



KAISER PERMANENTE®

DOCUMENT NUMBER: RIV-PPP-1102
DOCUMENT TITLE: Cxbladder Urine Sampling and Send Out
DOCUMENT NOTES:

LOCATION: RIV-rel	VERSION: 01
DOC TYPE: RIV PPP	STATUS: Release

EFFECTIVE DATE: 14 Apr 2023	NEXT REVIEW DATE: 14 Apr 2025
RELEASE DATE: 14 Apr 2023	EXPIRATION DATE:

AUTHOR:	PREVIOUS NUMBER:
OWNER:	CHANGE NUMBER: RIV-CR-0289

Cxbladder® Urine Sampling and Send Out

Purpose	This procedure provides instructions on how to handle Cxbladder® urine sampling and send out to Pacific Edge Diagnostics laboratory (PED).
Scope	This procedure is intended for all users.
Policy	<ul style="list-style-type: none">• Orders for Cxbladder® MUST be electronically placed in KPHC by the provider. Manual lab requisition orders from KP and Non-KP (outside contracted) providers are NOT acceptable. DO NOT PERFORM MANUAL ACCESSIONING.• Specimen collection for Cxbladder® must occur at the designated lab location(s) for each medical center area. Refer to Attachment A• Must use collection kit provided by the testing laboratory for specimen collection.• Do not add any preservative or chemical to the urine.• Cxbladder® tube MUST BE FILLED to the fill line on the tube.• DO NOT overlay Cerner accession barcode over vendor barcode on the tube.• Cxbladder®accession MUST be logged into In Lab status for the order to be electronically transmitted to Pacific Edge Diagnostics.• Cancel messages in Cerner do not get transmitted to PED. Notify PED if an In Lab status Cxbladder® accession/order/specimen is canceled in Cerner. This will allow PED to cancel the electronically received Cxbladder® order in their lab system and to not expect a specimen from Kaiser.
Testing Lab Contact Information	<ul style="list-style-type: none">• PED customer service email: cs-pedusa@pacificedgedx.com• PED Customer Service: 855-292-5237, Option 1
Safety or Special Safety Precautions	<ul style="list-style-type: none">• Refer to the safety manual for general safety requirements.• Lid from Cxbladder® urine collection cup must be disposed of in a sharps container.
Materials and supplies	Cxbladder® Urine Sampling System (collection kit) <ul style="list-style-type: none">• Urine collection cup• Urine transport tube inside specimen bag with absorbent pad• Pre-paid FedEx shipping bag

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Procedure

Cxbladder® Urine Sampling and Send Out

**Specimen
sources**

- Urine
-

**Specimen
storage**

- Store unopened Cxbladder® kit out of direct sunlight
 - Store at ambient temperature
 - Cxbladder® kit has a shelf life of 9 months prior to use. Do not use past the expiry date on the box/tube.
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Specimen collection

The test requires a fresh mid-stream urine sample, preferably from the second void of the day. Express the first few seconds of urine flow into the toilet then collect directly into the urine collection cup.

Step	Action
1	Remove the urine collection cup from the Cxbladder® collection kit and label with patient's name, MRN#, date of birth, and date and time of specimen collection.
2	Instruct patient to collect mid-stream urine directly into the labeled Cxbladder® urine collection cup until approximately 1/3 of the cup is filled. When completed, screw the lid back on the cup securely. DO NOT remove the white protective sticker on the lid.
3	Prior to transferring the urine into the Cxbladder® tube, invert the Cxbladder® urine collection cup several times and then peel back the white protective sticker on the cup to expose the rubber-covered needle. Sampling must be done within one hour of urine collection.
4	Push the Cxbladder® tube onto the rubber-covered needle and hold in position until the flow stops. Cxbladder® tube must be filled to the fill line. Remove tube and invert tube several times.
5	Accession Cxbladder® order and label Cxbladder® tube with Cerner accession barcode label and log in specimen. Take care NOT to cover the vendor barcode on the tube with the Cerner label.
6	Remove the lid from the Cxbladder® urine collection cup and dispose of it in a sharps container. Dispose of urine and collection cup according to your local medical center laboratory's policy.
7	Place the Cxbladder® tube and absorbent pads into the plastic specimen bag and seal.
8	Place specimen bag inside the Cxbladder® box and then inside the pre-paid FedEx shipping bags but do not seal the FedEx bag before putting on Cerner transfer list to medical center lab or Sherman Way Regional Reference lab (Kern County and Antelope Valley) for send out to Pacific Edge Diagnostics.
9	Medical Center lab or Sherman Way Regional Reference lab must log in Cxbladder® specimen before sealing and ship in pre-paid FedEx shipping bags to PED. In Lab status will trigger the electronic transmission of the Cxbladder® order to PED.
10	Results will transmit via interface to Cerner and KPHC and provider will get result in basket notification. Results are visible under the Lab tab in Chart Review.

Specimen rejection

- Specimen not shipped in ambient temperature
- Specimen not received within 7 days of collection

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- Reference Range**
- Cxbladder Monitor Score of <3.5
 - Cxbladder Triage Score of < 4.0

Interpretive Comments	Cxbladder Monitor	Assay Description: Cxbladder Monitor is a quantitative assay for recurrent UC that combines the gene expression from five mRNA biomarkers (CDK1, MDK, IGFBP5, HOXA13 and CXCR2) as measured by reverse transcription quantitative polymerase chain reaction (RT-qPCR) from a small sample of urine and two clinical factors associated with the patient's prior history of UC. An algorithm is applied to these parameters to calculate a Cxbladder Monitor score ranging from 0 to 10, and using a cut-off of 3.5 identifies those patients who have a low probability of recurrent UC.
	Cxbladder Triage	Assay Description: Cxbladder Triage is a qualitative assay for urothelial carcinoma (UC) that combines the quantitative measure of gene expression from five mRNA biomarkers (CDK1, MDK, IGFBP5, HOXA13, and CXCR2) as measured by reverse transcription quantitative polymerase chain reaction (RT-qPCR) from a small sample of the patient's urine and four patient characteristics: patient age, sex, smoking history and haematuria history. An algorithm is applied to these nine parameters to calculate a Cxbladder Triage Score ranging from 0 to 10 and using a cut-off of 4.0 identifies those patients with a low probability of having UC.

Controlled Document Attachment A: Collection Sites for Cxbladder®

- Non-Controlled Documents** The following non-controlled documents support this procedure.
- CxBladder Instructions for Use – Pacific Edge Diagnostics Laboratory
 - CxBladder sample result report

Author Marian Azuma, CLS

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Attachment A: Collection Sites for Cxbladder®

Medical Area	Collection Location
Anaheim	Kraemer 2 MOB Laboratory
Irvine	Alton/Sand Canyon Building 2 MOB Laboratory
Antelope Valley	Antelope Valley MOB Laboratory
Kern County (Bakersfield)	Chester MOB Laboratory
	Stockdale MOB Laboratory
	Tehachapi MOB Laboratory
Bellflower/Downey	Orchard MOB Laboratory
Baldwin Park	Baldwin Park Medical Center Laboratory
	Diamond Bar MOB Laboratory
Fontana	Fontana Medical Center Laboratory - MOB 3
	Victorville (High Desert) MOB Laboratory
	Redlands MOB Laboratory
	San Bernardino MOB Laboratory
Ontario	Ontario/Vineyard Bldg. D MOB Laboratory
South Bay	Normandie North
Panorama City	Panorama City Medical Office Laboratory
	Santa Clarita Specialty MOB2 Laboratory
Riverside/Moreno Valley	Murrieta MOB Laboratory
	Iris 2 MOB Laboratory
	Riverside Medical Center Laboratory
San Diego	Garfield MOB Laboratory
	Otay Mesa MOB Laboratory
	San Marcos MOB Laboratory
	San Diego Zion Medical Center Laboratory
	Vandever MOB Laboratory
Los Angeles	Pasadena/Foothill MOB Laboratory
	4900 Laboratory
West Los Angeles	West Los Angeles Medical Center Laboratory
Woodland Hills	Woodland Hills Medical Center Laboratory

Regional Parent Document Reference Number: SCPMG-PPP-0532 Rev: 01

Signature Manifest

Document Number: RIV-PPP-1102

Revision: 01

Title: Cxbladder Urine Sampling and Send Out

Effective Date: 14 Apr 2023

All dates and times are in Pacific Standard Time.

Preanalytic Regional

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	05 Apr 2023, 06:21:53 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	11 Apr 2023, 08:51:30 PM	Approved