

formfox[®] **flex**[™] URINE POCT

Collection Materials



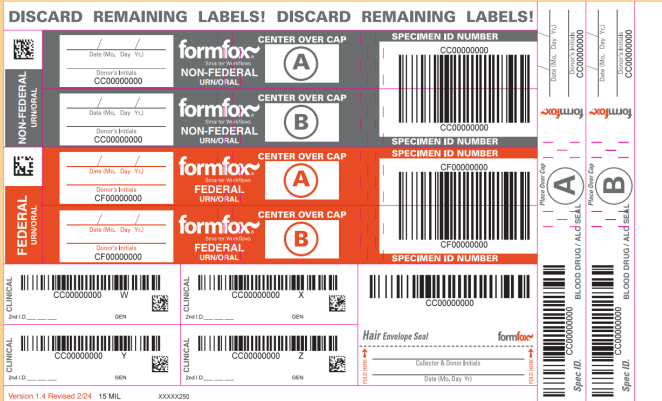
IPAD WITH FORMFOX APP



FORMFOX FLEX CUP



FORMFOX FLEX CUP STAND



FORMFOX LABELS



Flex Collection Setup

**PLACE FORMFOX
FLEX CUP ON STAND**



Note the fork/slot on the front of the cup stand.



Slide the cup stand fork/slot onto the bend/fold portion of the iPad case. This provides the optimal distance and angle to the iPad camera.

Before taking any photos, the cup, stand and iPad should be set up as shown. For the best photo accuracy, make sure the setup is placed in an area with adequate lighting.

The cup should be filled to no more than 60mL.

Flex Cup Issues To Avoid

Overfilling

- If the cup is overfilled by the donor, the collector should pour off the specimen to a level between 20mL and 60mL. (Closer to 20 mL works best)
- If available, allow the donor to void into the provided collection cup and pour the specimen into the Flex Cup to avoid donor overfill.
- Overfilling may obscure the test lines and result in a false positive test due to:
 - A. Fog or condensation inside the cup.
 - B. A water line that obscures the test line.
 - C. Dilution of the test lines.

Other factors that may result in a false positive reading

- The cup stand NOT attached properly to the case.
- The cup NOT being placed properly in the cup stand.
- The cup label being ripped off.
- Glares on the cup from overhead lighting sources.

(A.) and (B.)



(B.) and (C.)



Missing label



Cup not in stand

Starting a FormFox Flex Test Event from Scratch

Tap on **Lab Based Drug Test (Account Number)**.

The screenshot shows the home screen of the FormFox Flex application. On the left is a vertical menu with buttons for Home, Pending List, Open Events (108), Complete/Search, Account Book, POCT R&D, System, Reports, Technical Help, Training Center, and Contact Info. The main area is divided into three columns: 'What did the patient bring in?' with options for 'Authorization Form or Mobile Device' and '5 Part Paper Chain'; 'What do you want to do?' with options for 'Lab Based Drug Test (Account Number)', 'Alcohol Test', and 'New Occupational Health Services'; and 'Shortcuts' with options for 'Use Your Account Book', 'Use Your Favorites List', and 'Patient Check-In'. The 'Lab Based Drug Test (Account Number)' option is highlighted with a purple border.

Tap on **CRL** and key in your FormFox Flex lab account.

The screenshot shows the 'Locate Donor Test' screen. At the top, it says 'Locate Donor Test' and 'Please click on the Laboratory from the Custody and Control Form (CCF):'. Below this is a grid of laboratory logos: CRL (highlighted with a purple box and an arrow pointing to the next screen), Quest Diagnostics, LabCorp, Psychemedics, Omega, Legacy Lab, Keystone Lab, and DrugScan. On the left side of the screen is a vertical menu with buttons for Home, Pending List, Open Events (108), Complete/Search, Account Book, POCT R&D, System, Reports, Technical Help, Training Center, and Contact Info. Below the logo grid, the text 'LOCATE DONOR TEST' is displayed above the CRL logo. Underneath, it says 'Please Scan or Enter' followed by 'LABORATORY ACCOUNT NUMBER' and a text input field. To the right of the input field is a 'Lookup Account' button.

FormFox Flex Account Number

Enter the code or company name for the lab account.
Note that all Flex tests will use **FLX1**.

LOCATE DONOR TEST



Please Scan or Enter

LABORATORY ACCOUNT NUMBER

CRL.FLX1

Lookup Account

Enter the code or company name for CRL.FLX1.

Search

Select	Code	Company Name
<input checked="" type="radio"/>	OTHER	Company Not Listed

Please enter company name: DEMO

Continue

Fill out the donor's information and select **POCT** Test as the procedure. **Create New Test** when prompted.

LOCATE DONOR TEST



Please Scan or Enter

LABORATORY ACCOUNT NUMBER

CRL.FLX1.DEFNON

Lookup Account

Donor ID

SSN

999999999

Donor First Name

Fred

Donor Middle Initial

Donor Last Name

Fox

Date Of Birth

01/05/1992



PROCEDURE

- Non-Regulated Drug Test
- Regulated (DOT) Drug Test
- POCT Test

Create New Test

Search

A scheduled test was not found using the search criteria you entered.
Start a new test by clicking 'Create New Test'.

Select a Panel

Select the panel from the dropdown. The panels associated with the Flex account are set up at the lab.

• Select the test or tests to be performed and click 'Submit'.

FormFox Flex

- ✓ FormFox Flex
- 14SAP (FLEX)
- 5SAP+6AM (FLEX)

This is a **formfox flex** URINE POCT collection,
do you have Flex cups on hand?

Yes

No

If **Yes**, proceed with the FormFox Flex workflow.

If **No**, you will proceed with a regular urine collection.
Send the specimen to the lab for testing.

Since you do not have the required cup, proceed with a regular urine collection and send the specimen to the lab.

OK

Donor Information and Device Details



Employer
 DAVID KUNTZ
 NONDOT DEFAULT
 8433 QUIVIRA ROAD
 LENEXA, KS 66215
 Phone#: 913-693-5406 Fax#:

MRO
 DAVID KUNTZ
 CRL
 8433 QUIVIRA ROAD
 LENEXA, KS 66215
 Phone#: 913-693-5406 Fax#:

Fields marked with an asterisk () are required fields.*

* ID * Date of Birth:

* First Name M.I. * Last Name
(MM/DD/YYYY)

* Evening Phone * Day Phone
(10 digits or 'np' only) (10 digits or 'np' only)

* Donor Verified by: Photo ID Employer Representative Other

* Reason For Test:

Scan barcode on device package

Device Code 01
 Expiration Date 0724
 Lot Number L1234567

Select Panel to test

Confirm information above and tap "next"



Example of device package barcode

Fill out the required fields on the first screen.
 Verify the donor's identity and select a reason for test.

Scan the barcode from the Flex device's package using your iPad's front-facing camera. You can also carefully key in the barcode.

The device's code, expiration date, and lot number associated with the entered barcode will appear on the screen.


Flex Collections are Paperless



TAKE NOTE- Flex collections are now paperless. The lab copy of the CCF will be sent electronically. If the sample is non-negative and sent to the lab, a PAPER lab copy of the CCF does not need to be included with the specimen.

Employer
DAVID KUNTZ
NONDOT DEFAULT
8433 QUIVIRA ROAD
LENEXA, KS 66215
Phone#: 913-693-5406 Fax#:

Fields marked with an asterisk () are required fields.*


* ID * Date of Birth: 
(MM/DD/YYYY)

* First Name M.I. * Last Name

* Evening Phone * Day Phone
(10 digits or 'np' only) (10 digits or 'np' only)

* Donor Verified by: Photo ID Employer Representative Other

* Reason For Test:

Scan barcode on device package 

Device Code 01
Expiration Date 0724
Lot Number L1234567
Select Panel to test

Confirm information above and tap "next"

Obtain Specimen, Assign FormFox Specimen ID, and Collect Signatures

formfox flex
Formfox Electronic Lab Copy

Test Device: FormFox Flex Test Panel: FX01

* Lot Number: L1234567 * Expiration Date (YYYY/MM): 2024 / 07

Specimen Collection
Obtain Specimen from the donor.

Is temperature between 90 and 100 F? Yes No

Temperature Out of Range or Suspected Tampering

Actual Specimen Collection

Unable to void
Suspend test
Donor refused

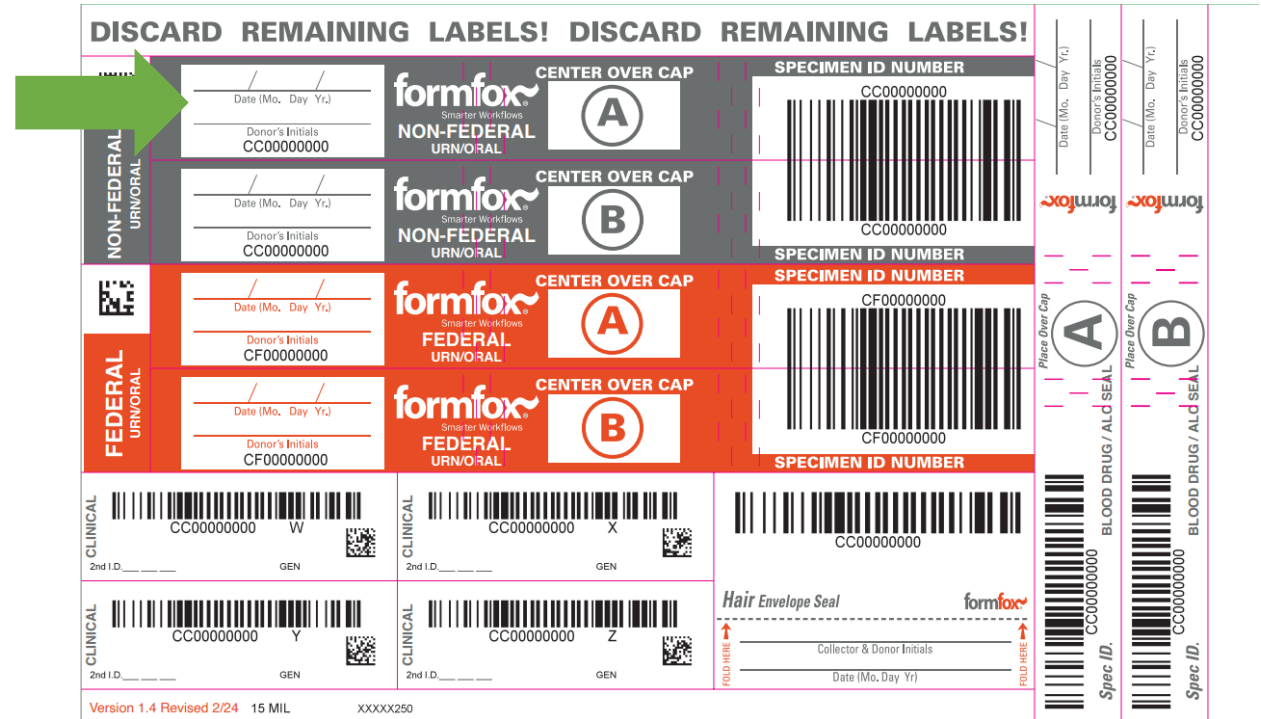
Remarks:

Scan or Enter Barcode
Place the FormFox seal on the cup, scan the barcode or enter the number, and have the donor initial the seal.

CC12218763 Scan Barcode

Collector Signature

Donor Signature



Obtain the specimen. If the specimen collection is eventful, tap on the button that best describes the collection status.

For uneventful collections, place a **gray non-federal FormFox label** on the cup (**ID begins with CC**). Scan/enter the FormFox ID into FormFox and have the donor sign the seal.

Once signatures have been collected, dismiss the donor. If they want documentation, dismiss them to your waiting area.

Allow Sample to Process in Flex Cup

Collect Signatures

Collector Signature

Donor Signature

Once signatures are collected, dismiss donor.
If Donor wants documentation, dismiss them to the waiting area.

Once the specimen and signatures have been collected, the sample will need to process in the Flex cup.
A 3:00 minute timer will begin. Let the cup activate for 3-5 minutes.

Let the cup activate for 3-5 minutes on a flat surface. Select "Next" to photograph the cup.

Back Next 2:46 

FormFox Inc. ©

If you select Next before the timer is at 0:00, you will be asked if you want to proceed.

0:00

Has the cup been allowed to completely activate?

Yes-Proceed
 No-wait

OK

FormFox Inc. ©

Take Photos: Stand Setup

**PLACE FORMFOX
FLEX CUP ON STAND**



Note the fork/slot on the front of the cup stand.



Take Photos: Stand Setup



Before taking any photos, the cup, stand, and iPad should be set up as shown. For the best photo accuracy, the setup should be placed in an area with adequate lighting.

Take Photos: Front of Cup



Note the Front side has a test strip that is used for specimen validity.

After the cup has been activated (3-5 minutes), **photograph the front and back of the Flex cup.**

*Make sure to focus your iPad's back-facing camera on the strips at an angle parallel to the flat side of the cup. Tap on the screen if you need to re-focus. Try to get the **green box** completely around the edge of the test strips. *

Review the image preview. Tap the white circle to capture the image. Tap **Retake** to capture a new image of the cup or **Save Image** if the image is focused and the test strips are visible.



Take Photos: Back of Cup



Note the Back side has no specimen validity test strip.

Repeat the photo process for the back of the cup.



View Results – Mark Specimen Validity

The Results screen contains a reference guide for specimen validity. **Select either Normal or Abnormal based on what you interpret from the Specimen Validity Strip.**

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Specimen Validity Test Result

Review the following chart and mark the specimen validity accordingly

	Normal	Abnormal
CREA	 20mg/dl 100mg/dl	 0mg/dl 10mg/dl
pH	 4.0 6.0 7.0 8.0	 2.0 3.0 9.0 12.0
SG	 1.005 1.015 1.025	 1.000 ≥1.035

* SPECIMEN VALIDITY TESTING:

Normal Abnormal

* OVERALL SCREEN RESULT:

Negative Send To Lab

Back

Next

FormFox will automatically mark the overall screen result as either **Negative** or **Send to Lab** based on the submitted photos and Specimen Validity Testing.

Users cannot change the overall screen result.

- If the result is **Negative**, the software will display a **STOP** icon and the following instructions: DO NOT send the CCF or specimen to the laboratory. Tap **Finish** to complete the negative Flex event.
- If the result is **Negative** but Specimen Validity is marked as Abnormal then the overall screen result will change to **Send to Lab**.
- If the result is **Send to Lab**, tap **Next**.

* SPECIMEN VALIDITY TESTING:

Normal Abnormal

* OVERALL SCREEN RESULT:

Negative Send To Lab

DO NOT send the CCF or specimen to the laboratory

Back

Finish

* SPECIMEN VALIDITY TESTING:

Normal Abnormal

* OVERALL SCREEN RESULT:

Negative Send To Lab

Back

Next

Negative - View Results and Mark Specimen Validity



Donor: J, J
Laboratory: CRL

User: Jared England Site: CRL/FF Test Clinic Only- DO NOT USE



Specimen Validity Test Result
Review the following chart and mark the specimen validity accordingly

	Normal	Abnormal
CREA	20mg/dl 100mg/dl	0mg/dl 10mg/dl
pH	4.0 6.0 7.0 8.0	2.0 3.0 9.0 12.0
SG	1.005 1.015 1.025	1.000 ≥ 1.035

* SPECIMEN VALIDITY TESTING:

Normal Abnormal

* OVERALL SCREEN RESULT:

Negative Send To Lab

DO NOT send the CCF or specimen to the laboratory

Back Print Result Report Print Donor Receipt Finish

To print a Result Report and/or Donor Receipt, select **Print Results Report** or **Print Donor Receipt** from the bottom buttons.

Once all reports have been printed, select **Finish**.

Non-Negative - Finish the Collection and Prepare for Shipment

formfox flex URINE POCT
Formfox Electronic Lab Copy

Please specify the courier that will be used to transport the specimen(s) to the laboratory

If selecting "Other", enter the name of the Courier here

*** Custody and Control Form**

Copy 1 Lab Copy (Lab Copy will be sent electronically) Copy 2 MRO Copy
 Copy 3 Collector Copy
 Copy 4 Employer Copy

Do you want to print a result report or donor receipt?

Result Report

Donor Receipt Print Email Text Message

Print / Send

Prepare the sealed screening kit for shipping to the Lab by placing it in a shipping pouch with the Lab copy of the CCF. (there is no need for a pour off or second collection.)

You must tap "Finish" to complete the collection.

Finish

Collector must distribute POCT results

Specify the courier.
Prepare the specimen for shipment.
Place the specimen in the shipping pouch.

The Lab Copy of the CCF will be sent electronically.
There is no need to send a paper copy with the sample.
There is no need for a pour off or second collection.

Note: Clinics in Hawaii, Tennessee, and Florida are currently exempt from Paperless CRL Non-DOT collections and will need to send a lab copy of the CCF with the sample.

The donor can receive a receipt via Print, Email or Text.

Click Finish to complete the Flex event in FormFox.
Distribute the POCT results like you normally would.

Questions?

If you have any questions or concerns, please contact Support.

877-376-3691 opt. 1

support@formfox.com

Thank you for using FormFox Flex!

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