



Laboratory Service Requisition for Tumor Profiling by PCDx™ (Paradigm Cancer Diagnostic)



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Ordering Physician Information		Patient Information	
Ordering physician's name:	First Name:	Last Name:	
Institution:	Date of Birth (day/month/year):	Gender: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE	
Address: (Street, City, State, ZIP, Country)	Address: (Street, City, State, ZIP, Country)		
Phone, Fax:	Phone, Fax:		
E-mail:	E-mail:		
Specimen Retrieval (Select one and include a copy of the pathology report)			
<input type="checkbox"/> I want TherapySelect to request specimen.		<input type="checkbox"/> I will arrange having sent the specimen.	
Name of Pathology:	Primary Tumor Type:		
Contact Name:	Pathology Dx/Histology: <input type="checkbox"/> Report attached		
Address: (Street, City, State, ZIP, Country)	Specimen Site:		
	Specimen/Block ID#(s):		
	Date & Time of Collection:		
Phone, Fax:	Tissue Types(s): <input type="checkbox"/> FFPE Block <input type="checkbox"/> Unstained Slides <input type="checkbox"/> Fresh Tissue		
E-mail:	Duration of Fixation (FFPE Blocks):		
PCDx™ (Paradigm Cancer Diagnostic) Service Provided			
Solid tumor biomarker analysis for therapeutic decision support and clinical trials matching. The offering below is updated frequently with the published evidence. The definitive list of biomarkers analyzed by tumor type, and list of available biomarkers can be found online at www.paradigmdx.com/pcdx/ ("Website"). The biomarkers included in the service may change from time-to-time. Before ordering testing services, please refer to the Website to view a link that provides the most up-to-date listing of biomarkers that will be performed by tumor type.			
<input type="checkbox"/> PCDx™ (Paradigm Cancer Diagnostic)			
Multiple platform biomarker analysis (IHC for protein expression; Next-Generation Sequencing (DNA mutations, including copy number variations, single nucleotide variations, amplifications, insertions, deletions); gene fusion analysis; microsatellite instability (MSI); tumor mutation burden (TMB); see Website for actual list of biomarkers performed for the tumor type submitted)			
Specimen Return (Select one)			
<input type="checkbox"/> Specimen shall be returned		<input type="checkbox"/> Specimen shall be stored at TherapySelect/Paradigm after usage	
Name and Contact Data (if different from the pathology data above):			
Tel, Fax, Email:			
Test Result Recipient(s)			
Ordering Physician <input type="checkbox"/> Post <input type="checkbox"/> Email <input type="checkbox"/> Fax	Other (Name and Contact Data):		Other (Name and Contact Data):
Patient <input type="checkbox"/> Post <input type="checkbox"/> Email <input type="checkbox"/> Fax	<input type="checkbox"/> Post <input type="checkbox"/> Email <input type="checkbox"/> Fax	<input type="checkbox"/> Post <input type="checkbox"/> Email <input type="checkbox"/> Fax	<input type="checkbox"/> Post <input type="checkbox"/> Email <input type="checkbox"/> Fax
Signature			
Date and Signature of Ordering Physician		For internal remarks only	

Notice: This requisition constitutes an order for services. I certify (a) that the services are medically indicated and necessary and will assist me in treating my patient, (b) that I maintain and will make available patient medical records documenting the foregoing, and (c) I have supplied information to the patient regarding testing and if required by law, the patient has given consent for testing to be performed. Final report will be delivered in English. Please see the next page for patient consent requirements and optimal specimen requirements. Terms and conditions of TherapySelect and Paradigm Diagnostics, Inc. apply. Visit download section of www.therapysselect.de and www.paradigmdx.com to view the terms and conditions in full.

Acknowledgment of Consent

By submitting this requisition, you, as the patient's physician, represent and verify that the patient has provided clear, unambiguous and explicit consent to send the patient's specimen and sensitive medical and other personal information to Paradigm Diagnostics, Inc. ("Paradigm") and to transfer that information to the United States for processing. Additionally, you represent that, as applicable to provisioning of this service, you and your office have complied with all applicable national and local privacy requirements and regulations.

For physicians and/or offices established in the European Economic Area, you and/or your office(s) (as applicable) agree that this engagement incorporates by reference the European Commission Standard Contractual Clauses for the Transfer of Personal Data to Processors Established in Third Countries (2010/87/EU), where Paradigm is "data importer," each of you and/or your office(s) are the "data exporter," the personal data processing is as described herein to provide the services requested (including as necessary for invoicing, debt collection, anonymization/ de-identification, and as otherwise required by law), and the security measures are that Paradigm has reasonable technical, administrative and organizational security measures.

The results for biomarkers tested under this requisition will be provided in a report associating one or more treatment agents to biomarkers based on published medical evidence, which may include published studies performed in the tumor type present in the tested sample or derived from a different tumor type. Decisions regarding care and treatment should not be based solely on selection of a test such as this test or the information provided related to this requisition. Decisions on patient care and treatment must be based on the treating physician's independent medical judgment, taking into consideration all relevant patient information, such as family history, physical examinations, results of other diagnostic tests, and patient preferences, and in accordance with the applicable standard of care. The selection of any or none of the matched agents is ultimately and solely in the discretion of the treating physician. Physician or practitioner hereby acknowledges and agrees to comply with any local, state/provincial, or national laws or regulations, rules or order of any governmental body, having jurisdiction over activities considered under this requisition.

Office Checklist for PCDx™ (Paradigm Cancer Diagnostic)

- Requisition Form (Complete and Signed by Physician)
- Patient Consent and Patient Order Form (Complete and Signed by Patient)
- Pathology Report
- Sufficient Tumor Specimen (Detailed Below)

Formalin Fixed Paraffin Embedded (FFPE) Samples

Sufficient tumor must be present to complete all analysis.

If you have any questions, please contact TherapySelect at +49 (0)6221-8936-152.

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fixed Tissue	One (1) tumor-containing formalin fixed paraffin embedded block (FFPE) from most recent surgery or biopsy. Successive four (4) micron sections will be created from the block until sufficient material for the testing orders is obtained. For the molecular analysis, tumor cells will be excised by microdissection until a total area of at least 50mm ² is obtained.
Unstained Slides	Unstained, positively charged, unbaked slides from one single, tumor-containing formalin fixed paraffin embedded block; 4 micron sections • PCDx™ - 55 slides • Next-Generation Sequencing only - 15 slides Note: At least a 5mm x 5mm section of tissue per slide is required. For small biopsies (tissue area < 5 mm x 5 mm) please cut two sections per slide for at least one half of the slides to ensure sufficient material for molecular assays.
Core Needle Biopsy	Four to six (4-6) biopsies formalin fixed paraffin embedded • 18 gauge needle preferred
Fine Needle Aspirate (FNA)	One (1) formalin fixed paraffin embedded block containing sufficient tumor
Malignant Fluid Cell Block	One (1) formalin fixed paraffin embedded cell block containing sufficient tumor (20% or more tumour nuclei).
Bone/Bone Metastasis	One (1) formalin fixed paraffin embedded block of tumor (primary bone malignancy or metastasis to the bone) decalcified using EDTA based method(s) or non-decalcified specimen.

Fresh Samples

Sufficient tumor must be present to complete all analysis.

Due to shipment times, contact TherapySelect at +49 (0)6221-8936-152 prior to shipment of fresh tissue.

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fresh Tissue	Two (2) or more samples with a maximum thickness of ~3mm (height, width, length) and submit in 10% neutral buffered formalin.
Core Needle Biopsy	Four to six (4-6) biopsies • 18 gauge needle preferred
Bone/Bone Metastasis	Two (2) or more samples with maximum thickness of 3mm (height, width, length) and submit in 10% neutral buffered formalin (DO NOT DECALCIFY)

Insufficient Specimen Quantity – Prioritization of Tests

In the event that a specimen is received with an insufficient quantity of tissue or insufficient percent tumor required to perform the entire profile or individual tests indicated on the requisition, the prioritization will be 1. NGS for DNA mutations, copy number variations and chromosomal changes, mRNA and 2. Protein by IHC. Please note: turnaround time may be longer for specimens with limited tissue.