

RECEIVING YOUR ONDOSE® RESULTS

STEP 1

An individualized report is generated and results are returned (usually within 7 days) in time to make therapeutic adjustments for the next cycle of treatment

- a. Refer to the OnDose Results Guide on how to interpret the results



STEP 2

OnDose test results are used to help guide an individualized dose for subsequent cycles of 5-FU chemotherapy

- a. After achieving target AUC levels, monitor patient as necessary to maintain target AUC



Any questions? Call Customer Service at **800-469-7423**.

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5-FU Dose Optimization Test Sampling Instructions

Following these instructions will avoid delays in the OnDose® testing process and ensure specimen integrity.



COLLECTING A SAMPLE FOR ONDOSE®

STEP 1

Complete the OnDose Test Request Form (TRF) and applicable insurance paperwork

- Complete with ordered dose in mg/m² and planned infusion duration
- Confirm the following:
 - The single blood sample was drawn in accordance with the pump type below
 - The pump must be connected and infusing at full rate at the time of blood draw
 - There must be no evidence of line occlusion within 1 hour prior to blood draw
 - The blood sample must be drawn from a peripheral vein; not the infusion port

NOTE: Sign the TRF to confirm all of the above.

STEP 2

Prepare OnDose Stabilizer and Transfer Device

- Remove the OnDose Stabilizer syringe from its outer foil package and the BD Transfer Device from its sterile package
- Unscrew cap of the supplied OnDose Stabilizer syringe, connect to the BD Transfer Device, and set combined unit aside

STEP 3

According to the patient's pump type (below), draw peripheral venous blood into the supplied, 6-mL K2-EDTA Vacutainer® tube

Battery Operated Pump
(eg, Gemstar, CADD, Walkmed)

Non-Battery Operated Pump
(eg, gravity, balloon types)

FOLFOX 6, FOLFOX 4, FOLFIRI

FOLFOX 6, FOLFIRI

- Draw sample between 18 hrs after the start of CI up to 3 hrs prior to planned completion
- FOLFOX 4 – Draw sample between 18-19 hrs (day 1 or 2)

- Draw sample between 18 hrs after the start of CI up to 10 hrs prior to planned completion
- Do Not use test on patients with FOLFOX 4 and non-battery pump

Note: Do not draw sample if any of the following occur:

- The 5-FU infusion has been interrupted or augmented prior to blood draw (eg, hydration)
- The IV tubing has been occluded anytime within 1 hour prior to blood draw
- Pump is empty

STEP 4

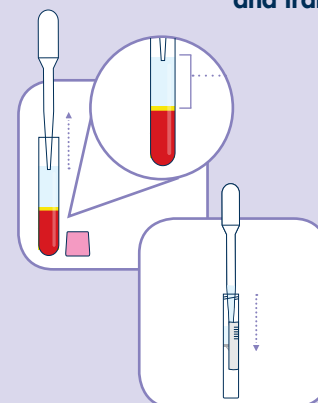
IMMEDIATELY dispense OnDose Stabilizer into blood sample

- Connect the combined OnDose Stabilizer unit (from step 2) over the K2-EDTA tube by firmly inserting the device through the tube stopper AND completely depress the OnDose Stabilizer syringe to dispense stabilizer into tube
- Mix sample by gently inverting the K2-EDTA tube **at least 3 times**
- Label K2-EDTA blood tube with appropriate patient identifiers (eg, patient name, DOB)
- Centrifuge the sample (1500 g–2000 g x 10 minutes)

COLLECTING A SAMPLE FOR ONDOSE®

STEP 5

Carefully draw no more than half of the plasma with the supplied disposable pipette and transfer plasma into a supplied, 3-mL Cryovial® tube

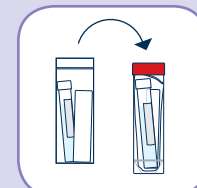


- Squeeze the bulb of the disposable pipette before inserting the tip into the plasma. Then, insert the pipette tip **just beneath the top** of the clear plasma layer and **slowly release the bulb**. Track down as plasma is being drawn
- Collect no more than half of the clear plasma layer. Aspirate only once to avoid disturbing the buffy coat/cellular layer between the plasma and red blood cells
- Transfer the plasma sample into the supplied, 3-mL Cryovial tube
- Mark the provided bar code label with the patient's name and date of birth (bar code is located at the top of the OnDose TRF). Attach the bar code lengthwise on the plasma tube

SENDING THE SAMPLE TO MYRIAD FOR ANALYSIS

STEP 1

Package the patient sample for shipment



- Place the labeled, 3-mL Cryovial tube into the supplied, small, clear ziplock bag with absorbent strip
- Place the clear bag and sample into the supplied, red-topped 50-mL tube
- Place the red-topped 50-mL tube into the supplied, red specimen bag

STEP 2

Place the red specimen bag into the supplied FedEx Clinical Pak® along with the appropriate patient forms



- Place the completed OnDose TRF and insurance paperwork into the white OnDose envelope. Then, insert the envelope into the outer pocket of the red specimen bag
- If insurance is to be billed, include the following:
 - A copy of both sides of the patient's insurance card(s)
 - Patient signature on the OnDose TRF
 - Applicable insurance-specific forms (eg, signed Medicare Advance Beneficiary Notice of Noncoverage)

STEP 3

Send the FedEx Clinical Pak® (prepaid) to Myriad (address provided on the FedEx airbill)

- If you do not have a scheduled FedEx pickup, call 800-GO-FEDEX (800-463-3339)

FedEx

NOTE: It is the shipper's responsibility to ensure that the package containing a diagnostic specimen conforms to FedEx guidelines along with all applicable local, state, federal, and international regulations.