

Use Of An Electronic Custody and Control Form for Federal Workplace Testing

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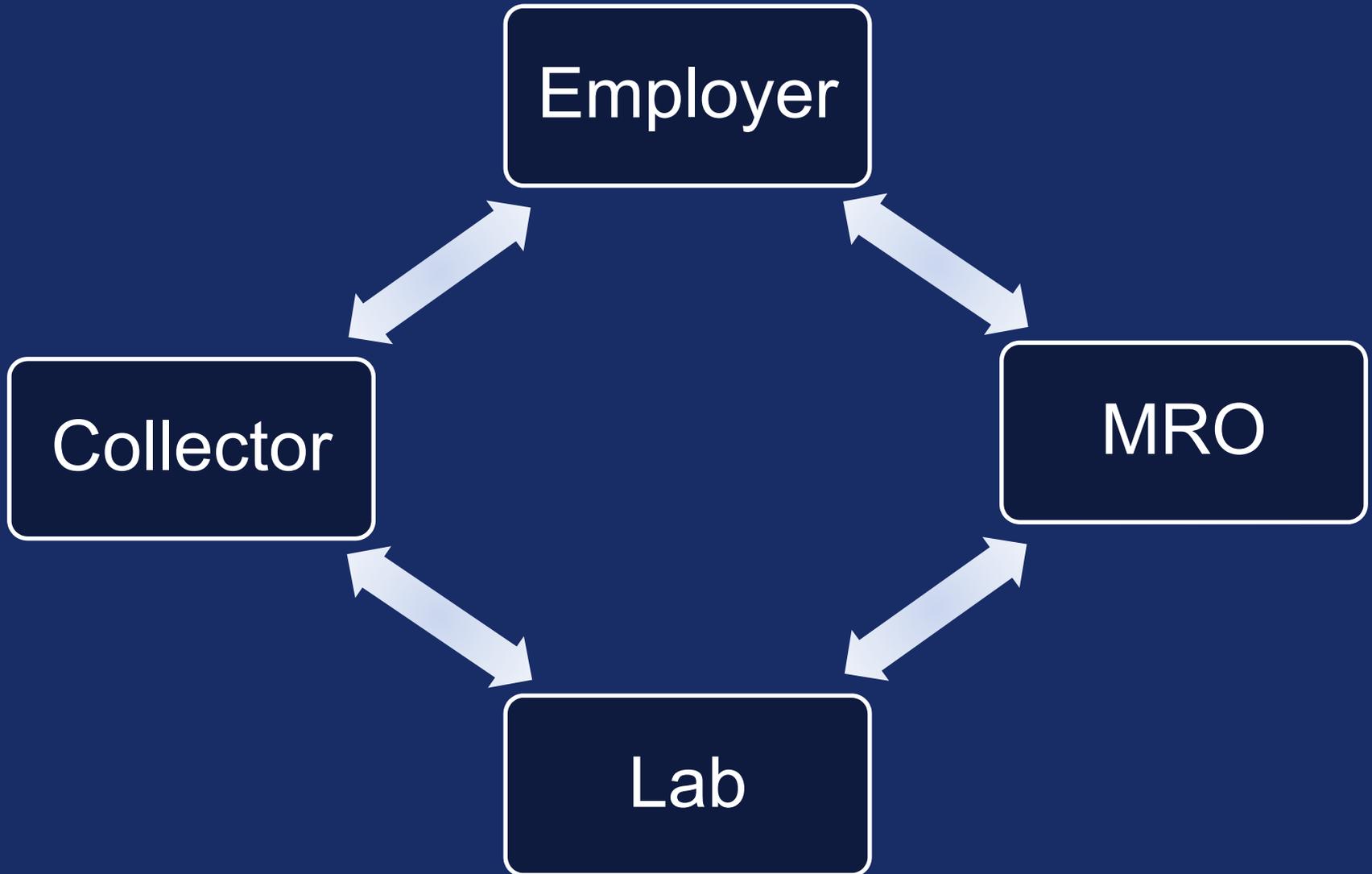
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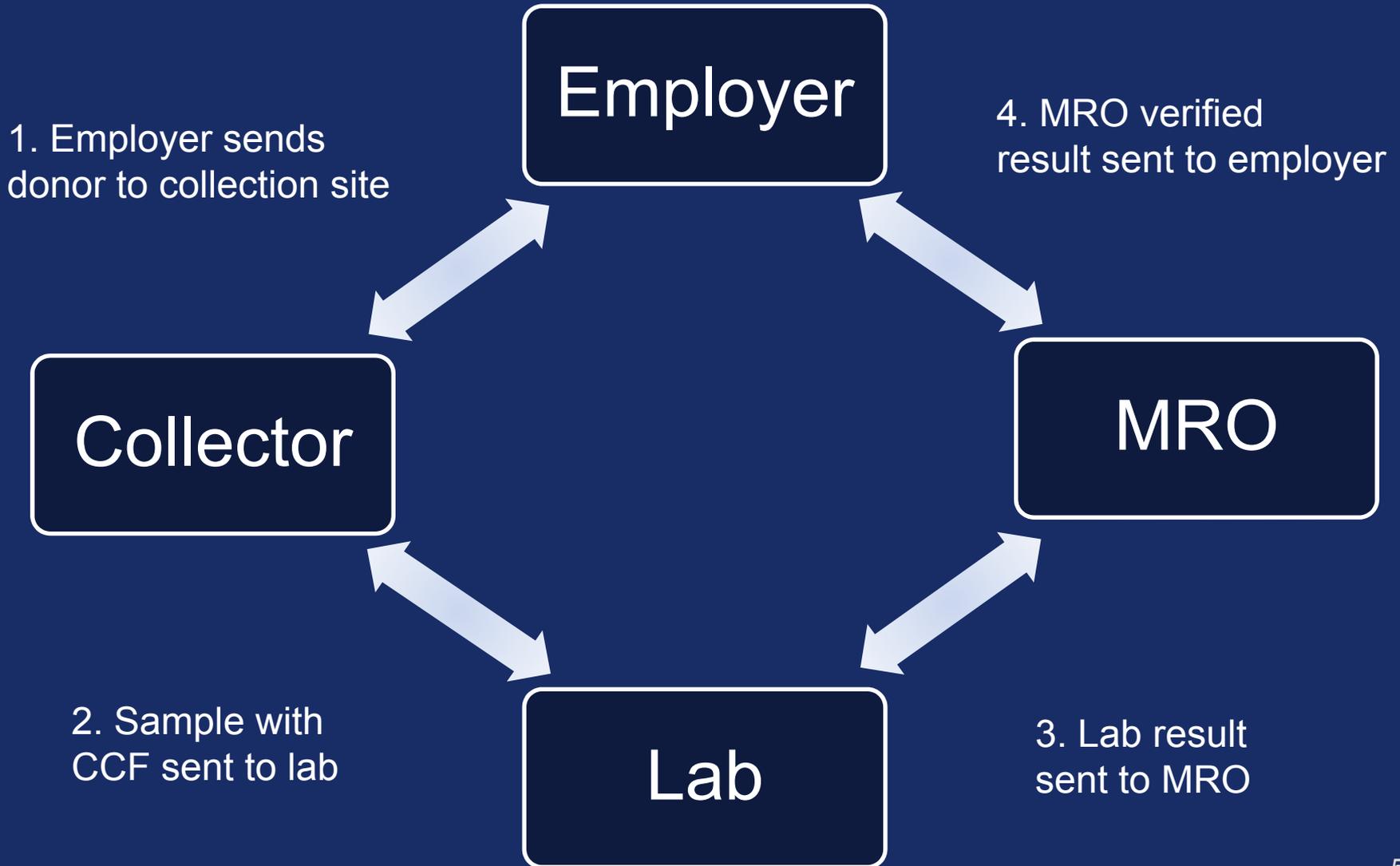
Why An Electronic CCF (eCCF)?

- Federal Drug Testing Program has successfully been operating for more than 22 years
- Began with a 7 part CCF (carbonless)
- Current form is now a 5 part CCF (carbonless)

Why An Electronic CCF (eCCF)?



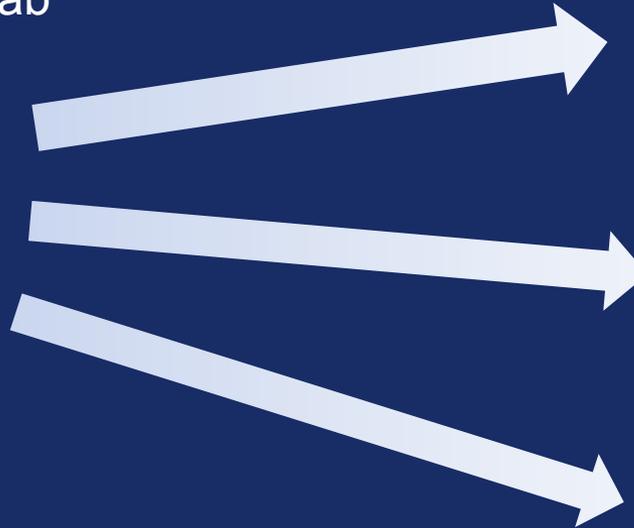
Why An Electronic CCF (eCCF)?



Why An Electronic CCF (eCCF)?

1. Printed Lab copy accompanies sample to lab

Collector



Lab

MRO

Employer

2. Collector faxes MRO copy to fax number on CCF
3. Collector mails employer copy to employer
4. Collector provides donor copy to donor at the time of collection
5. Collector files collector copy in collection site files

Why An eCCF?

- In 2009 Department of Transportation conducted 5,163,165 drug tests
 - Copy 1 Testing Facility
 - Copy 2 MRO Copy
 - Copy 3 Collection Site Copy
 - Copy 4 Employer Copy
 - Copy 5 Donor Copy

Why An eCCF?

- 5,163,165 drug tests
- Five part carbonless CCF
- Handling 25,815,825 individual pieces of paper

Current CCF Issues

- The current CCF requires higher quality impact printers to print legible copies
- Most common method of transmitting CCF copies are via fax
 - Some faxes are better quality than others
 - Some collection sites do not have fax machines
 - Mail copies of the CCF
 - Impacts TAT for the MRO review process

Current CCF Issues

- MROs are constantly contacting collection sites to:
 - Request copies of CCFs that they never received
 - Asking for “enhanced” copies of the CCF
 - Collection site either makes a darker copy and re-faxes or traces over the information on the CCF to make it darker and then re-faxes the CCF

Current CCF Issues

- Statistics from one large MRO organization
- In one 7 day period
 - Received 5842 DOT results
 - 411 donor signature issues
 - Illegible signatures or missing donor signature
 - 1283 CCFs unable to process
 - Missing the CCF or needed clarification
- 29% of DOT results delayed due to CCF issues

Current CCF Issues

- Incomplete information on CCF
 - Temperature box not checked
 - Lab must attempt to obtain a certificate of correction from the collection site
 - If certificate of correction not received after 5 days, lab may report the result to the MRO
 - Delays results reporting to the MRO

Current CCF Issues

- Illegible information on CCF
 - Can't read collectors name (lab uses best guess technique)
- Donor id (SSN or other identifier) illegible or incorrect
 - Lab uses best guess technique
 - Can result in the incorrect reporting of a result
 - Often results in collection site sending a memorandum of correction to correct the SSN
 - Problematic on a non-negative result

Current CCF Issues

- Additional MRO statistics
- 9738 reviewed DOT tests
- 5.1% had collector errors
 - Temperature box not checked
 - No collector signature
 - Incorrect dates
 - Missing donor signature
 - Incorrect employer information

Current CCF Issues

- This missing or incorrect information adds anywhere to 1-6 additional days to the MRO process
- Hidden costs
 - One large MRO group determined that “chasing” CCF copies and getting certificates of correction added an additional \$4.00 per sample to their costs.

Current CCF Issues

- Immense inventory of CCFs in the field
 - Labs incur higher direct costs to maintain field inventory
 - Laboratories send out on average 1.8 chain of custodies for every one that they get back
- Not unusual to see versions of CCFs submitted to the laboratory that are several years old

Current CCF Issues

- Information on the CCFs are not always current
 - MRO changes
- Collection sites have to deal with maintaining inventory of CCFs for each lab
 - Collection site may also have to deal with maintaining inventory for multiple clients for the same laboratory

Industry Moves Forward with eCCF

- The drug testing industry has moved forward with electronic CCFs (eCCFs) for non-regulated collections and testing. Organizations with eCCFs include but are not limited to:
 - MedTox eChain
 - eScreen
 - FormFox – eCCF provider for Quest and several other laboratories
 - Quest
 - LabCorp

Industry Moves Forward with eCCF

			
401 West County Road 11 Burnsville, MN 55112 651-636-7466, 800-832-2244		eChain®	
		RA01002476	
CHAIN OF CUSTODY FORM LABORATORY COPY #1 (Send this copy with the specimen to MEDTOX)			
Client/Employer Information:			
Name: MEDTOX DREAM NORN DOT Address: 409 W. COUNTY RD 11 St Paul, MN 55112 P: 651-636-7466 FAX: 651-636-7466		MRO Name: DR. MRO Address: Fourn and Blakely Avenues, MN 55112 Phone and Fax #:	
Account #: 55558			
Donor Information:			
Name: Eric Erickson Date of Birth: 11/11/11		Date of Birth: 11/11/11 Daytime Phone #: 111-111-1111 Evening Phone #:	
Clinic/Collection Site Information:			
Name: EQMO ONLY Test Collection Site Address: 401 County Road D New Brighton, MN 55112		Site #: 19887 Phone #: N/A Collector Name: METX 1086	
Test Information:			
Test Ordered: 3 (Send) + Valzay (88564)		RA01002476 Reason For Test: Pre-Employment	
Collection/Specimen Information:			
Specimen Type: Urine Collected Date/Time: 4/21/2011 9:27:00 AM Volume: 1 oz (30 ml) Observations:		Temperature: 92 F Specimen Collection: Single	
DONOR CERTIFICATION AND CONSENT I certify that I provided my assistance to the collector, that the applicant/collector was tested with a proper protocol in my presence, and that the information provided on this form, and on the label affixed to the specimen bottle is correct. I am not an MRO, I am not a doctor or other health care provider, I am not an employee, proprietor, employer, employer representative, or under direct medical supervision of a health care provider.			
Donor Signature: _____		Date: 4 / 21 / 2011 Month Day Year	
COLLECTOR CERTIFICATION I, the collector, by signing below, certify that the Specimen stated to be on this form is the Specimen given to me by the Donor identified above and that the Specimen has been collected, labeled, and returned in the correct manner in accordance with all applicable requirements.			
Collector Name/Signature: METX 1086		Date: 4 / 21 / 2011 Month Day Year	
MEDTOX LABORATORY USE ONLY I certify that on the date indicated, I received this Specimen from the Courier, accessioned and transferred this Specimen to temporary storage.			
Received By Name/Signature: _____		Date: _____ Month Day Year	
COMPLETED BY MRO - PRIMARY SPECIMEN In accordance with applicable requirements, my determination/verification is: <input type="checkbox"/> NEGATIVE <input type="checkbox"/> POSITIVE <input type="checkbox"/> DILUTE <input type="checkbox"/> TEST CANCELLED <input type="checkbox"/> REFUSAL TO TEST BECAUSE: <input type="checkbox"/> ADULTERATED <input type="checkbox"/> SUBSTITUTED			
MRO Name/Signature: _____		Date: _____ Month Day Year	
COMPLETED BY MRO - SPLIT SPECIMEN In accordance with applicable requirements, my determination/verification for the split specimen is/are: <input type="checkbox"/> RECONFIRMABLE <input type="checkbox"/> FAILED TO RECONFIRM - REASON: _____			
MRO Name/Signature: _____		Date: _____ Month Day Year	
©2009 MEDTOX & affiliates, Inc. All rights reserved. Printed Date: Thursday, April 21, 2011 9:28 AM EDT			

Industry Moves Forward with eCCF

eScreen 10895 Grandview, Suite 220 Overland Park, KS 66210 (800)881-0722		Chain Of Custody 00000001 *000000001*	Lab ID: LABONE Lab Acct #: TEST Lab Panel ID: CD51 Panels: 5 Panel
eScreen STEP 1.	Company Account Test Account 5900 Wilshire Blvd. Los Angeles CA 90036 (800)733-6676 Jackie	00000010-9999 Medical Review Officer Test Test 123 Nowhere Test KS 66211	
STEP 2. TO BE COMPLETED BY COLLECTOR Specimen temperature for urine specimens must be read within 4 minutes of collection. Specimen temperature within range: Yes Verified Donor ID <input checked="" type="checkbox"/>		STEP 3. TO BE COMPLETED BY COLLECTOR AND DONOR Collector affixes bottle seal on specimen. Type: <input checked="" type="checkbox"/> Urine <input type="checkbox"/> Oral <input type="checkbox"/> Blood <input type="checkbox"/> Breath	
STEP 4. Reason for Test: <input checked="" type="checkbox"/> Pre-employment <input type="checkbox"/> Return to duty <input type="checkbox"/> Promotion <input type="checkbox"/> Post-accident <input type="checkbox"/> Follow up <input type="checkbox"/> Transfer <input type="checkbox"/> Random <input type="checkbox"/> Reasonable suspicion/cause			
STEP 5. TO BE VERIFIED BY			
999-99-9999 Donor SSN	12/19/1972 Date of Birth	(913)327-5915 Daytime Phone Number	Evening Phone Number
		Other ID	
<small>I certify that I provided my specimen to the collector, that I have not adulterated it in any manner, that the 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 the specimen bottle is correct.</small>			
John Smith Donor's Name		11/07/2002 03:40 PM CST Date & Time	 Signature of Donor
STEP 6. TO BE VERIFIED BY COLLECTOR			
Name of Collection Site, Address, City, ST, Zip Test Account 5900 Wilshire Blvd. Suite 2200 Los Angeles CA 90036			Collection Site ID 00010
<small>I certify that the specimen identified on this form as the specimen presented to me by the donor providing the certification on Step 4 of this chain of custody form, that it bears the same specimen identification number as was set forth above, and that it has been collected, labeled and sealed as in accordance with applicable requirements.</small>			
Christy Schroeder Collector's Name		11/07/2002 03:40 PM CST Date & Time	 Signature of Collector
STEP 7. LAB RECEIVED			
		Date & Time	Signature

ORIGINAL MUST ACCOMPANY SPECIMEN TO LABORATORY

Industry Moves Forward with eCCF

FORENSIC DRUG TESTING CUSTODY AND CONTROL FORM

5 1 0 3 2 3 2 7 7 9 1 6 0 0

0090098065

QUEST Diagnostics

SPECIMEN ID NO. 791803 LAB ACCESSION NO.

Employer Name, Attention, Address, Phone and Fax No. FORMFOX TEST COMPANY ATT. 1414 S MAIN ST SALT LAKE CITY, UT 84115 Phone# (888)888-8888	Site Location TEST LOCATION FORMFOX Doctor, MD FORMFOX MRO 1414 S MAIN ST SALT LAKE CITY, UT 84115 Phone: (888)888-8888, Fax: (801)888-8888	MRO Name, Attention, Address, Phone and Fax No.
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Donor SSN or Employee ID: 111111111 Donor Name: Doe, John
Reason for Test: Random
Tests to be Performed: SAP 10-50/2000 W/NIT(2318N)

Collection Site Name: FormFox Collections Collection Site Code: UT111
Address: 1414 South Main Street Collector Phone No. (888)888-8888
City, State and Zip: Salt Lake City, UT 84115 Collector Fax No. (801)888-8888

Read specimen temperature within 4 minutes. Is temperature between 50° and 100°F? **Yes** Specimen Collection: **Single**

REMARKS:

I certify that the specimen prior to or the donor's signature is a collection under the Step 3 of the form was collected, sealed, sealed and released to the Editor. Some valid in accordance with applicable requirements.

Time of Collection: 5:43 PM

Signature of Collector: FormFox Collector Date of Collection: 3/28/2007

Signature of Donor: John M. Doe Date of Birth: 9/28/2007

Primary Specimen Bottle Seal Intact: Yes No, Enter Remark Below

SPECIMEN BOTTLE(S) RELEASED TO:
 Quest Diagnostics Courier FedEx
 DHL / Airborne Other

COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector, that I have not and I have not in any way, each specimen bottle used was collected in a proper manner, and that the location and the date provided on this form are the same as the date and time of collection.

Signature of Donor: John M. Doe Date of Birth: 9/28/2007
Daytime Phone No. 555-555-5555 Evening Phone No. 555-555-5555 Date of Birth: 9/28/2007

Company: FORMFOX TEST COMPANY MRO: FORMFOX MRO, MD Phone#: 8888888888
Reason: Random Specimen#: 791803
Date: 3/28/2007 22:40 Site: FORMFOX COLLECTIONS
Testing Lab: Quest Diagnostics Account: 51032327

DONOR RECEIPT: Should the results of the laboratory tests for this form be confirmed positive, you may be contacted and asked about prescription or over-the-counter medications you may have taken. You may want to make a list of those medications or the back of this receipt for your own records.

3/28/2007 Date Donor's Initials (A) 0090098065
3/28/2007 Date Donor's Initials (B) 0090098065

3/28/2007 Date Donor's Initials (A) 0090098065
3/28/2007 Date Donor's Initials (B) 0090098065

Industry Moves Forward with eCCF

		URINE CHAIN OF CUSTODY FORM		COPY 1 – LABORATORY <small>300 P Revised 1/2008</small>	
<small> Laboratory Corporation of America Holdings 1904 Alexander Dr., Research Triangle Park, NC 27709 69 First Ave., Raritan, NJ 08869 </small>		<small> 7207 North Gessner, Houston, TX 77040 1120 Main St., Southaven, MS 38671 </small>		 1234567890	
Specimen Id No. 1234567890					
STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE					
A. Employer Name, Address, Phone, Fax, I.D. No.: . 00000 Phone: aull Fax: (555)222-2222 Location: 992629		B. MRO Name, Address, Phone, Fax: DR. MRO 500 SECOND STREET ANYWHERE, NC 26000 Phone: (555)333-3333 Fax: (000)000-0000		 992629	
C. Donor SSN: 111111111 Donor I.D.: DONORID D. Reason for Test: EXAMPLE COC FORM - DO NOT USE - DO NOT SUBMIT!					
E. Collection Site Address: 1515 Main St MYSORE, TX 12345 Collector Phone No. (123)555-9999 Collector Fax No. (123)555-9999					
F. Donor Identification Verified By: PHOTO ID					
STEP 2: TO BE COMPLETED BY COLLECTOR Read specimen temperature within 4 minutes. Is temperature between 90 & 100 F? YES Split Specimen Collection? NO Collection Observed? NO REMARKS: EXAMPLE COC FORM - DO NOT USE - DO NOT SUBMIT! EXAMPLE COC FORM - DO NOT USE - DO NOT SUBMIT!					
STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR Collector affixes bottle seal(s) to container(s). Collector dates seal(s). Donor initials seal(s)					
STEP 4: TO BE COMPLETED BY COLLECTOR AND DONOR G. Daytime Phone: (919)123-4567 Evening Phone: (919)123-4567 Date of Birth (Mo/Day/Yr): 11/01/0068 Clinic Info : ClinicInfo , Donor Sex : m , Dept ID : DEPTIDRANDOMTEST , License Number : 1234567 , Parole Officer : Paroleofficer					
H. TEST(S) REQUESTED BY EMPLOYER: 70010, 70011, 70012, 70013, 70014, 70015, 70016, 70017, 70018, 70019.					
Customizable text line 1 Customizable text line 2 Customizable text line 3 Customizable text line 4 Customizable text line 5					
I authorize the collection of this specimen for the purpose of a drug screen. I acknowledge that the specimen container(s) was/were sealed with tamper-proof seal(s) in my presence; and that the information provided on this form and on the label(s) affixed to the specimen container(s) is correct. I authorize the laboratory to release the results of the test to the company identified on this form or its designated agents.					
Firstname Lastname Donor's Name (First MI Last) _____		Signature of Donor _____		04/21/2011 Month Day Year	
STEP 5: CHAIN OF CUSTODY-INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY I certify that the specimen given to me by the donor identified on this form was collected, labeled, sealed, and released to the Delivery Service noted in accordance with applicable requirements.					
X _____ Signature of Collector <small>See Collector Collector's Name (First Last)</small>		Collection Time: 10:33 AM EDT Collection Date: 04/21/2011		SPECIMEN BOTTLE(S) RELEASED TO: LabCorp Courier <small>Name of Delivery Service Transferring Specimen to Lab</small>	
RECEIVED AT LAB: X _____ Signature of Accessorator <small>(Print Accessorator's Name (First, MI, Last))</small>		Primary Specimen Bottle Seal Intact [] Yes [] No, enter remark below		SPECIMEN BOTTLE(S) RELEASED TO: _____ Date _____ Donor's Initials _____	
CONTAINER SEAL WEB  1234567890		 1234567890  1234567890		+ A _____ Date _____ Donor's Initials _____ + B SPLIT _____ Date _____ Donor's Initials _____	
 Align the + with the center of top to seal both sides.					

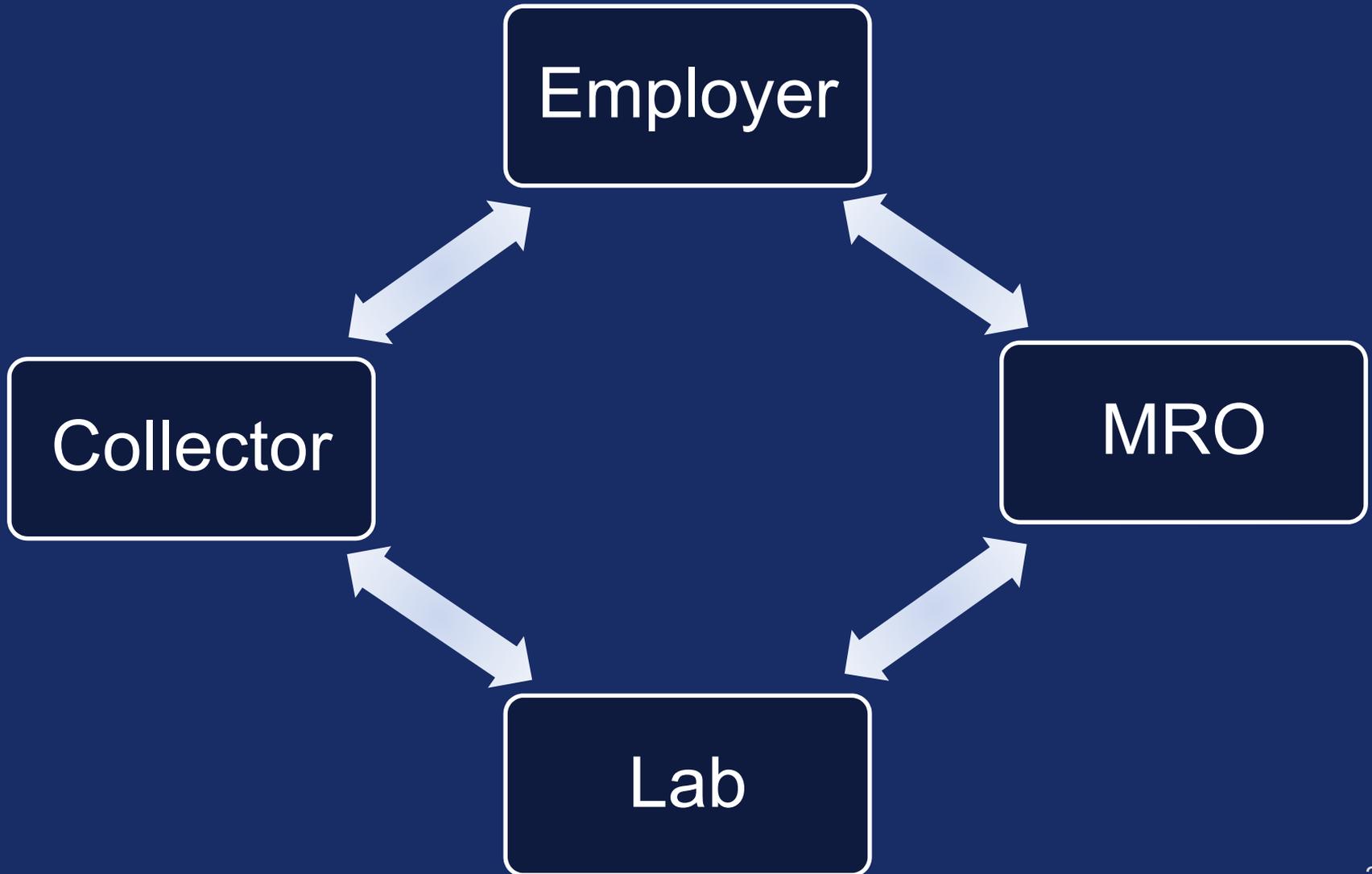
Industry Moves Forward with eCCF

- Industry currently comprised of :
- Print On Demand
 - Follows established collection protocols
 - Instead of stocking CCFs, collection site can download or enter donor, customer, lab, MRO data and print the CCF-hence the term Print On Demand
 - May use wet or digitized signature for donor and collector

Industry Moves Forward with eCCF

- Industry currently comprised of :
- Variations of print on demand
 - Collection site may only print copy for donor and lab copy to send with sample
 - Other forms sent electronically to customer and MRO
 - May use wet or digitized signature
- Systems have flexibility to do combinations of print on demand or full electronic CCFs

eCCF Features And Advantages

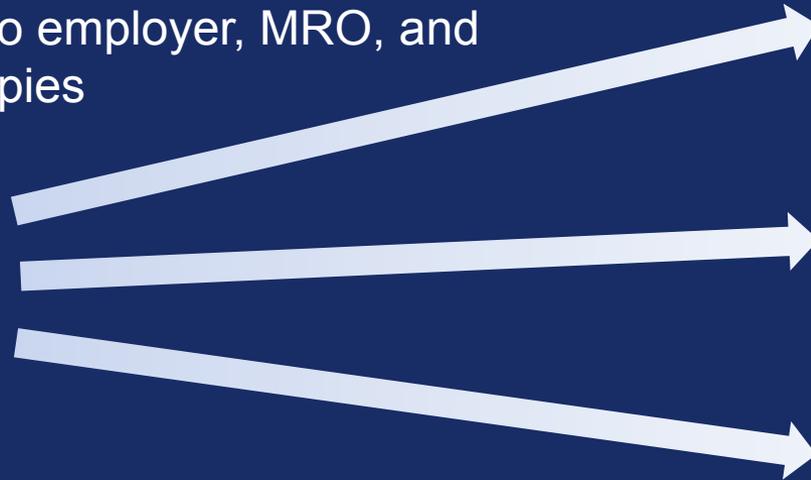


eCCF Features And Advantages

1. Lab copy accompanies sample to lab (optional)

2. Collector has option to email, auto fax, or provide download link to employer, MRO, and donor for respective copies

Collector



Lab

MRO

Employer

3. Collector's copy is saved electronically

eCCF Features And Advantages

- One Category 5 SAMHSA Certified Laboratory
 - Processing over 12,000 specimens a day
 - 600-1000 per day using their eCCF
- This lab's eCCF process is completely paperless
 - Collection site performs collection using eCCF
 - Bottle scanned at laboratory pulls up completed eCCF
 - MRO copy sent electronically
 - Employer copy sent electronically
 - Collection site copy maintained electronically
 - Can print donor copy if requested

eCCF Features And Advantages

- Increased accuracy and legibility of the information
- Systems are web based
 - Collection site can enter donor and customer demographics base on information provided by the employer
 - “Passport”
 - Other authorizations such as Applicant Tracking Systems

eCCF Features And Advantages

- Employer can pre-populate authorization which is then downloaded to the collection site
- Donor arrives at collection site
- Presents identification and authorization
- Can use other authorization such as bar-coded authorization sent to iPhone
- Collection site scans bar-code or enters authorization, donor, employer, lab, MRO information loaded

eCCF Features And Advantages

- Ability to make data fields “mandatory”
 - Eliminates missing data such as checking the temperature box
 - Eliminates delays in reporting by the laboratory and subsequent delays in the MRO review process
- Significant improvement in the accuracy and legibility of information

eCCF Features And Advantages

- One organization has been using their eCCF for over 10 years
- Processed over 15,000,000 eCCFs
- No affidavits

eCCF Features And Advantages

- Eliminates the need to fax copies
 - Copy 2 is sent electronically to the MRO
 - Improved accuracy and legibility = better TAT
 - Copy 4 can be sent electronically to the employer
 - Significantly reduces inventory of CCFs by lab and storage of multiple CCFs at the collection sites = cost savings

eCCF Features And Advantages

- Web based systems are easier to administer and update, keep secure and maintain real time synchronization
- Most collection sites have computers with internet access

eCCF Features And Advantages

- Existing eCCF processes:
 - Are web based systems
 - Combination of eCCF and print on demand features
 - Utilize encrypted transmissions
 - Have flexible input mechanisms for donor, customer and laboratory information
 - Utilize unique specimen numbers assigned by the lab
 - Utilize digitized signatures

eCCF Issues To Address

- Instructions for completing the Federal CCF
- Public Burden Statement
- Privacy Act Statement
- Proposed Resolution
 - These documents can be presented electronically to the donor
 - Donor reads and acknowledges these statements through the use of a digitized signature, which is captured and stored

eCCF Issues To Address

- Security and integrity of the eCCF
 - How is the eCCF information structured and protected from change once the document is created

eCCF Issues To Address

- Use of Electronic Signatures
- Specifically electronic/digital vs. digitized signatures

eCCF Issues To Address

- Electronic/digital signatures are cryptographic mechanisms
- Signed using a digital certificate often tied to biometric credentials
- Digitized signatures are a facsimile of a wet-signature
- Pen-like device in conjunction with a sensitized surface translates the movement of the pen into electronic data

eCCF Issues To Address

- Federal Motor Carrier Safety Administration (FMCSA)
 - Federal Register: January 4, 2011
 - Volume 76, Number 2
- FMCSA issues regulatory guidance concerning the use of electronic signatures and documents to comply with FMCSA regulations.

Electronic Signatures

- References the Government Paperwork Elimination Act, October 1998 (GPEA)
- The Electronic Signatures in Global and National Commerce Act, June 2000.

Electronic Signatures

- GPEA defines an electronic signature....
 - Identifies and authenticates a particular person as the source of the electronic communication
 - Indicates such person's approval of the information contained in the electronic communication
- GPEA states that electronic records and their related electronic signatures shall not be denied legal effect, validity or enforceability merely because they are in electronic form

Electronic Signatures

- FMCSA
 - “Any electronic document or signature is considered the legal equivalent of a paper document or signature if it is the functional equivalent with respect to integrity, accuracy and accessibility. The substance of the document must otherwise comply with applicable Federal laws and Agency rules.”
- Must be able to store and retrieve the electronic data in accordance with Agency requirements.

Electronic Signatures

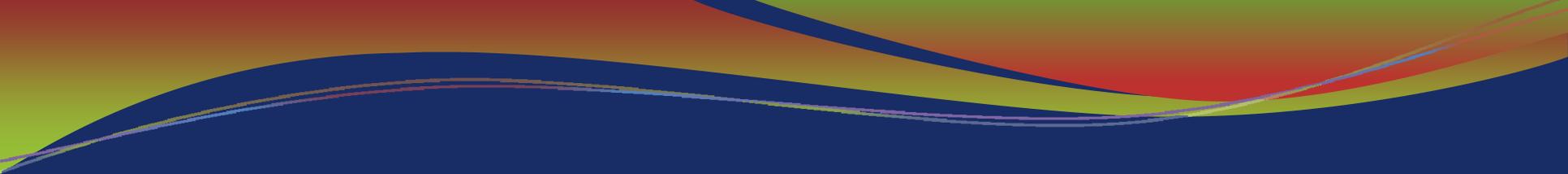
- Currently a variety of software programs available for the use of digitized signatures extensively used in:
 - Retail
 - Health Care
 - Banking
- Third party vendors

Electronic Signatures

- Laboratories and service providers that are currently using digitized signatures
- Have processed over 16,000,000 eCCFs using digitized signatures without incident
- Critical component is the ability of the application to maintain integrity of these digitized signatures and the electronic document

eCCF Summary

- Existing eCCF processes:
 - Are web based systems
 - Combination of eCCF and print on demand features
 - Utilize encrypted transmissions
 - Have flexible input mechanisms for donor, customer and laboratory information
 - Utilize unique specimen numbers assigned by the lab
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QUESTIONS?