myriad

MYRIAD myChoice® CDx

MYRIAD GENETIC LABORATORIES, INC.
320 Wakara Way • Salt Lake City, Utah 84108
Phone: (877) 283-6709
Fax: (801) 883-8998
Email: myChoiceCDx@Myriad.com

Test Request Form

TO AVOID DELAYS PLEASE COMPLETE ENTIRE FORM

PATIENT INFORMATION

PATIENT NAME (LAST, FIRST, INITIAL)

PATIENT ID # (OPTIONAL) ☐ Female ☐ Male BIRTH DATE (MM/DD/YYYY)

STREET ADDRESS

CITY STATE ZIP

DAYTIME PHONE NUMBER E-MAIL ADDRESS

ORDERING PHYSICIAN (Only fill out first line unless new customer or HCP# is unknown)

NAME (LAST, FIRST, DEGREE) MYRIAD HCP ACCOUNT #

NPI # E-MAIL ADDRESS

ADDRESS

CITY STATE ZIP

OFFICE CONTACT PHONE FAX

EMAIL

CLINICAL INFORMATION

☐ Ovarian Cancer (Ovary, Fallopian Tube, Peritoneum) Age at Dx: _____

Date of Biopsy or Surgery: _____ (MM/DD/YYYY)

FOR MEDICARE PATIENTS ONLY:

AT THE TIME OF BIOPSY OR SURGERY:

☐ Hospital Inpatient (>24 hour stay) Discharge Date: _____ (MM/DD/YYYY)

☐ Hospital Outpatient ☐ Non-Hospital Patient

TEST REQUESTED

☐ **Myriad myChoice® CDx** - Next generation sequencing-based *in vitro* diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status with treatment with the approved targeted therapy for Zejula® (niraparib).

SPECIMEN INFORMATION

Sample Fixative: (check one): ☐ Fixed tissue ☐ Other (describe): _____

Tissue Type Submitted (e.g., Ovary): _____

# of Block(s): _____ # of Slide(s): _____

Date Specimen Retrieved from Archive: _____

Specimen Identification Number as it appears on the tissue block(s) or slides submitted to Myriad:

_____ _____

_____ _____

_____ _____

_____ _____

SPECIMEN RETRIEVAL

☐ I want Myriad Genetic Laboratories, Inc. to request the specimen. (COMPLETE the information below.)

LOCATION OF SPECIMEN PHONE FAX CONTACT NAME

AUTHORIZED SIGNATURE

I hereby authorize testing and confirm that informed consent has been obtained, if required by state law.
I hereby attest that the person listed in the Ordering Physician space above is authorized by law in the relevant jurisdiction to order the test(s) requested herein.

HEALTHCARE PROVIDER'S SIGNATURE DATE

BILLING/PAYMENT INFORMATION

☐ **OPTION 1**: PLEASE BILL INSURANCE (For Medicare patients: only available if test order date is more than 2 weeks after discharge date)

Include enlarged copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.

☐ **OPTION 2**: PATIENT PAYMENT (Please call Customer Service for questions regarding test prices or for credit card payment)

☐ **OPTION 3**: Other billing (To establish an account, submit billing information with this form)

☐ Bill our institutional account #: _____ or established research project code #: _____ or Authorization/Voucher #: _____

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IMPORTANT INFORMATION FOR PATIENT*

BILLING TERMS: I represent that I am covered by insurance and authorize Myriad Genetic Laboratories, Inc. (MGL) to give my designated insurance carrier, health plan, or third party administrator (collectively "Plan") the relevant health information necessary for reimbursement. I authorize Plan benefits to be payable to MGL. I understand MGL will contact me if I will be financially responsible for any non-covered service. By agreeing to testing I also authorize Myriad to obtain a consumer credit report on me from a consumer reporting agency selected by Myriad. I understand and agree that Myriad may use my consumer credit report to confirm whether my income qualifies me for financial assistance. I further understand that this is not a credit application and will not impact my credit score. I agree to assist MGL in resolving insurance claim issues and if I don't assist, I may be responsible for the full test cost. I permit a copy of this authorization to be used in place of the original.

NON-DISCRIMINATION: Federal law (GINA) and laws in most states prohibit discrimination regarding employment eligibility, health benefits, or health insurance premiums based solely on genetic information. Myriad Genetic Laboratories, Inc. (Myriad) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

AFFORDABILITY: Myriad Promise™

- The majority of appropriate patients pay $0
- Myriad will work with your insurance provider to help you get the appropriate coverage
- If you encounter ANY financial hardship associated with your bill, Myriad will work with you toward your complete satisfaction
- For more information please refer to the billing information at MyriadPromise.com

*Translation of Billing Terms are available in Mandarin and Spanish at MyriadPromise.com. Myriad also provides free language services to people whose primary language is not English through qualified interpreters. If you need these services, contact Customer Service at 800-469-7423,

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Email: myChoiceCDx@Myriad.com

Test Request Form

TO AVOID DELAYS PLEASE COMPLETE ENTIRE FORM

PATIENT INFORMATION

PATIENT NAME (LAST, FIRST, INITIAL): Doe, Jane T

PATIENT ID # (OPTIONAL): 00000

☒ Female ☐ Male

BIRTH DATE (MM/DD/YYYY): 09/10/1954

STREET ADDRESS: 123 Generic Street

CITY: This City STATE: ST ZIP: 45678

DAYTIME PHONE NUMBER: 222-000-0000 E-MAIL ADDRESS: janedoe@email.com

ORDERING PHYSICIAN (Only fill out first line unless new customer or HCP# is unknown)

NAME (LAST, FIRST, DEGREE): Physician, Bob, MD MYRIAD HCP ACCOUNT #: 2222222

NPI # E-MAIL ADDRESS

ADDRESS

CITY STATE ZIP

OFFICE CONTACT PHONE FAX

EMAIL

CLINICAL INFORMATION

☒ Ovarian Cancer (Ovary, Fallopian Tube, Peritoneum) Age at Dx: 62

Date of Biopsy or Surgery: 9/18/2018 (MM/DD/YYYY)

FOR MEDICARE PATIENTS ONLY:

AT THE TIME OF BIOPSY OR SURGERY:

☐ Hospital Inpatient (>24 hour stay) Discharge Date: _____ (MM/DD/YYYY)

☒ Hospital Outpatient ☐ Non-Hospital Patient

TEST REQUESTED

☒ **Myriad myChoice® CDx** - Next generation sequencing-based *in vitro* diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status with the approved targeted therapy for Zejula® (niraparib).

SPECIMEN INFORMATION

Sample Fixative: (check one): ☒ Fixed tissue ☐ Other (describe): _____

Tissue Type Submitted (e.g., Ovary): Ovary

# of Block(s): 1 # of Slide(s): _____

Date Specimen Retrieved from Archive: 10/25/2018

Specimen Identification Number as it appears on the tissue block(s) or slides submitted to Myriad:

9324-1234-A

SPECIMEN RETRIEVAL

☐ I want Myriad Genetic Laboratories, Inc. to request the specimen. (COMPLETE the information below.)

LOCATION OF SPECIMEN PHONE FAX CONTACT NAME

AUTHORIZED SIGNATURE

SIGN&DATE

I hereby authorize testing and confirm that informed consent has been obtained, if required by state law.
I hereby attest that the person listed in the Ordering Physician space above is authorized by law in the relevant jurisdiction to order the test(s) requested herein.

Bob Physician, MD 10/25/2018

HEALTHCARE PROVIDER'S SIGNATURE DATE

BILLING/PAYMENT INFORMATION

☒ **OPTION 1**: PLEASE BILL INSURANCE (For Medicare patients: only available if test order date is more than 2 weeks after discharge date)

Include enlarged copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.

☐ **OPTION 2**: PATIENT PAYMENT (Please call Customer Service for questions regarding test prices or for credit card payment)

☐ **OPTION 3**: Other billing (To establish an account, submit billing information with this form)

☐ Bill our institutional account #: _____ or established research project code #: _____ or Authorization/Voucher #: _____

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AFFORDABILITY: Myriad Promise™

- The majority of appropriate patients pay $0
- Myriad will work with your insurance provider to help you get the appropriate coverage
- If you encounter ANY financial hardship associated with your bill, Myriad will work with you toward your complete satisfaction
- For more information please refer to the billing information at MyriadPromise.com

*Translation of Billing Terms are available in Mandarin and Spanish at MyriadPromise.com. Myriad also provides free language services to people whose primary language is not English through qualified interpreters. If you need these services, contact Customer Service at 800-469-7423,

MYRIAD myChoice® CDx Specimen Instructions

BLOCKS ARE PREFERRED OVER SLIDES WHENEVER POSSIBLE

FOR TUMOR BLOCK(S):

1. Please select and label at least one formalin-fixed paraffin-embedded tumor block with a cross sectional area ≥ 25mm^2 that contains at least 40 microns of tumor. The block should contain at least 20% tumor by pathologic review.

2. Place each tumor block(s) into the provided plastic block holder and cover with an ice pack that has been frozen for 24 hours.

Include the Test Request Form (TRF) and Pathology Report in the kit.

Once we receive your test, Myriad will automatically replenish your kit supply. If you would like to order additional kits or have any questions about your specimen submission, please call Myriad Customer Service at 877-283-6709.

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MYRIAD myChoice® CDx Specimen Instructions

BLOCKS ARE PREFERRED OVER SLIDES WHENEVER POSSIBLE

FOR SLIDES:

1. Please select a formalin-fixed paraffin-embedded tumor block that contains at least 40 microns of tumor. The block should contain at least 20% tumor by pathologic review.

2. Cut and label one **5 micron** section for H&E staining on a **charged slide**.

   Cut and label **5 micron** sections on **uncharged slides** according to the table at right:

Area of tumor (mm^2)	# of 5 µm unstained slides
20-25	8
15-19	12
10-14	16
5-9	20

3. Include Test Request Form (TRF) and Pathology report in the kit.

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MCCDxTSCSPEC/10-19 MGL CDxDC 0197 Rev0

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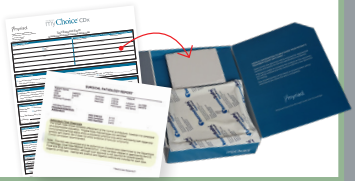
MYRIAD myChoice® CDx Mailing Instructions

1. Remove the **Myriad Clinical Pack Overwrap bag** and the **mailing label** (found beneath the cardboard tray).

2. Place completed **TEST REQUEST FORM** with **PATHOLOGY REPORT** in the test kit. Please **do not** write the patient's name on the test kit.



3. Close the box and place it into the Myriad Clinical Pack Overwrap bag. Affix the enclosed pre-paid mailing label onto the front of the bag.*

4. If you don't have a regularly scheduled FedEx pickup, call 800-GO-FEDEX (800-463-3339) to request one. Press "0" and specify that you are shipping with a prepaid air bill.

Once we receive your test, Myriad will automatically replenish your kit supply. If you would like to order additional tests or have any questions about your specimen submission, please call Myriad myChoice CDx Customer Service at 1-877-283-6709.

*It is the shipper's responsibility to ensure that the package containing a diagnostic specimen conforms to FedEx guidelines along with all applicable local, state, federal and international regulations.

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MCHRDCDXTSCMAIL/10-19
MGL CDxDC 0199 rev 0

MMM522367

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MYRIAD myChoice® CDx

Myriad myChoice® CDx Test Result

ORDERING HEALTHCARE PROVIDER

Bobby Doctor PhD
The Doctor's Place
123 Street Name
Anywhere, UT 84101

PATHOLOGIST

Jonny Pathologist PhD

SPECIMEN

Specimen Type:	**Tissue Block**
Tissue:	**Ovary**
Surgery/Biopsy Date:	**Sept 22, 2019**
TRF Received:	**Oct 1, 2019**
Sample Received:	**Oct 1, 2019**
Report Date:	**Oct 15, 2019**

PATIENT

Last Name:	**Pt Last Name**
First Name:	**Pt First Name**
Date of Birth:	**Jan 7, 1967**
Patient ID:	**Patient id**
Gender:	**Female**
Accession #:	**08000148-BLD**
Requisition #:	**08000148**

Block(s) Analyzed: **UUH201912345-A, UUH201912345-B**

Myriad myChoice® CDx Status: POSITIVE

Genomic Instability Status: **POSITIVE**

The Genomic Instability Score is a measurement of three biomarkers (loss of heterozygosity, telomeric allelic imbalance, and large-scale state transitions) associated with homologous recombination deficiency.

Tumor Mutation *BRCA1/BRCA2* Status: **POSITIVE FOR A CLINICALLY SIGNIFICANT MUTATION**

GENE	CLINICALLY SIGNIFICANT MUTATION(S)	INTERPRETATION
BRCA1	c.2433del (p.Lys812Argfs*3)	Deleterious

NOTE: This result represents findings from all analyzable regions. It may or may not reflect the germline status of this individual. Follow-up germline testing may be appropriate. In addition, the variants listed above may not be present in all tumor cells.

ASSAY DESCRIPTION

Intended Use: Myriad myChoice® CDx is a next generation sequencing-based *in vitro* diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status for treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling.

TABLE 1: Companion diagnostic indications

TUMOR TYPE	BIOMARKER	THERAPY
Ovarian Cancer	Myriad HRD (defined as deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes and/or positive Genomic Instability Score)	Zejula® (niraparib)

This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, Inc., a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108

This **Authorized Signature** pertains to this laboratory report:

Benjamin B. Roa, PhD
Diplomate ABMGG
Laboratory Director

Karla Bowles, PhD
Diplomate ABMGG
Laboratory Director

Hillary Zalaznick, MD
Diplomate FCAP
Laboratory Director
Anatomic Pathology

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MMM522515

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MYRIAD myChoice® CDx

Myriad myChoice® CDx Test Result

ORDERING HEALTHCARE PROVIDER

Bobby Doctor PhD
The Doctor's Place
123 Street Name
Anywhere, UT 84101

PATHOLOGIST

Jonny Pathologist PhD

SPECIMEN

Specimen Type:	**Tissue Block**
Tissue:	**Ovary**
Surgery/Biopsy Date:	**Sept 22, 2019**
TRF Received:	**Oct 1, 2019**
Sample Received:	**Oct 1, 2019**
Report Date:	**Oct 15, 2019**

PATIENT

Last Name:	**Pt Last Name**
First Name:	**Pt First Name**
Date of Birth:	**Jan 7, 1968**
Patient ID:	**Patient id**
Gender:	**Female**
Accession #:	**08000147-BLD**
Requisition #:	**08000147**

Block(s) Analyzed: **UUH201912345-A, UUH201912345-B**

Myriad myChoice® CDx Status: NEGATIVE

Genomic Instability Status: **NEGATIVE**

The Genomic Instability Score is a measurement of three biomarkers (loss of heterozygosity, telomeric allelic imbalance, and large-scale state transitions) associated with homologous recombination deficiency.

Tumor Mutation *BRCA1/BRCA2* Status: **NEGATIVE FOR A CLINICALLY SIGNIFICANT MUTATION**

ASSAY DESCRIPTION

Intended Use: Myriad myChoice® CDx is a next generation sequencing-based *in vitro* diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status for treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling.

TABLE 1: Companion diagnostic indications

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Hillary Zalaznick, MD
Diplomate FCAP
Laboratory Director
Anatomic Pathology

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Appendix PB 134

MYRIAD myChoice® CDx

INSIDE YOU WILL FIND:

- √ Specimen Requirements
- √ Packing Instructions and specimen transportation materials including an ice pack. **Please freeze this pack for 24 hours prior to shipping**.
- √ FedEx packaging and shipping label

TO AVOID DELAYS IN TESTING, PLEASE INCLUDE THE FOLLOWING WHEN SUBMITTING A SPECIMEN:

- ☐ TRF (Test Request Form)
- ☐ A copy of the pathology report
- ☐ Specimen block* (with frozen ice-pack)

  or
- ☐ Slides* (in provided slide box)

**See Specimen Instructions for specific tissue requirements.*

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MYRIAD myChoice® CDx

TUMOR SPECIMEN COLLECTION & TRANSPORTATION KIT

Upon arrival, this specimen will be assessed for appropriate quantity and quality for the test specifications by Myriad.

If Myriad is unable to complete the analysis on the specimen, you will be notified and may need to submit a new specimen for testing.

Any unused portion of the block or unused slides will be returned to you when the test is completed.

MYRIAD myChoice® CDx

Once this test kit is received, Myriad will automatically replenish your kit supply. If you would like to order additional test kits or have any questions about your specimen submission, please call our dedicated Myriad myChoice CDx Customer Service at 1-877-283-6709.

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320 Wakara Way
Salt Lake City, Utah 84108

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TUMOR SPECIMEN COLLECTION & TRANSPORTATION KIT

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If you have any questions about your specimen submission or to obtain additional test kits, please call our dedicated Myriad myChoice CDx Customer Service at 1-877-283-6709.

Myriad myChoice® CDx Test

TUMOR SPECIMEN COLLECTION & TRANSPORTATION KIT

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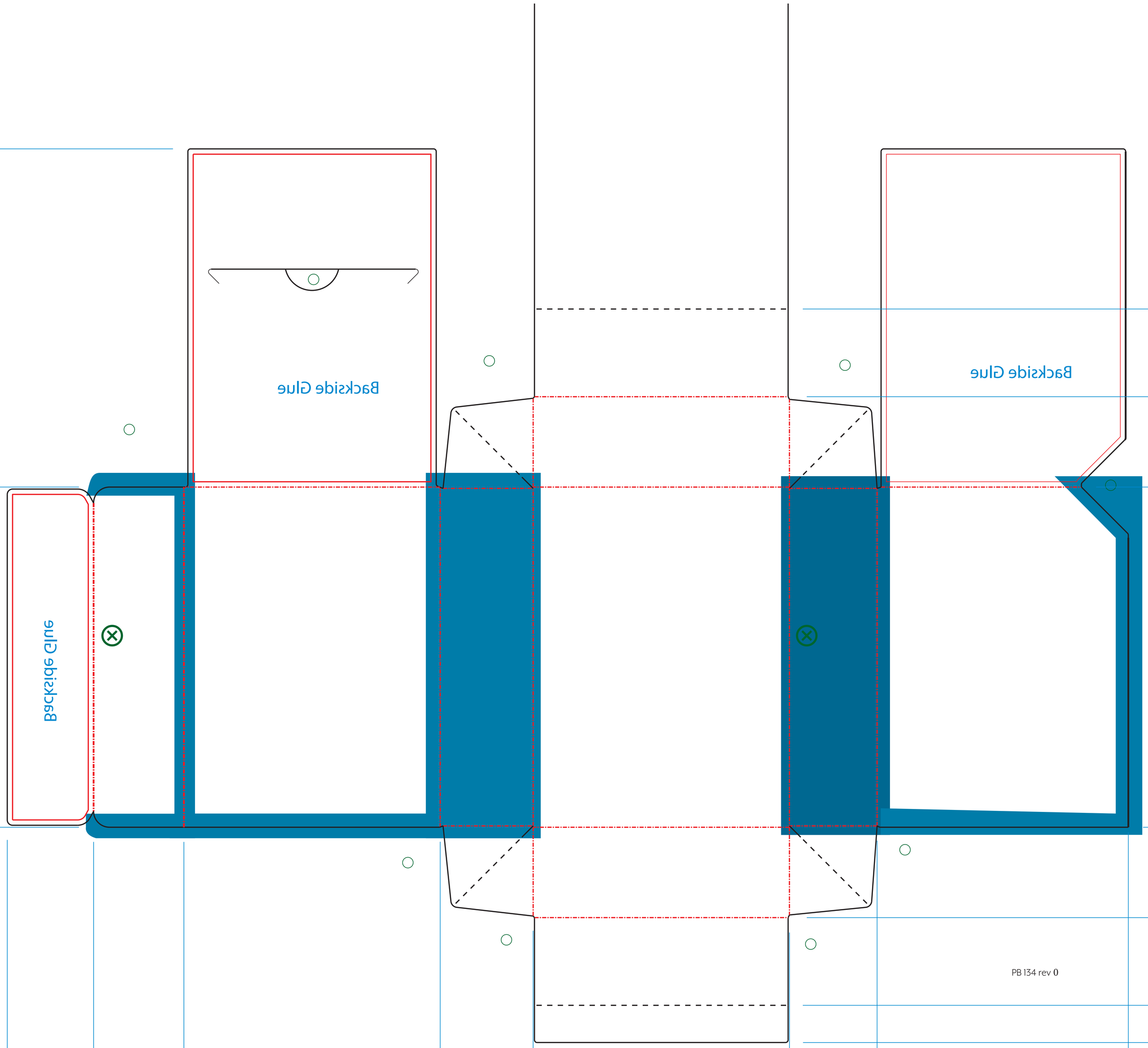
TUMOR SPECIMEN COLLECTION & TRANSPORTATION KIT

PB 134 rev 0



PB 134 rev 0