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SPECIMEN INFORMATION

Toll-free: 1.888.92.PHENO P 1.206.374.9000 F 1.206.374.9009

www.phenopath.com

IHC/ISH

PHENOPATH USE ONLY

THIS SECTION FOR PHENOPATH USE ONLY

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performed at an additional charge. for other disease states may also be available; full consult available; visit our website or call 1.866.927.4366 for more information. authorize the send out and agree to accept financial responsibility. Send: Reqs (List req #) Transport Kits TC Transport Kits RPMI Other Date Needed By:	<ul> <li>Adenovirus</li> <li>ALK protein (p80)</li> <li>ALK (for lung CA</li> <li>Alpha-1 antitryp</li> <li>Alpha-fetoprotein</li> <li>AMACR (p5048)</li> <li>Amyloid A</li> <li>Amyloid Beta</li> <li>Amyloid Beta</li> <li>Amyloid Beta</li> <li>Amyloid P</li> <li>Androgen Recept</li> <li>Arginase-1</li> <li>Arginase-1</li> <li>Arginase-1</li> <li>Arginase-1</li> <li>Arginase-1</li> <li>Bolo-2 (clone 124)</li> <li>bcl-2 (clone 124)</li> <li>bcl-2 (clone 124)</li> <li>bcl-2 (clone C2)</li> <li>bcl-6</li> <li>bcl-10</li> <li>N/A BCMA</li> <li>Ber-Ep4</li> <li>Beta-catenin</li> <li>Bg8 (blood group A</li> <li>Blood Group A</li> <li>Blood Group B</li> <li>Bob-1</li> <li>Brachyury</li> <li>Breast Multiple:</li> <li>Calcitonin</li> <li>Caldesmon</li> <li>Caldesmon</li> <li>Caldesmon</li> <li>Caldesmon</li> <li>Caldesmon</li> <li>Caldesmin K</li> <li>CD1a</li> <li>CD3</li> <li>CD4</li> </ul>	0)	CD8     CD10(     CD14     CD15     CD15     CD20     CD22     CD22     CD23     CD25     CD34     CD33     CD34     CD33     CD34     CD45     CD45     CD45     CD45     CD56(     CD57     CD56(     CD57     CD56(     CD57     CD56(     CD57     CD57     CD56(     CD57     CD57     CD56(     CD57     C	IL-2Ra) Ki-1) NCAM) (KP-1) a 3 3 3 7 mon II-7) nogranin A 9 7 noocktail 3 D1 in	<ul> <li>EBV by ISH (EBEF</li> <li>EBV by IHC</li> <li>EGFR</li> <li>EMA</li> <li>ER (SP1)</li> <li>ERG</li> <li>Fascin</li> <li>FOXP1</li> <li>FOXP3</li> <li>FSH</li> <li>Galectin-3</li> <li>GATA-3</li> <li>GCDFP-15 (BRST</li> <li>GIucagon</li> <li>Glucagon</li> <li>Glucamine Synthm</li> <li>Glycophorin A</li> <li>Glycophorin A</li> <li>Glycophorin A</li> <li>Glycophorin A</li> <li>Glycophorin A</li> <li>Glycophorin A</li> <li>Hairy cell Leuk (DE</li> <li>HBME-1</li> <li>HCG (Beta-HCG)</li> <li>Hep B surface an</li> <li>Hep Surface an</li> <li>Hep Surface an</li> <li>Hep Surface an</li> <li>HER2 by IHC (no re</li> <li>NA HER2 by IHC (no re</li> <li>HAB45</li> <li>HK4-DR</li> <li>HMB45</li> <li>HSV I/II</li> <li>IDH1</li> <li>IgA</li> </ul>	2) 2) 2) 20 2 2) 20 2 2) 20 2 2 2) 20 2 2 2 2	IgG IgG4 & IgG IgM3 INhibin-alp INI-1 (SMA INPP4B Kappa by II Kappa by II Kappa by II Kapta i SMA Keratin 7 Keratin 7 Keratin 7 Keratin 7 Keratin 20 Keratins (A Keratins (A Keratins (G Keratins (G K	RCB1) HC SH* SCAR) SCAR) BE12,HMW) -1) HC HC ISH* obin elan A) t tria	Myo     Nap     Nesi     Nesi	globin sin A in N ofilaments 1) 2.2 3.1 2 3/4 (INK4a) NTR reatic polypeptide ovirus 5 7 3 1 (CD279) 1 (22C3) 1 (22C3) 1 (22C3) 1 (22C3) 1 (22C3) 1 (22C3) 1 (22C3) 1 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 2 (22C3) 2 (22C3) 1 (22C3) 2 (22C3) 2 (22C3) 2 (22C3) 2 (22C3) 3 (22C3) 2 (22C3) 3 (22C3) 2 (22C3) 3 (22C3) 3 (22C3) 2 (22C3) 3 (22C3) 3 (22C3) 3 (22C3) 3 (22C3) 3 (22C3) 4 (22C3) 2 (22C3) 3 (22C3) 3 (22C3) 3 (22C3) 3 (22C3) 4 (22C3) 5 (22C3) 5 (22C3) 4 (22C3) 5 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 2 (22C3) 2 (22C3) 3 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 2 (22C3) 3 (22C3) 1 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 2 (22C3) 1 (22C3) 1 (22C3) 2 (22C3) 1 (22C4) 2 (22C3) 1 (22C4) 2 (22C3) 1 (22C4) 2 (22C3) 1 (22C4) 2 (22C3) 1 (22C4) 2 (22C4)	<ul> <li>PU.1</li> <li>N/A ROS-1</li> <li>S-100</li> <li>SALL4</li> <li>Serotonin</li> <li>SF-1</li> <li>SMMHC</li> <li>Smooth muscle actin (1A4)</li> <li>Smoothelin</li> <li>Somatostatin</li> <li>SOX10</li> <li>SOX11</li> <li>SSt2A</li> <li>STAT6</li> <li>Synaptophysin</li> <li>TCL1</li> <li>TCR-delta</li> <li>TdT</li> <li>Thrombomodulin</li> <li>Thyroglobulin</li> <li>TiA-1</li> <li>Toxoplasma gondii</li> <li>Transthyretin</li> <li>TSH</li> <li>TSH</li> <li>TSH</li> <li>TSH</li> <li>Uroplakin</li> <li>Varicella Zoster Virus</li> <li>Villin</li> <li>Villin</li> <li>Vimentin</li> <li>VIP</li> <li>VWF</li> <li>WT-1</li> <li>ZAP-70</li> <li>G = staining w/o interp</li> </ul>		
	performed at an additional charge. for other disease states may also be available; full consult available; visit our website or call 1.866.927.4366 for more information. authorize the send out and agree to accept financial responsibility.												
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## By submitting a specimen with this requisition form, you agree:

- 1) The information provided on this form and accompanying paperwork is complete and accurate.
- 2) If the information is not accurate, and PhenoPath cannot obtain reimbursement for services that have been requested and provided, Client agrees to accept financial responsibility.
- 3) If the test order is ambiguous, PhenoPath may contact client to determine intent. Testing may be delayed.
- Requests for testing PhenoPath does NOT perform (for current test menu, consult PhenoPath's website www.phenopath.com or contact Client Services at 1.206.374.9000, or Toll-free at 1.888.92.PHENO (1.888.927.4366):
  - a) PhenoPath may forward specimens to an alternate facility for testing it does not perform, upon authorization by Client.
  - b) PhenoPath will manage return of applicable specimen to Client.
  - c) By signing the authorization form, Client agrees to pay for authorized services that are not paid for by a third party. PhenoPath can only bill for professional services provided by PhenoPath.

**ICD-10** – All providers, laboratories, institutions, hospitals, and other providers ordering laboratory testing to be performed by PhenoPath Laboratories must provide all clinically relevant ICD-10-CM diagnosis codes for all testing submitted.

**Direct Bill Law** – Washington is a "direct-bill" state for anatomic pathology services (http://apps.leg.wa.gov/rcw/default.aspx?cite=48.43.081, RCW 48.43.081). This means that for specimens originating in the State of Washington, PhenoPath can only send a bill to the entity that ordered the services (or to the patient or their insurance).

**MEDICARE COVERAGE DETERMINATIONS** – PhenoPath is a Medicare participating provider, and is subject to the local coverage determinations (LCD) of the Medicare Administrative Contractor (MAC) for Jurisdiction F, Noridian Healthcare Solutions, Contractor No. 02402. Additional information can be obtained online at: https://www.noridianmedicare.com/partb/coverage/active.html.

**MEDICARE MEDICAL NECESSITY REQUIREMENTS** – When ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements may apply:

- 1) Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests, except for certain specifically approved procedures, and may not pay for non-FDA-approved tests or tests considered experimental.
- 2) If there is reason to believe that Medicare will not pay for a test, the patient should be informed, and asked to sign an Advanced Beneficiary Notice (ABN) to indicate whether he/she accepts responsibility for the cost of the test if Medicare denies payment.
- 3) The ordering physician must provide all clinically relevant ICD-10 diagnosis codes, not a narrative description, in order to support the medical necessity of each test ordered. Providing ICD-10 codes on the Requisition will avoid unnecessary phone calls to physician and client offices as well as delays in service to patients to obtain medical necessity documentation. PhenoPath may contact Client to obtain diagnosis information for reasons including, but not limited to the following:
  - A diagnosis code is not provided.
  - The provided diagnosis appears inconsistent with the patient's demographic, the patient's medical condition or the testing services being ordered.
  - The provided diagnosis does not meet the coverage criteria as supporting medical necessity for testing services covered by a Medicare LCD.
- 4) Organ- or disease-oriented panels should be billed to Medicare only when every component of the panel is medically necessary. The OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties. PhenoPath- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary. PhenoPath offers groups of tests based on accepted clinical practice.

Advanced Beneficiary Notice ("ABN") – An ABN, Form CMS-R-131, is a standardized notice you must issue to a Medicare beneficiary before providing certain Medicare Part B (outpatient) or Part A (limited to hospice, home health agencies [HHAs], and Religious Nonmedical Healthcare Institutions only) items or services. You must issue the ABN when:

- You believe Medicare may not pay for an item or service;
- Medicare usually covers the item or service; and
- Medicare may not consider the item or service medically reasonable and necessary for this patient in this particular instance. You should only provide ABNs to beneficiaries enrolled in original (fee-for-service) Medicare. ABNs allow beneficiaries to make informed decisions about whether to get services and accept financial responsibility for those services if Medicare does not pay. The ABN serves as proof the beneficiary knew prior to getting the service that Medicare might not pay. If you do not issue a valid ABN to the beneficiary when Medicare requires it, you cannot bill the beneficiary for the service, and you may be financially liable if Medicare doesn't pay. You may also use the ABN as an optional (voluntary) notice to alert beneficiaries of their financial liability prior to providing care that Medicare never covers. ABN issuance is not required to bill a beneficiary for an item or service that is not a Medicare benefit and never covered.
- If you order a test that does not meet Medicare's medical necessity guidelines, it is important that you complete an ABN and have it signed by the patient at the time of service. This will allow you and PhenoPath to bill the patient for the services provided if Medicare does not reimburse us for the test(s) and if the patient has accepted the financial responsibility. Medicare defines medical necessity as services that are: reasonable and necessary, for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and not excluded under another provision of the Medicare Program. All services reported to the Medicare Program by healthcare professionals must demonstrate medical necessity through the use of International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnostic coding carried to the highest level of specificity for the date of service.

Physician Clinical Consultant: PhenoPath's pathologists are available to discuss appropriate testing and test ordering with ordering physicians.

