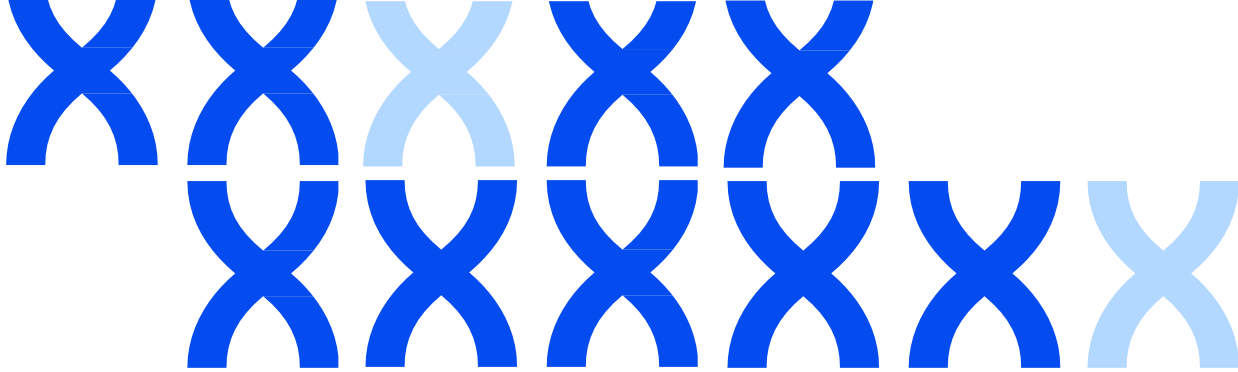


oncoguard[®] liver

Implementation Guide



**EXACT
SCIENCES**










THANK YOU FOR CHOOSING THE ONCOGUARD[®] LIVER SOLUTION

The Oncoguard[®] Liver solution is an innovative offering to aid the consistent and reliable detection of hepatocellular carcinoma (HCC). The solution includes a sophisticated, yet simple, blood test that demonstrates enhanced performance for early-stage HCC detection. The Oncoguard[®] Liver test is complemented by a Patient Engagement Program designed to help empower patients to proactively protect their health and follow through with routine surveillance. Together, the Oncoguard[®] Liver solution offers a streamlined approach to HCC surveillance and support to help more patients access the vital testing they need.

This guide is designed to help ensure that you have the support needed to successfully implement the Oncoguard[®] Liver solution in your practice. Your Exact Sciences representatives are also available to answer questions and provide additional support.

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BEFORE YOU START TESTING, IT IS IMPORTANT THAT YOU:



Obtain the supplies needed to collect specimens



Complete set up to order and receive results using your preferred method



Understand how to order tests and receive results

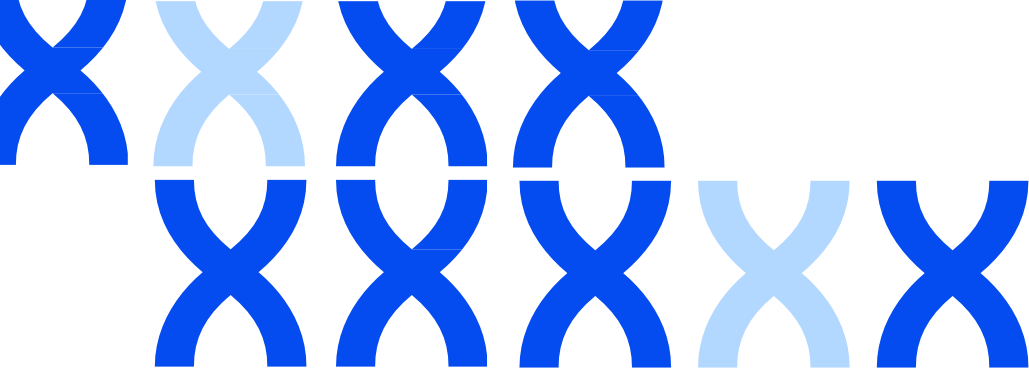


Know where to get support when you need it

1

REQUEST COLLECTION SUPPLIES





1 REQUEST COLLECTION SUPPLIES

The following supplies are required to perform the Oncoguard® Liver test:



Exact Sciences Blood Collection Kit – includes blood collection tubes, labels, and shipping materials for specimen collection and shipment to the performing lab.

Part Number: 100360

The following supplies are also available for use with the Oncoguard® Liver test:



Order Requisition Forms – to be used for manual test ordering

Part Number: 200933 or available for download at OncoguardLiver.com/forms



Specimen Label Tear Pad – blood collection tube labels that may be used for proper specimen identification

Part Number: 200997

Two ways to order supplies for the Oncoguard® Liver test:



Call our Customer Care Center at 1-844-870-8870 to request supplies when you need them.



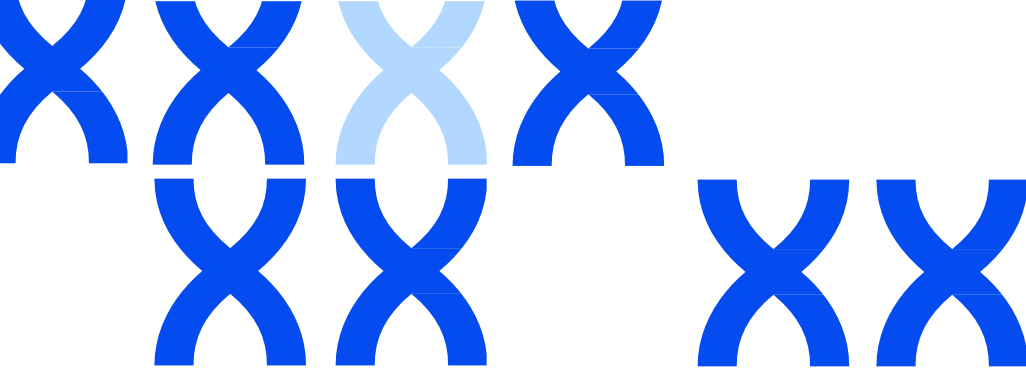
To set up a monthly or quarterly standing order to receive supplies automatically, work with your account representative or call our Customer Care Center.

All supplies are shipped using UPS® ground the next business day after an order is placed.

The required Exact Sciences Blood Collection Kits and optional supplies are provided at no charge, and are for use solely with the Oncoguard® Liver test.

A woman with dark hair in a bun, wearing blue scrubs and a headset, is shown from the chest up. She is looking down, possibly at a computer screen. The background is a blurred clinical or office environment. A blue banner is overlaid on the top of the image, containing the text '2 PRIOR AUTHORIZATION' in white.

2 PRIOR AUTHORIZATION



2 PRIOR AUTHORIZATION

Coverage policies vary from health plan to health plan, and most require prior authorization for the Oncoguard[®] Liver test. Please complete prior authorization before specimen collection.



A signed Advance Beneficiary Notice of Noncoverage (ABN) is required with each order for standard Medicare plans. Please include a signed ABN form in the Blood Collection Kit when ordering via a Requisition Form or upload the signed form in EpicCare[®] Link[®] when ordering the Oncoguard[®] Liver test electronically.

If you believe that the Oncoguard[®] Liver test is appropriate for your patient, we have an example of an Oncoguard[®] Liver test Statement of Medical Necessity available for use. Please include the prior authorization response documentation in the Blood Collection Kit with the Requisition Form or upload the document to EpicCare[®] Link[®] for the order.



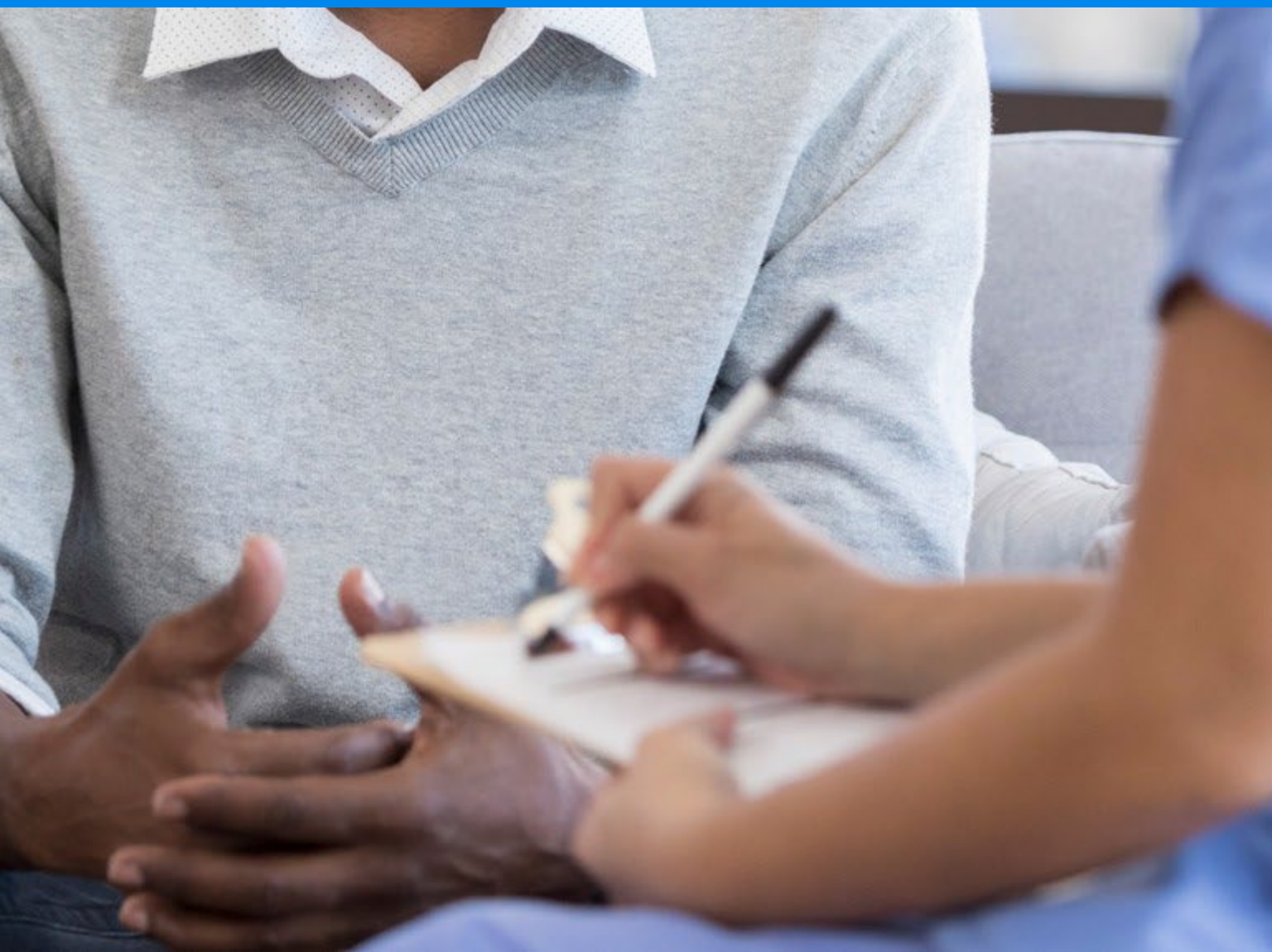
These forms can be accessed at OncoguardLiver.com/resources

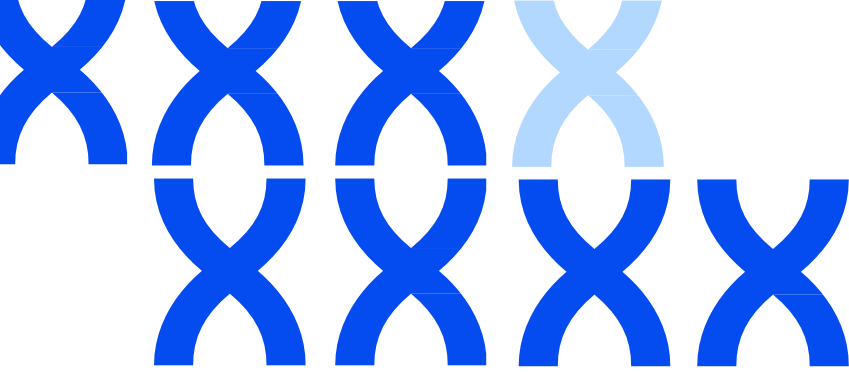
FOR ADDITIONAL INFORMATION:

Please contact the Customer Care Center at 1-844-870-8870



3 TEST ORDERING





3 TEST ORDERING

ORDERING INFORMATION:

Test Name: Oncoguard® Liver
Test Order Code: EXAS3000

CPT® Code: 81599
DEX Z-Code®: ZBBJO

Completing an Order

Be sure to have the following information prior to placing an order:

- Patient demographic information, including biological sex
- Patient insurance information
- Payor authorization response or signed Advance Beneficiary Notice of Noncoverage (ABN) for standard Medicare plans

ONCOGUARD® LIVER TESTS CAN BE ORDERED TWO WAYS:

1. Quick and convenient electronic ordering via EpicCare® Link®



EpicCare® Link® is a HIPAA-secure online tool that gives users the ability to place electronic orders for Oncoguard® Liver tests, view results, and access reports that can help with management of ongoing HCC surveillance testing.

If you don't have an EpicCare® Link® account, getting one is easy. Simply:

- Login to EpicCareLink.ExactSciencesLabs.com
- Select "Request New Account"
- Select "Site" and provide required information for your clinical practice, followed by information for anyone else at your site who should also have an EpicCare® Link® account with Exact Sciences

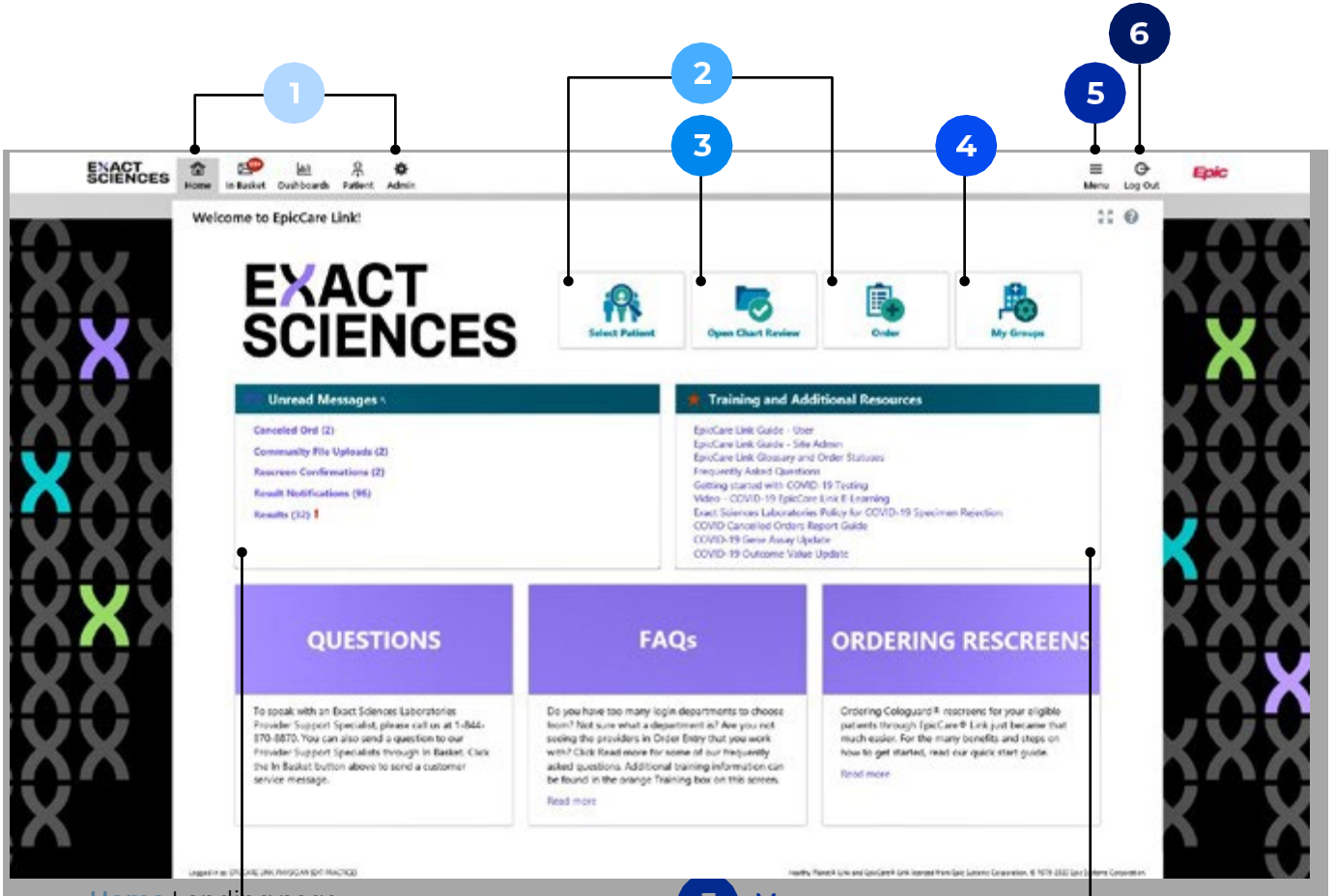
You will receive two emails within two business days for access to EpicCare® Link®. One email will contain your username and the second email will contain your password.

TO ORDER ONCOGUARD® LIVER TESTS:

1. Log into your account at EpicCareLink.ExactSciencesLabs.com
2. Click on *"Select Patient"* to find an existing patient by *"Search All Patients."* If the patient is not in database, add a new patient by clicking on *"Create a New Chart"* and the platform will walk you through steps to successfully create a new chart
3. Once in the patient's chart, click on *"Upload Insurance"* to upload the front and back of patient's primary (and secondary) insurance card(s)
4. Click on the *"Order Entry"* tab in the patient's chart to begin ordering the Oncoguard® Liver test
5. Select the *"Ordering Clinic,"* the *"Authorizing Provider,"* and click *"Accept"*
6. In the *"New Procedure"* search field, type in *Oncoguard,* and then select *"Oncoguard Liver."* You may also type in the test code EXAS3000. For ease of ordering, click *"Preference List"* and check the *Oncoguard Liver test.* Then click *"Accept Orders"*
7. Start by adding all appropriate ICD-10 codes that represent patients' signs and symptoms in the *"Dx Association"* field
8. Answer the listed questions:
 - Confirm patient's sex assigned at birth.
 - Select if patient is Self-Pay or has coverage.
 - Next select appropriate primary coverage.
 1. For Medicare insurance select appropriate responses for the following:
 - ABN - (if uploading the ABN, click Add Files with ABN as the file type)
 - Hospitalization status
 2. For commercial insurance upload any Payor Prior Authorization response and the completed Statement of Medical Necessity. To upload files click *"Add Files"* and name the file with the appropriate document type.
9. Click *"Accept"* to place the order
10. Review the order information for accuracy and click *"Pencil"* if you need to update the information.
11. Click *"Sign Orders"* to complete placing the test order
12. Click on *"Chart Review,"* select recently placed order and click *"Print."* The printed order will need to be included in the Blood Collection Kit.

Please reference the Training and Additional Resources section within EpicCare® Link® for more detailed instructions.

EpicCare® Link® home page



- 1** Home Landing page
- 2** Select Patient or Order
To begin ordering
- 3** Open Chart Review
To print Requisition Form
- 4** My Groups
How to add/remove users
- 5** Menu
List of Navigation Bar
- 6** Log Out
Log out of EpicCare® Link®
- 7** Unread Messages – All unread communications including
 - Result notifications
 - Resource confirmation
- 8** Training and Additional Resources
 - Training guides
 - Oncoguard® Liver Advanced Beneficiary Notice of Noncoverage (ABN)



process described in Section 1 of this guide. A digital fillable RF can be accessed online at OncoguardLiver.com/resources

A completed RF and supporting documentation (insurance cards, signed ABN, Prior Authorization Response) must be included in the Blood Collection Kit for every Oncoguard® Liver test ordered.

Provider & Order Information Recommended. Type all information. Editable, printable PDF available at OncoguardLiver.com/forms

PROVIDER INFORMATION	CLINICAL INFORMATION/TESTING INDICATION
Healthcare Organization: _____ Provider Name: _____ NPI #: _____ Location Address: _____ City, State, Zip: _____ Phone Number: _____ Secure Fax Number*: _____ <small>*To receive faxed results for this order, please provide secure FAX number only</small>	ICD-10 Code(s): _____ <small>See reverse side for a list of codes.</small> Prior-Authorization Code: _____ Exact Sciences Study Code: _____ <small>(if applicable)</small> Ordering Provider Signature _____ Date of Order _____
SPECIMEN INFORMATION	
Collection Date: _____ Collection Time: _____ AM PM <small>(mm/dd/yyyy)</small> Phlebotomist Name: _____ Phone Number: _____ Institution: _____ Oncoguard™ Liver test specimen requirements (tubes included in Blood Collection Kit): Peripheral Blood ■ Three LBGard® Blood Tubes (completely filled) ■ One Serum Separator Tube (centrifuged)	
Patient Demographics	
Patient ID/MRN: _____ First Name: _____ Last Name: _____ DOB: _____ <small>(mm/dd/yyyy)</small> Sex: Male Female <small>(Biological sex/sex at birth is required)</small>	Billing Address: _____ Billing City: _____ State: _____ Zip: _____ Phone: _____ <small>Home Mobile Work</small> Email: _____ Language Preference: _____
Patient Insurance/Billing Information	
Does patient wish Exact Sciences to bill their insurance? Yes (complete below) No (patient will self-pay) Policyholder Name: _____ Policyholder DOB: _____ Relationship to patient: Self Spouse Other Primary Insurance Carrier: _____ Type: Private Medicare Medicare Advantage Medicaid Tricare Subscriber Name: _____ DOB: _____ Subscriber ID/Policy Number: _____ Group Number: _____ Plan: _____	
Hospital Status at Time of Specimen Collection <small>(Medicare only)</small>	
<input type="radio"/> Non-hospital Patient <input type="radio"/> Hospital Outpatient <input checked="" type="radio"/> Hospital Inpatient <input type="radio"/> Discharge date: _____	
For Lab Use Only	
Specimen Receipt Date: _____ Time: _____ <input type="radio"/> AM <input type="radio"/> PM	

CHI297-2 January 2022

1

2

3

4

5

6

1 Provider Information

- Complete all information related to the ordering provider
- To receive faxed results, provide a secure fax number

2 Clinical Information/Testing Indication

- Provide all applicable ICD-10 code(s).
- Must have the payor prior authorization response and ordering provider signature and date
- If your patient is enrolled in an Exact Sciences clinical study, it is important to note the Study Code in this section

3 Specimen Information

- Fill out at the time of blood draw
- Include the collection date, time and phlebotomist contact information

4 Patient Demographics

- Complete this section with all requested information including Patient name as it appears on insurance card, preferred future communication and language preference
- Biological Sex (sex at birth) is required for accurate results

5 Patient and Billing Information

- Include a copy of the front and back of the primary (and secondary) insurance card

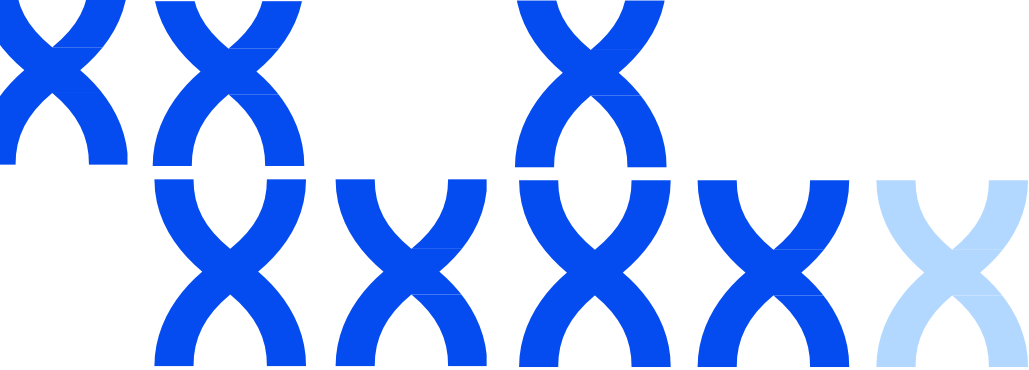
6 Hospital Status at time of Specimen Collection

- Select Hospital Inpatient if testing is being request when the patient is/was an inpatient
- If not an inpatient, appropriately select either Non-hospital or Hospital Outpatient



4

**COLLECT,
PROCESS,
AND SHIP**

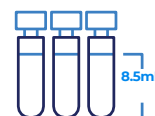


4 COLLECT, PROCESS, AND SHIP

The tubes and materials for shipping specimens to the lab are included in the Exact Sciences Blood Collection Kit (see section 1). Proper specimen collection and handling is essential to ensure accurate results from the Oncoguard[®] Liver test.

The Oncoguard[®] Liver test uses serum from one BD Vacutainer[®] SST[®] tube and plasma from three LBgard[®] Blood Tubes for processing.

1. Check the expiration on the kit. If expired, do not use the kit.
2. Label all tubes with the **patient's name, date of birth, and date and time of collection**. Tubes can be labeled by writing the required information directly on each tube or by applying a label with the required information to each tube
3. Fill the BD Vacutainer SST tube with approximately 7.5 mL of blood, then immediately mix by five complete inversions
4. Completely fill each LBgard Blood Tube to the black line with 8.5 mL of blood, then immediately mix by 10 complete inversions*
5. Allow tubes to sit upright in a rack at **room temperature** for 30 minutes, but not more than two hours, to allow a dense clot to form in the bottom of the **SST tube**

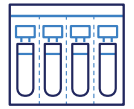


*Note: the Oncoguard[®] Liver test requires two completely filled LBgard Blood Tubes for testing. Three LBgard Blood Tubes are requested to allow for the test to be repeated if an invalid result is obtained.

6. Centrifuge the SST tube for 15 minutes at 1,100 x g – 1,300 x g RCF (relative centrifugal force). **Use this formula $RCF = 1.12 \times \text{Radius} \times (\text{rpm}/1000)^2$ to calculate RPM. Do not centrifuge the LBgard Blood Tubes**



7. Place all tubes in the absorbent sleeve, one tube per slot



8. Place the absorbent sleeve containing the filled blood tubes into the biohazard bag, seal the bag, and place it in the kit with the gel packs. If ordering the test via a Requisition Form, place the completed form, a copy of the front and back of the patient's insurance card(s), prior authorization response, and a statement of medical necessity or a signed ABN form (when appropriate) in the kit with the specimens



9. If ordering through EpicCare® Link®, print and include the order in the kit with the specimens. NOTE: Upload all other forms into EpicCare® Link® with the order. If you have not done so, include them in the kit with the printed order.



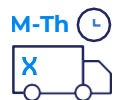
10. Peel the backing off the adhesive box seal, close the kit, and make sure it is tightly sealed



11. Confirm the return shipping label is adhered to bottom of the box



12. Ship via FedEx® (1-800-463-3339) for priority overnight delivery Monday–Thursday only. Specimens collected Friday through Sunday or on observed holidays must be stored at room temperature and shipped the next business day for overnight delivery.





Important Notes

1. Sample collection order is important to limit contamination. The BD Vacutainer SST tube should be collected first.
2. It is important that all three LBgard Blood Tubes are completely filled with blood and the SST tube is at least half filled to ensure enough plasma and serum is obtained for testing. Note: Two filled LBgard Blood Tubes are required for testing; three filled tubes are requested to allow for repeat testing in case of an invalid result.
3. Specimens should be shipped on the same day they are collected. The laboratory does not accept samples on holidays and weekends. If a specimen is collected Friday, Saturday, Sunday or on observed holidays, it must be stored at room temperature and shipped per the shipping schedule (oncoguardliver.com/collection) for overnight delivery.
4. Each specimen **MUST** be handled according to instructions for each tube type and **MUST** include two patient identifiers (patient's name and date of birth) and the date and time of collection.
5. When applying a label with required patient identification to the tubes, ensure that each label is applied straight along the length of the tube—do not wrap the label around the tube horizontally, diagonally across it, or as a flag.
6. Specimens must remain at **room temperature** after collection—do not refrigerate or freeze specimens.
7. Ship specimens to the lab using the Exact Sciences Blood Collection Kit.
8. Do not refrigerate or freeze Blood Collection Kits or remove the gel packs from the kit.
9. Gel packs may freeze during transport; however, the kits are designed to keep specimens stable.

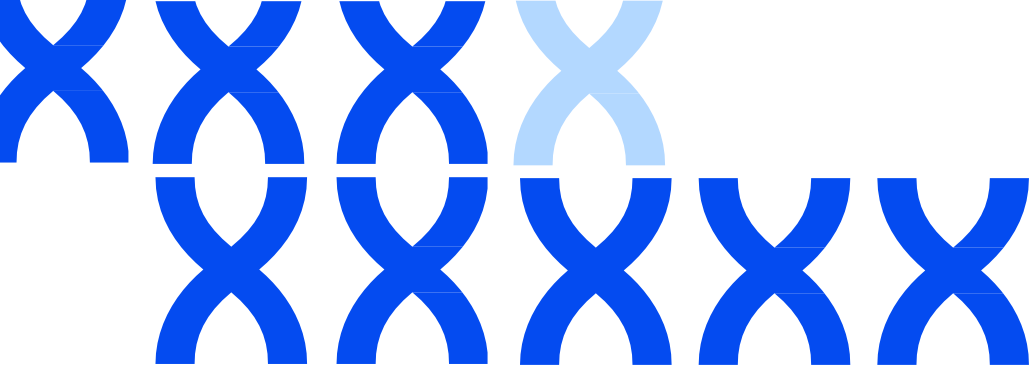
Refer to the “Instructions For Use” included in each Blood Collection Kit for additional details about proper specimen collection, processing, and shipping.

A short specimen collection video, printable Specimen Collection Guide, and shipping schedule are available at OncoguardLiver.com/resources.



5

RECEIVE
TEST
RESULTS



5 RECEIVE TEST RESULTS

The Oncoguard® Liver test generates easy-to-read and understandable qualitative results: Positive or Negative.



Positive test: may indicate the presence of HCC.



Negative test: indicates a lower likelihood of presence of HCC.

In rare instances, a technical failure or insufficient clinical material in the sample yields an invalid result. A negative result does not guarantee the absence of cancer. Patients with a negative result should continue participating in an HCC surveillance program with a method and interval suitable for the individual.

Results from the Oncoguard® Liver test will typically be available within a week from the laboratory receiving the specimens. Results are delivered based on the way the test was ordered.



Requisition Form: Results will be delivered via secure fax using the secure fax number included on the form



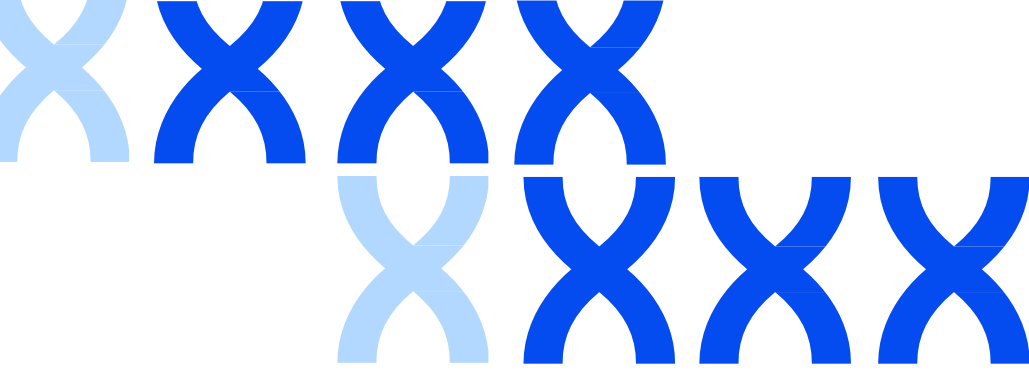
EpicCare® Link®: Results will be available in a patient's online chart

*You will get an immediate alert to your EpicCare Link **In-Basket** when results have been posted to the patient's chart and a nightly email to review unread messages posted in EpicCare® Link®. Click on **Results Notification** under **Unread Messages** to view result reports.*



6

CONTINUED ENGAGEMENT SUPPORT



6 CONTINUED ENGAGEMENT SUPPORT

The Oncoguard® Liver solution includes a **Patient Engagement Program** that helps empower patients to actively protect their health and stay on top of their recommended care.

- The program includes educational materials, patient outreach, and testing reminders designed to help patients understand the importance of ongoing HCC surveillance.
- Patients will be automatically enrolled to receive educational materials from Exact Sciences during the account setup process*

Resources available to your practice:

As part of the **Patient Engagement Program**, Exact Sciences offers resources that you can implement and utilize with your patients. You will have access to:

An educational flyer with information on liver disease, liver cancer, and the importance of regular HCC surveillance. Call our Customer Care Center at 1-844-870-8870 to request a supply of educational flyers.



Reports providing information on patients who may be due for routine HCC surveillance*—monthly reports can be accessed within the EpicCare® Link® portal. In addition, you can request to have these reports sent via secure fax or mailed by calling our Customer Care Center representatives.



**The Patient Engagement Program is flexible, allowing you and your patients to opt out at any time by calling our Customer Care Center team at 1-844-870-8870*



7

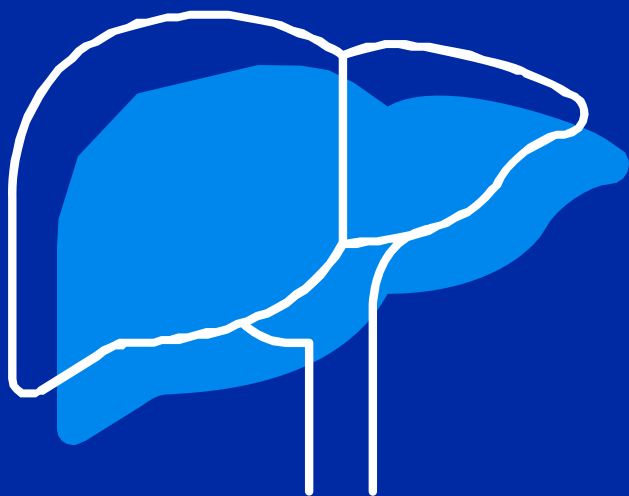
CONTACT US

The Customer Care Center is available to help make implementing the Oncoguard® Liver solution into your practice as easy as possible. Our focus is on ensuring that logistical and administrative hurdles don't stand in the way of early cancer detection.

We're here to help—reach a Customer Care Center representative at 1-844-870-8870 or at [OncoguardLiver.com/contactus](https://www.oncoguardliver.com/contactus)

oncoguard™ liver

Surveillance. Simply advanced.



EXACT SCIENCES CORPORATION
5505 Endeavor Lane
Madison, WI 53719

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