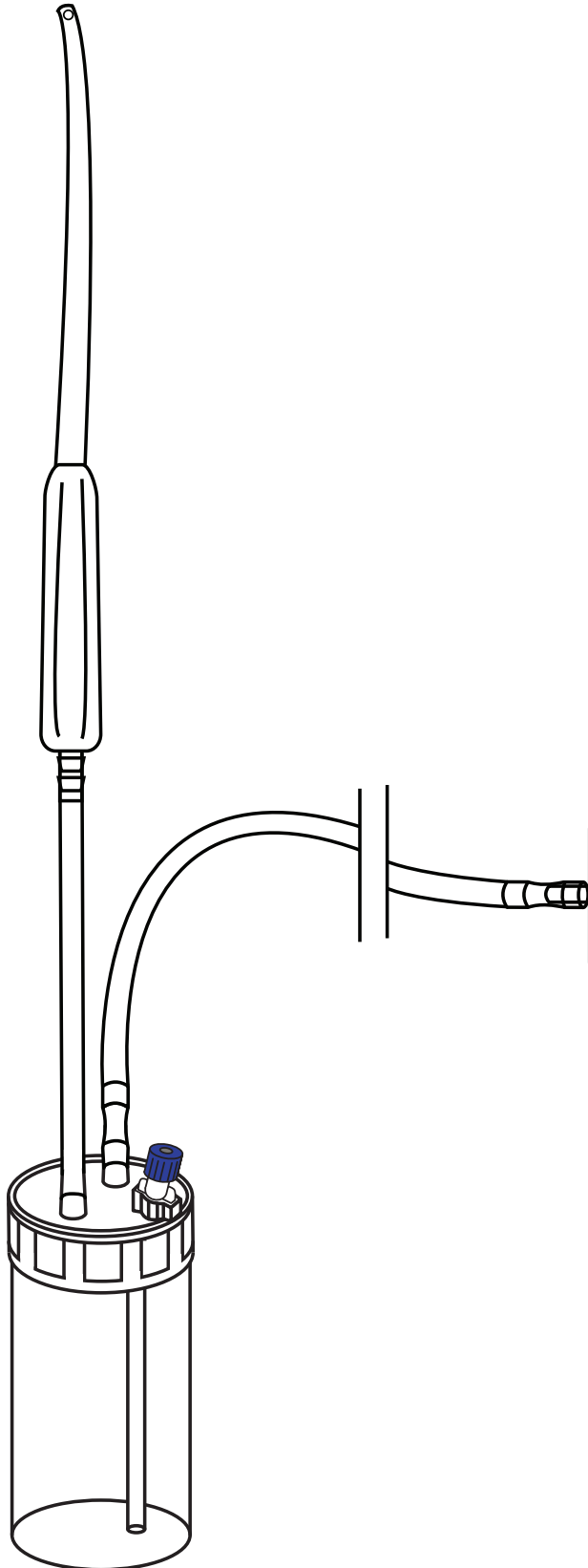





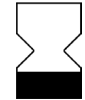





NOT MADE WITH NATURAL RUBBER LATEX



Final Assembly Pictured
Rev. 1 (09/2019)

Explanation of symbols on package labeling

	Caution, Consult Accompanying Documents
	Lot Number
	Catalog Number
	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use By
	Open Here
	Fragile, Handle With Care
	This Way Up

INTRODUCTION

The Recibio, Inc. CeaLogic™ Specimen Collection Kit consists of SINGLE USE components to be used solely for the assembly of the CeaLogic™ Specimen Collection Kit.

Indications for Use

The Recibio, Inc. CeaLogic™ Specimen Collection Kit is intended for use of normal suction and specimen collection.

Description

The Recibio, Inc. CeaLogic™ Specimen Collection Kit is intended for specimen collection as deemed necessary by the surgeon’s determination of the clinical use requirements to facilitate specimen collection.

Warnings

SINGLE USE, Resterilizing or re-use may compromise the structural integrity of the device, its components and lead to device failure. Reuse of this single patient device creates a risk of patient and user infections. Contamination of the device may lead to injury, illness or possibly death of the patient and user.

Cautions

NON-PYROGENIC DEVICE

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DO NOT RE-STERILIZE.

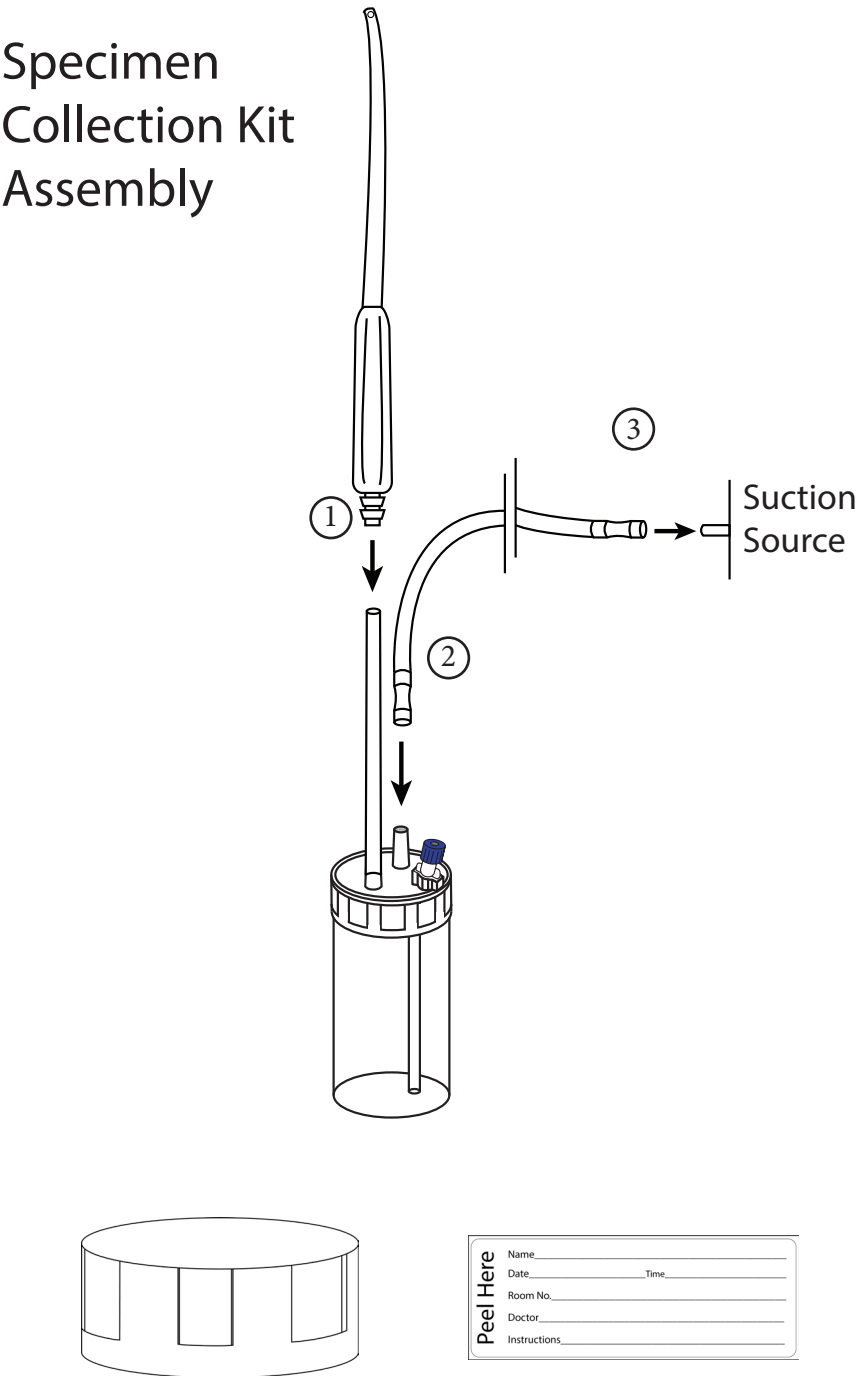
Instructions

Note: Using aseptic technique, remove components of the CeaLogic™ Specimen Collection Kit from the sterile package.

- ①. Connect Yankauer Suction Catheter to latex-free inlet tubing.
- ②. Connect end of supplied or additional 3/8 inch suction tubing to open port.
- ③. Connect opposite end of suction tubing to normal suction source.

Additional Instructions:

- Use CeaLogic™ Specimen Collection Kit to collect specimen based on surgeon's determination of clinical use requirement.
 - Specimen Container Lid and Label are included for use by physician should sterile sample need to be transported. To use, remove the lid from the Specimen Collection Container and affix Specimen Container Lid and Specimen Container Label.
 - Be certain to remove blue cap prior to connecting a sterile Luer-Lok™ syringe for sterile specimen removal.
-



Recibio, Inc. CeaLogic™ Specimen Collection Kit Limited Warranty¹ (USA)

THE FOLLOWING LIMITED WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

- This Limited Warranty provides the following assurance to the customer who receives the Recibio, Inc. CeaLogic™ Specimen Collection Kit, hereafter referred to as the “Product”.
 - Should the product fail to function within normal tolerances due to a defect in materials or workmanship prior to its “Use before Date” Recibio Inc., will at its option (1) issue a credit equal to the purchase price, as defined in Section 1 (B), against the purchase of the replacement product or (2) provide a functionally comparable replacement at no charge.
 - As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement.
- To qualify for the limited warranty, these following conditions must be met.
 - The product must be used prior to expiration and/or before its “use by date”
 - The unused, non-contaminated portion of the CeaLogic™ Specimen Collection Kit must be returned to Recibio, Inc. within 30 days of use and shall be come property of Recibio, Inc..
 - The product must not have been altered, subject to improper assembly, misuse, abuse, or accident.
 - The product may not have been used by any other customer other than the purchaser or a representative of the purchaser.
- This Limited Warranty is limited to its express terms. In exact:
 - Except as expressly provided by this Limited Warranty, RECIBIO, Inc. IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILUER OR Malfucntion of the product, whether the claim is based on warranty, contract, tort, or otherwise.
 - This Limited Warranty is made only to the customer in whom the product is used. AS TO ALL OTHERS, RECIBIO, INC. MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIE WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOMOR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE CUSTOMER SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN 1(A.) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUDE REMEDY AVAILABLE TO ANY PURCHASER, AS DESCRIBED ABOVE.
 - The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of the applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of a competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may have other rights which vary from state to state.
 - No person has any authority to bind Recibio, Inc to any representation, condition or warranty except this Limited Warranty.

¹ This Limited Warranty is provided by Recibio, Inc. 1860 FM 359 #171, Richmond TX 77406, USA. It applies only to the United States of America. Areas outside of the United States should contact their local The Recibio, Inc. CeaLogic™ Specimen Collection Kit representative for the exact terms of the Limited Warranty.

Recibio, Inc. CeaLogic™ Specimen Collection Kit Limited Warranty¹(OUTSIDE USA)

THE FOLLOWING LIMITED WARRANTY APPLIES TO ALL CUSTOMERS OUTSIDE THE UNITED STATES OF AMERICA.

- This LIMITED WARRANTY provides assurance for the customer who receives a Recibio, Inc. CeaLogic™ Specimen Collection Kit (“Product”) that should the product fail to function to specification, Recibio, Inc. will issue a credit equal to the original purchase price(but not exceed the value of a replacement product) against the purchase of any replacement product used for that customer. THE WARNINGS CONTAINED IN THE PRODUCT LABELING ARE CONSIDERED AN INTEGRAL PART OF THIS LIMITED WARRANTY. Contact your local Recibio, Inc. representative to obtain information on how to process a Limited Warranty claim.
- To qualify for the Limited Warranty, these following conditions must be met.
 - The product must be used prior to expiration and/or before its “use by date”
 - The unused, non-contaminated portion of the CeaLogic™ Specimen Collection Kit must be returned to Recibio, Inc. within 30 days of use and shall be property of Recibio, Inc..
 - The product must not have been altered, subject to improper assembly, misuse, abuse, or accident.
 - The product must not have been used more than one time for any customer.
- This LIMITED WARRANTY is limited to its express terms. In particular:
 - In no event shall any replacement credit be granted where there is evidence of improper handling, improper use or material alteration of initial or replaced product.
 - Recibio, Inc. is not responsible for any direct, incidental or consequential damages based on any defect, failure or malfunction of the product, whether the claim is based on warranty, contract, tort, or otherwise.
- This LIMITED WARRANTY does not cover those parts that, by their nature, Recibio, Inc. considers used outside standard assembly and use.
- The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of the applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of a competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.
- No representative, agent, dealer, retailer, or intermediary of Recibio, Inc. shall have the authorization to amend the contents of this LIMITED WARRANTY.
- The validity, interpretation and performance of the agreement for which this LIMITED WARRANTY is issued, as well as any disputes relating to or connected thereto is controlled by and construed under the laws of the State of Texas, USA.

Components

All components are shipped sterile in package.

The Recibio, Inc. CeaLogic™ Specimen Collection Kit consists of the following components:

- One (1) Specimen Collection Container
 - One (1) 10' - 1/4" Suction Tubing with Male Adapter
 - One (1) Yankauer Suction Tip
 - One (1) Specimen Cap
 - One (1) Specimen Label
 - One (1) Product Sticker Sheet
 - One (1) Assembly Diagram/Information Booklet
 - One (1) Extension Set
 - One (1) 5 in 1 Connector
-



1860 FM 359 #171
Richmond, TX 77406 USA
www.recibio.us

Toll free USA 1-844-732-4246

Made in the U.S.A. including foreign components
Assembled by Busse Hospital Disposables