" area, print & sign collector area
- This completed form with all appropriate areas checked.
- Testing Authorization Form (if one was provided).
- Attach any other written documentation you deem important.

Midwest Toxicology Services, Inc.
Your Key to Success
MTS