



URINE COLLECTION KIT SPECIMEN REQUIREMENTS & SHIPPING INSTRUCTIONS (International)

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Thank you for choosing IGeneX, Inc. for your testing needs. Now that you have received your test collection kit, consult with your physician to choose the appropriate tests/panels.

Contact Customer Service Team with questions at +1 (650) 424-1191, option 1 or email at customerservice@igenex.com.

DETERMINE THE SPECIMEN REQUIREMENTS

Refer to page 2 to identify:

- Each test specimen and requirements
- Specimen container/tube and stability (temperature) requirements
- Collections and preparation instructions
- Required forms or special instructions

SPECIMEN PREPARATION AND COLLECTIONS

Note: Consult with your physician for specific urine collection instructions and preparation before you start your urine collection.

Urine must be collected in such a manner as to minimize contamination as much as possible. Please follow these instructions carefully to maintain sterility of the specimen:

1. Use the clear sterile urine collection cup to collect first morning clean-catch mid-stream sample of urine.
Please refer to Instructions for Clean-catch on page 2
2. Transfer urine into the gray top BD Vacutainer tube (REF #364953):
Important Note: You will need two (2) gray top tubes for each collection day.
 - a. Carefully pull gray top off of tube.
 - b. Place transfer pipette in the urine collection cup.
 - c. Squeeze top of transfer pipette to vacuum urine specimen into pipette.
 - d. Pipette urine specimen into the tube and fill tube past the minimum fill line indicated on the manufacturer's label.
 - e. Remove pipette from tube and place pipette back in the urine collection cup.
 - f. Place gray top back onto tube and carefully tightened the top to avoid leakage.
 - g. Gently invert tube 8-10 times to mix preservative with the specimen.
 - h. Label tube(s) with enclosed white labels with the following information:
 - Patient's first name and last name
 - Patient's date of birth
 - Date of collection*Note: Two (2) tubes should have the same collection date. Unlabeled tube(s) will not be accepted.*
 - i. Refrigerate tube(s) until ready to ship.
 - j. Repeat steps a through h of the "transfer urine into the gray top BD Vacutainer tube instructions" for second tube.
 - k. Repeat steps 1 and 2 for each additional collection day.
3. Ensure that all specimen tube caps are properly tightened to prevent leakage.
4. Insert each labeled tube inside one of the white absorbent tube holder slots.
5. Place the white absorbent tube holder inside biohazard ziplock bag and seal.
6. Place biohazard ziplock bag inside the silver bubble pouch. Remove the protective strip and securely seal pouch
7. Place silver bubble pouch inside the specimen kit box. Store box in refrigerator until ready to ship.
8. Complete "Specimen Information" sections on Test Requisition Form.

COMPLETE REQUIRED FORMS

- Complete and sign "Patient Information" and "Billing Information" sections on Test Requisition Form.
Please note: Incomplete form may result in delay of testing
- For billing information, please visit www.igenex.com/resources or email at billing@igenex.com

PREPARE COLLECTION KIT FOR SHIPPING

1. Insert completed Test Requisition Form along with any additional paperwork inside the specimen kit box.
2. Place specimen kit box inside the UN3373 FedEx Pak. Remove the protective strip and make sure the FedEx Pak is completely sealed.
3. Complete all sections on FedEx International Air Waybill. Be sure to include payment information in "Section 7 – Payment" and sign in "Section 8 – Required Signature on the waybill."
Please note: IGeneX is NOT responsible for international shipping cost. Sender is responsible for shipping cost. It is Sender's responsibility.
4. Retain Sender's Copy of the FedEx International Air Waybill for tracking reference of your package.
5. Upon completion on the FedEx International Air Waybill, insert the following documentation inside of the enclosed FedEx documentation pouch:
 - Completed FedEx International Air Waybill

- Completed Commercial Invoice
- CDC Permit

Note: If CDC permit is expired. Please contact our Customer Service Team at (650) 424-1191, option 1 or email at customerservice@igenex.com. You may also visit www.igenex.com/resources and download the latest permit.

6. Take the package to your nearest FedEx location. Visit www.fedex.com for assistance with your shipping needs.

INSTRUCTIONS FOR CLEAN-CATCH URINE COLLECTION

Instructions for Females

Note: If you are menstruating, replace used tampon with a fresh tampon before proceeding.

1. Wash your hands thoroughly with antibacterial soap and warm water. Dry hands with a paper towel or allow to air dry.
2. Take out urine collection cup from collection kit. Avoid contact with inside of the urine collection cup.
3. Open towelette and separate the labia (*folds of skin*) with fingers and clean inside using one towelette, moving from the front to the back.
4. Continue holding the labia apart and begin urinating into the toilet.
5. As you start to urinate, allow a small amount of urine into the toilet (this will eliminate any contaminants).
6. After the urine stream is well established, urinate into the provided sterile urine collection cup until an adequate amount of urine fills the cup (maximum 60ml/2oz).
7. Remove collection cup from the urine stream and pass the remaining urine into the toilet.
8. Transfer urine sample into gray top tubes. Please refer to steps a through h of the “transfer urine into the gray top BD Vacutainer tube instructions”

Instructions for Males

1. Wash your hands thoroughly with antibacterial soap and warm water. Dry hands with a paper towel or allow to air dry.
2. Take out urine collection cup from collection kit. Avoid contact with inside of the urine collection cup.
3. If uncircumcised, retract foreskin.
4. Open towelette and wipe the end of penis with towelette provided.
5. Begin urinating into the toilet. As you start to urinate, allow a small amount of urine into the toilet (this will eliminate any contaminants).
6. After the urine stream is well established, urinate into the provided sterile urine collection cup until an adequate amount of urine fills the cup (maximum 60ml/2oz).
7. Remove collection cup from the urine stream and pass the remaining urine into the toilet.
8. Transfer urine sample into gray top tubes. Please refer to steps a through h of the “transfer urine into the gray top BD Vacutainer tube instructions”

PANELS

PANEL	PANEL DESCRIPTIONS	PREPAY PRICE	TUBE(S)/SPECIMEN REQUIREMENTS
*LU1	Lyme Urine Panel 1 #805 Lyme Dot Blot Assay (3-samples), #465 Lyme Urine PCR (pooled samples)	\$468.00	6 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*TBD7	Tick Borne Disease Panel 7 Real-time PCR with urine: #450 Lyme, #559 TBRF, Babesia, Bartonella, HME, HGA, Rickettsia	\$495.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube

INDIVIDUAL TESTS

TEST CODE	TEST NAME	PREPAY PRICE	TUBE(S)/SPECIMEN REQUIREMENTS
► LYME (Borrelia burgdorferi)			
*800	Lyme Dot Blot (1 sample)	\$85.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*802	Lyme Dot Blot (2 samples)	\$170.00	4 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*805	Lyme Dot Blot (3 samples)	\$255.00	6 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
450	Lyme Multiplex PCR – Urine	\$265.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
465	Lyme Multiplex PCR – Urine (pooled)	\$265.00	6 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
► TBRF			
559	TBRF PCR – Urine	\$265.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
562	TBRF PCR – Urine (pooled)	\$265.00	6 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
► CO-INFECTIONS			
*665	Babesia PCR – Urine (NEW)	\$230.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*282	Bartonella PCR – Urine (NEW)	\$230.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*780	HME (Ehrlichia chaffeensis) PCR – Urine (NEW)	\$230.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*785	HGA (Anaplasma phagocytophilum) PCR – Urine (NEW)	\$230.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube
*970	Rickettsia PCR Panel – Urine (NEW)	\$230.00	2 x BD Gray Top Tubes/ minimum 3mL of Urine per tube