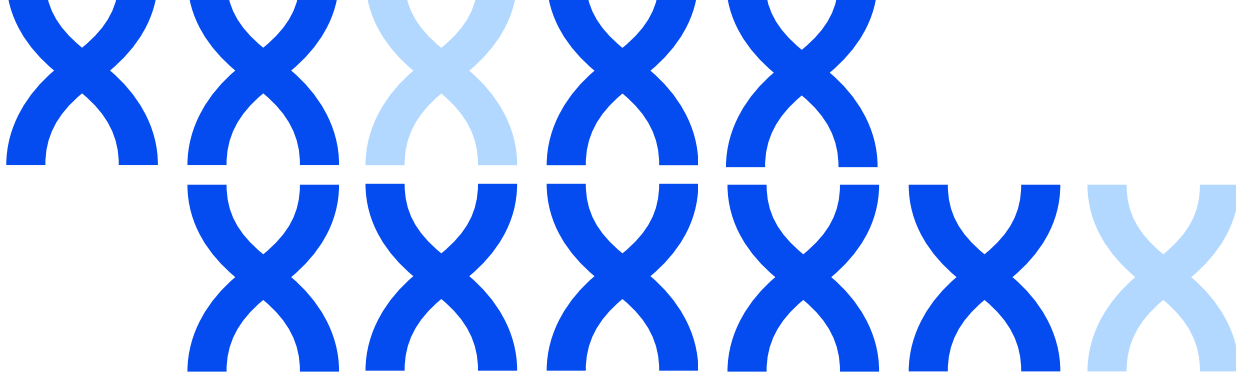


oncoguard<sup>™</sup> liver

# 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.

*\*When compared to guideline recommended blood tests.*

# CONTENTS

1		REQUEST COLLECTION SUPPLIES	5
2		PRIOR AUTHORIZATION	7
3		TEST ORDERING	9
4		COLLECT, PROCESS, AND SHIP	15
5		RECEIVE TEST RESULTS	19
6		CONTINUED ENGAGEMENT SUPPORT	21
7		CONTACT US	23

## BEFORE YOU START TESTING, IT IS IMPORTANT THAT YOU:



Obtain the supplies needed to collect specimens



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



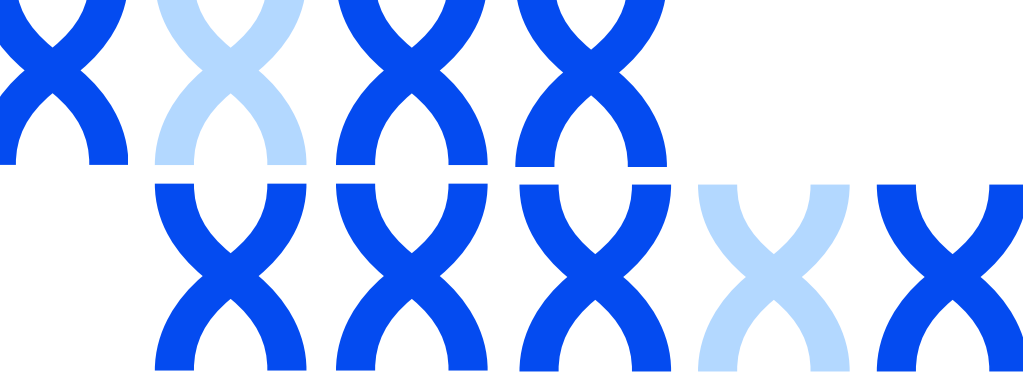
Understand how to order tests and receive results



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 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](https://OncoguardLiver.com/forms)



**Specimen Labels** – 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.*

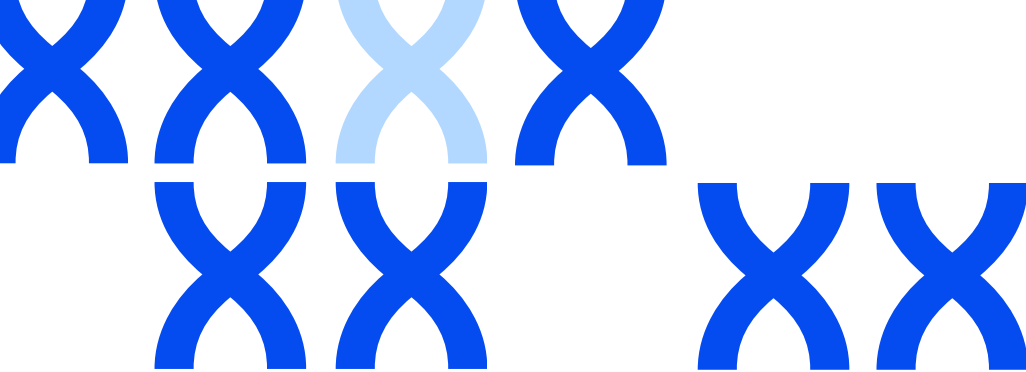
*Exact Sciences Blood Collection Kits and optional supplies are provided at no charge, and are for uses solely with the Oncoguard Liver test.*





# 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](https://OncoguardLiver.com/resources)

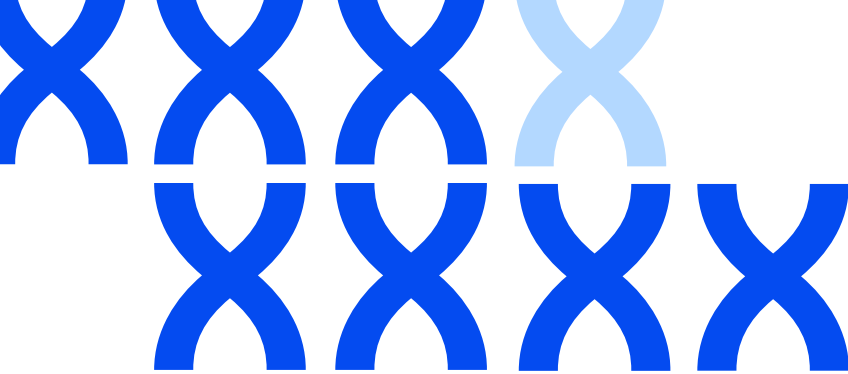
### FOR ADDITIONAL INFORMATION:

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



A photograph of a middle-aged Black man with a grey beard and mustache, wearing a grey V-neck sweater over a white collared shirt. He is looking towards a healthcare professional on the right, who is wearing blue scrubs and has their back partially to the camera. The professional is holding a clipboard and a pen, appearing to be taking notes. The background is a bright, out-of-focus indoor setting.

# 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](https://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

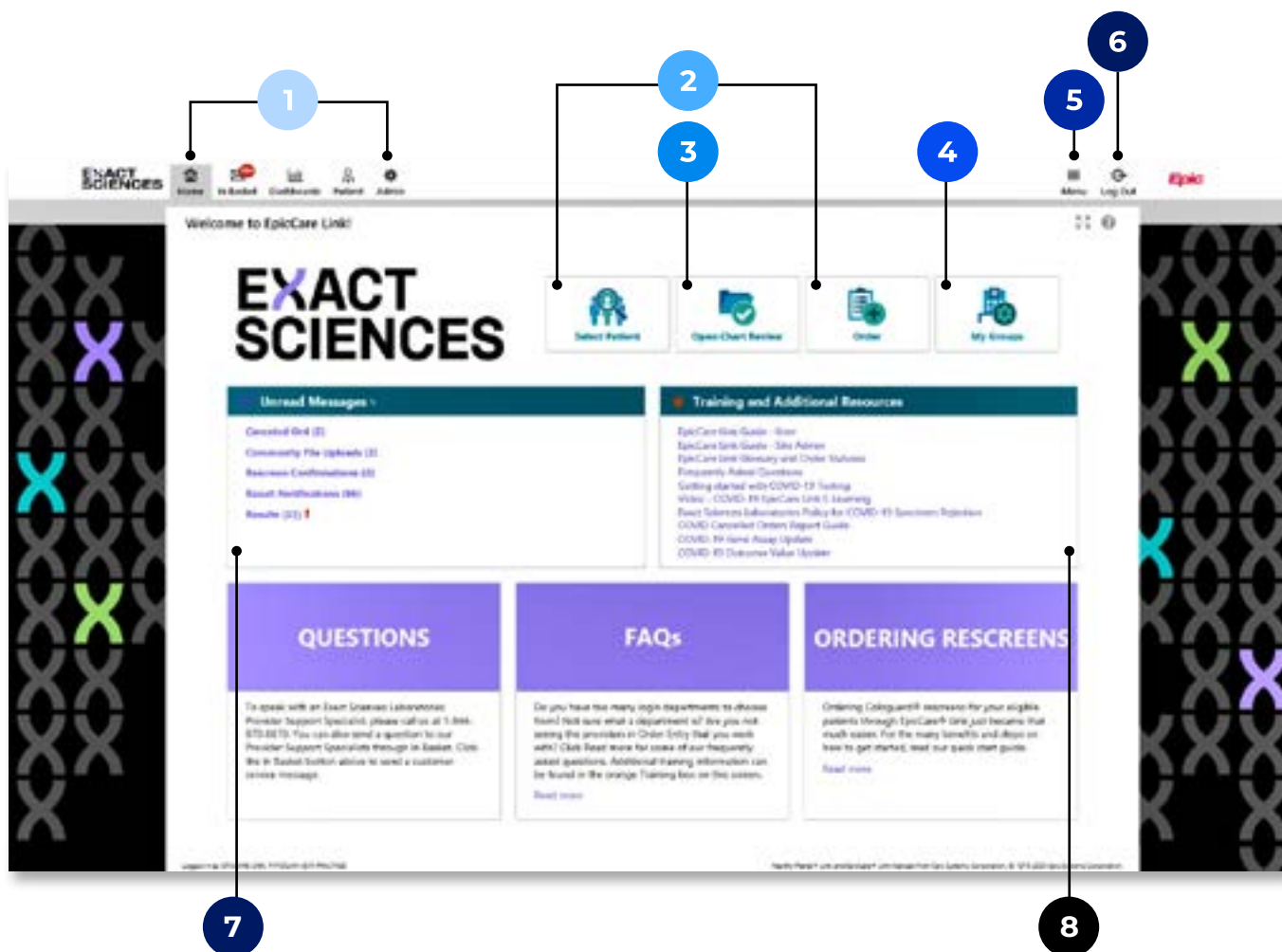
*You will receive two emails within two business days for access to EpicCare® Link™. One email will contain your username and the second email will contain your password.*

## TO ORDER ONCOGUARD LIVER TESTS:

1. Log into your account at [EpicCareLink.ExactSciencesLabs.com](https://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 ensure to 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



**Home** Landing page

**In Basket** Find all messages

**1 Dashboards** Ability to view Oncoguard Liver surveillance reports

**Patient** Search or create a new patient chart

**Admin** Account management options

**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)





## 2. Ordering the Oncoguard Liver test via a Requisition Form



Requisition Forms (RF) can be acquired through the order fulfillment process described in Section 1 of this guide. A digital fillable RF can be accessed online at [OncoguardLiver.com/resources](https://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.

**1** **Provider & Order Information** Recommended: Type all information. Editable, printable PDF available at [OncoguardLiver.com/forms](https://oncoguardliver.com/forms)

**2** **CLINICAL INFORMATION/TESTING INDICATION**

**3** **SPECIMEN INFORMATION**

**4** **Patient Demographics**

**5** **Patient Insurance Billing Information** Attach a copy of the front & back of primary and/or secondary insurance cards.

**6** **Hospital Status at Time of Specimen Collection** (Medicare and Medicaid)

**For Lab Use Only**

Specimen Receipt Date: \_\_\_\_\_ Time: \_\_\_\_\_ ☐ AM ☐ PM

CHI297 Rev. 4, 2020-12

**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 a 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 a specimen ID (if applicable), collection, date, time

**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

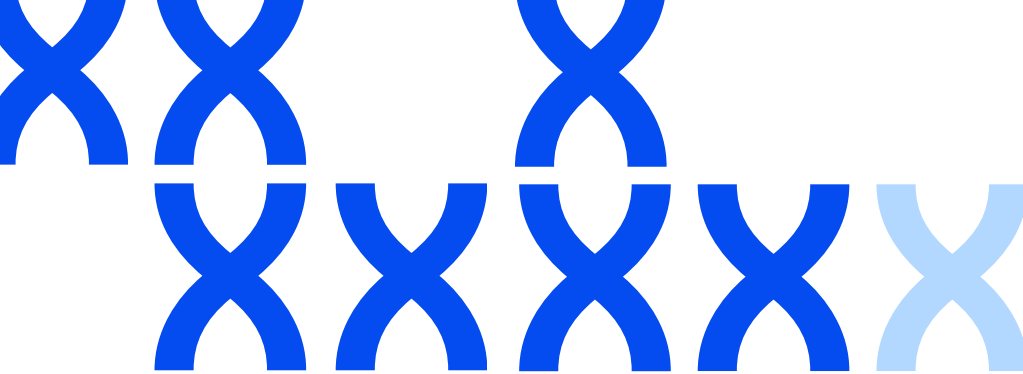
**6 Hospital Status at time of Specimen Collection**

- 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

A healthcare worker, likely a nurse, is shown from the chest up, wearing green scrubs and blue gloves. She is smiling and looking down at a patient who is lying in a hospital bed, partially covered by a white sheet. The background is a blurred hospital room with warm lighting. A dark blue horizontal band is overlaid across the middle of the image, containing the text.

# 4 COLLECT, PROCESS, AND SHIP



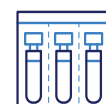
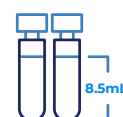


## 4 COLLECT, PROCESS, AND SHIP

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 requires serum from one BD Vacutainer® SST™ tube and plasma from two LBgard® Blood Tubes for processing.

1. 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
2. Fill the BD Vacutainer SST tube with approximately 7.5 mL of blood, then immediately mix by five complete inversions
3. Completely fill each LBgard tube to the black line with 8.5 mL of blood, then immediately mix by 10 complete inversions
4. 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**
5. Centrifuge the SST tube for 15 minutes at 1,100 x g – 1,300 x g **RCF (relative centrifugal force)** equivalent to 3134 – 3407 RPM—**do not centrifuge the LBgard tubes**
6. Place all tubes in the absorbent sleeve, one tube per slot



7. Place the absorbent sleeve containing the fill 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
8. If ordering through EpicCare® Link™, print and include the order in the kit with the specimens. NOTE: be sure to 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.
9. Peel the backing off the adhesive box seal, close the kit, and make sure it is tightly sealed
10. Confirm the return shipping label is adhered to bottom of the box
11. Ship via FedEx® (1-800-463-3339) for priority overnight delivery Monday–Thursday only. Specimens collected Friday through Sunday, and over holidays must be stored at room temperature and shipped on Monday.





## Important Notes

1. Sample collection order is important to limit contamination. The BD Vacutainer SST tube should be done first.
2. It is important that both LBGard 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.
3. Specimens should be shipped on the same day they are collected—do not ship specimens on Friday, Saturday, Sunday, or holidays. The laboratory does not accept shipments over the weekend or holidays.
4. It is recommended that specimens are collected Monday-Thursday only. If this is not possible, specimens collected Friday, Saturday, Sunday, or holidays must be stored at **room temperature** and shipped to arrive on the next business day.
5. Each specimen **MUST** be handled according to instructions for each tube type and **MUST** include two patient identifiers (patients' name and date of birth) and the date and time of collection.
6. 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.
7. Specimens must remain at **room temperature** after collection—do not refrigerate or freeze specimens.
8. Ship specimens to the lab using the Exact Sciences Blood Collection Kit.
9. Do not refrigerate or freeze Blood Collection Kits or remove the gel packs from the kit.
10. Gel packs may freeze during transport; however, the kits are designed to keep specimens stable.

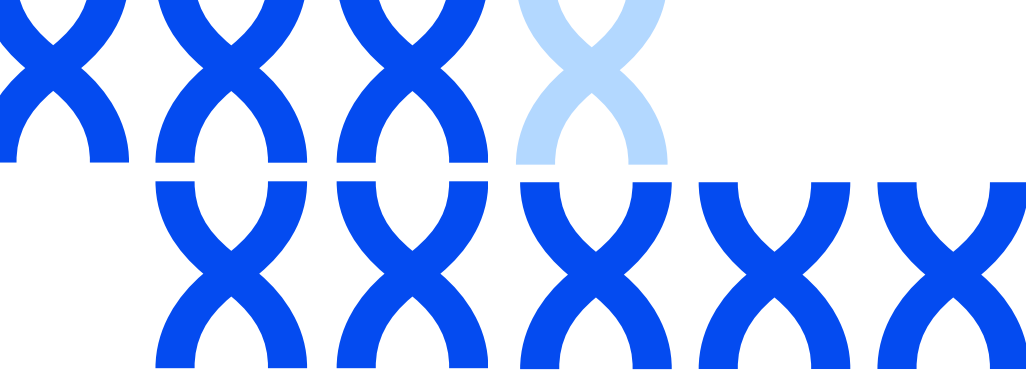
*Refer to the "Instructions For Use" included in each Blood Collection Kit for additional details about proper specimen collection, processing, and shipping.*

*A short specimen collection video and printable Specimen Collection Guide are available at [OncoguardLiver.com/resources](https://OncoguardLiver.com/resources).*



# 5

## RECEIVE TEST RESULTS



## 5 RECEIVE TEST RESULTS

The Oncoguard™ Liver test generates easy-to-read and understand 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

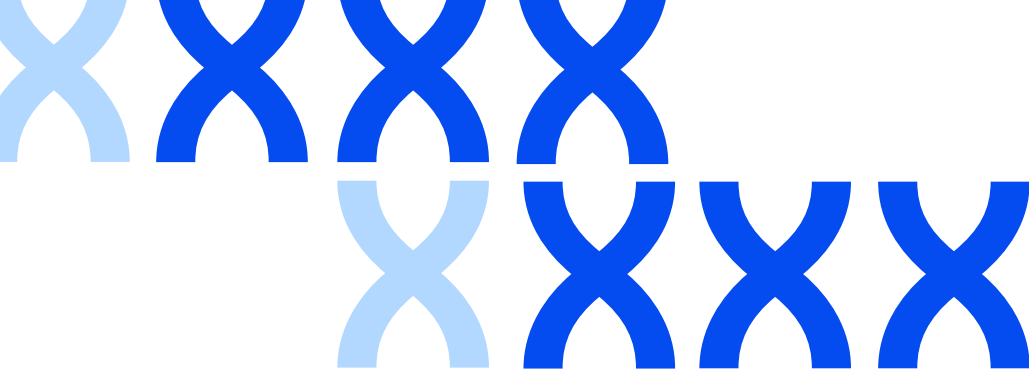
*You will get an immediate alert to your EpicCare Link **In-Basket** when results have been posted to the patient's chart and a nightly email to review unread messages posted in EpicCare® Link™. Click on **Results Notification** under **Unread Messages** to view result reports.*





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

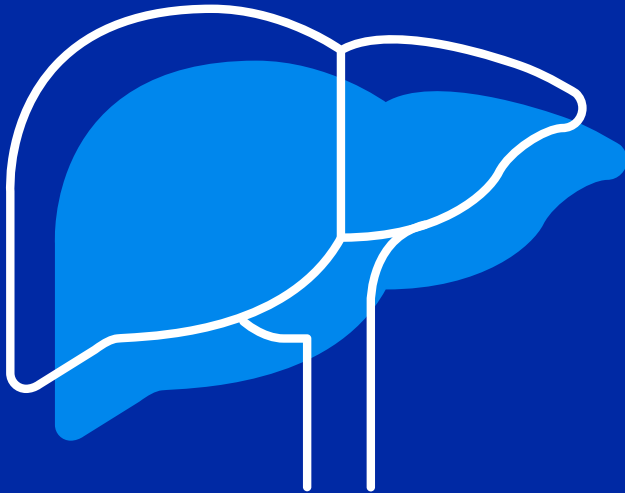
## CONTACT US

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://OncoguardLiver.com/contactus)

# oncoguard<sup>™</sup> liver

## Surveillance. Simply advanced.



EXACT SCIENCES CORPORATION  
5505 Endeavor Lane  
Madison, WI 53719

Oncoguard is a trademark of Exact Sciences Corporation in the US. Epic and EpicCare Link are trademarks of Epic Systems Corporation. CPT is a trademark of the American Medical Association. All third-party marks—® and ™—are the property of their respective owners.

© 2021 Exact Sciences Corporation. All rights reserved. LG.3917-1.HCP 04/2021

**EXACT  
SCIENCES**