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CANCER TYPE

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| Facility specimen collected at | | | | | | | Block(s), submitted stained slides and report will be returned to the Ordering Physician at the address/FAX listed below (unless otherwise requested): | | | | | | | | | | |
| Collection Date Collection Time | | | | me | | | Name (Client ID) | | | | | | | | | | |
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| Pathology Report: | | | | | | | City, ST Zip | | | | | | | | | | |
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| PROG | NOSTIC MARKER ST | UDIES FIX | XATION (AS | CO/C | AP Red | quirement) | | | | | | caid) have medica | | | | | |
| Fixative: ☐ 10% NBF (Neutral Buffered Formalin) ☐ Oth | | | | ther _ | | | | | | | | | | | | ent of the patient. | |
| Fixation duration (please circle): <6 hours 6-72 hours >72 | | | | 72 hou | ırs Un | known | Pheno | Path may bill t | comp the re | questing e | ccur | rate patient billi y) | ng intoi | rmatic | on is not | provided, | |
| Collection Time: AM/PM Time Placed in Fixativ | | | | tive:_ | | AM/PM | | □Insurance | □ P | | | | | | | | |
| PATII | ENT INFORMATION | | | | | | PO# | | | | | quired ICD-10 | | | | | |
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| Phone | | | | | | | | | | hilling pu | rnos | | n the n | ame o | f the tre | ating physician) | |
| PHOHE | • | | | | | | | | | | | | | | | OT be faxed or mailed | |
| | ☐ Inpatient ☐ | Outpatient | ☐ Non-Ho: | spital | Patient | | | cian Name: | | 81. 7 | | | | , - | | | |
| CONT | ACT INFORMATION | • | | <u>'</u> | | | Facili | ty Name: | | | | | | | | | |
| Person | n completing form | | | | | | | | | | | | | | | | |
| | | | | | | | Mailing Address | | | | | | | | | | |
| Date | | | Phone | | | | | | | | | LEAV# | | | | | |
| Date | | | Phone | | | | Phone | e #: | | | | FAX#: | | | | | |
| G=Glob | oal (w/ interp)/TC=Tech only UNOTHERAPY BIOMAR | | Phone | | | / interp)/TC=Te | Phone | e #: | | | | obal (w/ interp)/ TC | | | | NOMA | |
| G=Glob | JNOTHERAPY BIOMAR | TC KERS | | | NG CAI | RCINOMA | Phone ch only | e #: (w/o interp) | 0) 111 | [| YNG TO | obal (w/interp)/TC CH SYNDROM C | E & CC | OLON G TO | CARCII | | |
| G=Glob | JNOTHERAPY BIOMAR | TC KERS | (28-8) IHC | LUI G | NG CA TC PD | | Phone ch only | e #: (w/o interp) | -8) IH | C [| YNG TO | bbal (w/ interp)/TC CH SYNDROM C MLH1 IHC | E & CO | OLON G TO | CARCII | 2 IHC | |
| G=Glob IMMU G TC | JNOTHERAPY BIOMAR G A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) | RKERS TC N/A PD-L1 (Opdive | (28-8) IHC o) (SP142) IHC | LUI G | NG CAI | RCINOMA -L1 (22C3) IHO eytruda) -L1 (SP142) | Phone ch only | #: (w/o interp) TC N/A (Opdivo) N/A PD-L1 (E1 | | C [| YN: 3 TO 1 [| bbal (w/ interp)/TC CH SYNDROM C MLH1 IHC MSH6 IHC HER2 IHC | E & CC | G TO | CARCII MSH2 PMS2 A HER2 | 2 IHC 1HC FISH | |
| G=Glob IMMU G TC N/A | JNOTHERAPY BIOMAR PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) PD-L1 SP263 (FDA-app | RKERS TC N/A PD-L1 (Opdivo N/A PD-L1 (Tecent | (28-8) IHC o) (SP142) IHC triq) | G G | NG CAI TC N/A PD (Ke | -L1 (22C3) IH(eytruda) -L1 (SP142) C (Tecentriq) | Phone ch only | to #: (w/o interp) TC N/A (Opdivo) N/A (PD-L1 (28 (Opdivo) N/A (generic) | | C [| YN: | obal (w/ interp)/TC CH SYNDROM C MLH1 IHC MSH6 IHC HER2 IHC /A HER2 IHC (if | equivo | G TO O D O D O D O D O D O D O D | CARCINC MSH2 MSH2 PMS2 (A HER2 un HER2 | 2 IHC 2 IHC FISH FISH) | |
| G=Glob IMMU G TC N/# | JNOTHERAPY BIOMAR PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) PD-L1 SP263 (FDA-app MLH1 IHC | RKERS TC N/A PD-L1 (Opdive N/A PD-L1 (Tecent proved) MSH2 | (28-8) IHC o) (SP142) IHC triq) | G G | NG CAI TC N/A PD (Ke N/A PD IHC | RCINOMA -L1 (22C3) IHO eytruda) -L1 (SP142) C (Tecentriq) | Phone ch only | #: (w/o interp) TC N/A (Opdivo) N/A PD-L1 (E1 | | C [| YN(G TO O O | bbal (w/ interp)/TO CH SYNDROM C MSH6 IHC MSH6 IHC HER2 IHC /A HER2 IHC (if MMR IHC pa | equivonel (ML | G TO N/ N/ Cal, ru _H1, M | CARCING MSH2 MSH2 PMS2 /A HER2 un HER2 MSH2, MS | 2 IHC 2 IHC FISH FISH) | |
| G=Glob IMMU G TC N/# | JNOTHERAPY BIOMAR G A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) A PD-L1 SP263 (FDA-app MLH1 IHC MMR IHC panel (MLH1, MSH2. | RKERS TC N/A PD-L1 (Opdive N/A PD-L1 (Tecent proved) MSH2 PMS2 | (28-8) IHC o) (SP142) IHC triq) IHC | LUI G 1 I | NG CAI TC N/A PD (Ke N/A PD IHC N/A AL IHC run N/A RO | -L1 (22C3) IHC eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or e | Phone ch only | w/o interp) TC N/A PD-L1 (28 (Opdivo) N/A PD-L1 (E1 (generic) ROS1 IHC I, run ROS1 by FISH | L3N) | C | YNO G TO G TO G TO G TO G TO NA | bbal (w/ interp)/TO CH SYNDROM C MLH1 IHC MSH6 IHC HER2 IHC /A HER2 IHC (if MMR IHC pa MMR IHC pa MMR IHC pa PMSZ, run BRA | equivonel (ML | G TO N/ Ocal, ru H1, M lon) (iff | CARCII MSH2 PMS2 /A HER2 un HER2 MSH2, MS | P. IHC I IHC FISH FISH) SH6, PMS2) Doss of MLH1 and | |
| G=Glob IMML G TC N/A N/A | JNOTHERAPY BIOMAR G A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) A PD-L1 SP263 (FDA-app MLH1 IHC MMR IHC panel (MLH1, MSH2, MSH6, and PMS2) | RKERS TC N/A PD-L1 (Opdive N/A PD-L1 (Tecent Proved) MSH2 MSH6 | (28-8) IHC o) (SP142) IHC triq) IHC IHC | LU G T T T T T T T T | NG CAI TC N/A PD (Ke N/A PD IHC N/A ALI N/A RO N/A ALI | -L1 (22C3) IH(eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or er K (for lung ca) IHC | Phone Ch only G C C C C C C C C C C C C C C C C C C | #: (w/o interp) TC N/A (Dpl-L1 (28 (Opdivo) N/A PD-L1 (E1 (generic) ROS1 IHC L, run ROS1 by FISH N/A ROS1 by FISH | L3N) | C | YN(G TO O O | obal (w/ interp)/TOCH SYNDROMC CH SYNDROMC C | equivo nel (ML nel (col AF V600 B nel (enc MLH1 pr | OLON G TO D D D D N/ cal, ru LH1, M lon) (iff by PCR domet romote | CARCII MSH2 MSH2 PMS2 A HER2 IN HER2 MSH2, MS there is lot crial) (if the | P IHC PISH FISH SH6, PMS2) oss of MLH1 and ere is loss of MLH1 tion analysis *) | |
| G=Glob IMML G TC N/A N/A | JNOTHERAPY BIOMAR A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) PD-L1 SP263 (FDA-app MLH1 IHC | RKERS TC N/A PD-L1 (Opdive N/A PD-L1 (Tecent Proved) MSH2 MSH6 | (28-8) IHC o) (SP142) IHC triq) IHC IHC | LU G | NG CA TC N/A PD (Ke N/A PD IHC N/A IHC run N/A RO N/A AL N/A AL | -L1 (22C3) IHC eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or e | Phone Ch only G C C C C C C C C C C C C C C C C C C | w/o interp) TC N/A PD-L1 (28 (Opdivo) N/A PD-L1 (E1 (generic) ROS1 IHC I, run ROS1 by FISH | L3N) | C | YNO G TO G TO G TO G TO G TO NA | bobal (w/ interp)/TO CH SYNDROM C | equivo nel (ML nel (col AF V600 I nel (enc MLH1 pi nel (if th | G TO G TO G N/ Cal, ru LH1, M lon) (iff by PCR domet romote here is , and if | CARCING MSH2 MSH2 MSH2 MHER2 MSH2, MS there is lo crial) (if there methylatelloss of MIL BRAF is n | 2 IHC 1 IHC FISH FISH) SH6, PMS2) poss of MLH1 and ere is loss of MLH1 | |
| G=Glob IMML G TC N/A N/A | JNOTHERAPY BIOMAR Q A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) A PD-L1 SP263 (FDA-app MLH1 IHC | RKERS TC N/A PD-L1 (Opdive N/A PD-L1 (Tecent Proved) MSH2 MSH6 | (28-8) IHC o) (SP142) IHC triq) IHC IHC | LUI G I I I I I I I I | NG CAI TC PD (Ke N/A PD IHC N/A IHC N/A RO N/A AL N/A AL N/A ME N/A RE | RCINOMA -L1 (22C3) IH(eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or er K (for lung ca) IHC K by FISH T by FISH | Phone ch only G C quivoca ch only | (w/o interp) TC PD-L1 (28 (Opdivo) N/A (Opdivo) ROS1 IHC ROS1 BY FISH N/A ROS1 by FISH N/A ROS1 by FISH N/A BRAF V60 | L3N) | C [] IHC [] C C [] PCR [] | YNO G TO G TO G TO G TO NA NA | Dobal (w/ interp)/TC CH SYNDROM C MLH1 IHC MSH6 IHC HER2 IHC MMR IHC pa MMR IHC pa MMR IHC pa MMR IHC pa A MMR IHC pa B MR MR IHC pa A MMR IHC pa A MMR IHC pa B MR MR IHC pa A MR IHC pa B MR MR IHC pa B MR | equivo nel (ML nel (col AF V600 k nel (enc MLH1 pi nel (if tt) by PCR, nylation a | G TO N/ Cal, ru H1, M lon) (iff by PCR domet romote here is a, and iff analysis separat | CARCII MSH2 PMS2 MHER2 IN HER2 MSH2, MS MSH2 MSH2, MS MSH2 MSH2, MS MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MS | P. IHC I IHC FISH FISH) SH6, PMS2) oss of MLH1 and ere is loss of MLH1 tion analysis *) LH1 and PMS2, egative, run MLH1 and normal tissue | |
| G=Glob IMML G TC N/A N/A N/A BREA G TC | JNOTHERAPY BIOMAR G A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) A PD-L1 SP263 (FDA-app MLH1 IHC MMR IHC panel (MLH1, MSH2, MSH6, and PMS2) A MSI PCR (requires separate tt (peripheral blood is acceptable ST CARCINOMA G ER IHC | RKERS TC N/A PD-L1 (Opdive N/A PD-L1 (Tecent rroved) MSH2 PMS2 MSH6 Morand normal for the normals TC PRIHC | (28-8) IHC o) (SP142) IHC triq) IHC IHC IHC all tissue specimens | LU G | NG CAI TC N/A PD (Ke N/A PD IHO N/A AL N/A RO N/A AL N/A BE N/A EG | RCINOMA -L1 (22C3) IH(2) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca- ALK by FISH) S1 IHC (if + or er K (for lung ca) IH(K by FISH T by FISH FR PCR (if neg- | Phone ch only G C C C C C C C C C C C C C C C C C C | (w/o interp) TC PD-L1 (28 (Opdivo) N/A (Opdivo) N/A (generic) ROS1 IHC I, run ROS1 by FISH N/A ROS1 by F N/A BRAF V60 In ALK FISH) | H) FISH PCR 0 by P | C [IHC [C] [C | YNO NO NO NO NO NO NO NO | bal (w/ interp)/TC CH SYNDROM C S MLH1 IHC MSH6 IHC HER2 IHC /A HER2 IHC (if MMR IHC pa PMS2, run BRA /A MMR IHC pa and PMS2, run MR IHC pa run BRAF V600 promoter metr /MSI by PCR (re specimen) | equivo nel (ML nel (col AF V600 I nel (enc MLH1 pr nel (iff th b by PCR, nylation a quires s ripheral | G TC N/ccal, ru H1, M lon) (iff by PCR domet romote here is , and if analysi eparat blood | CARCII MSH2 PMS2 A HER2 IN HER2 ISH2, MS trial) (if the remethylatiloss of ML BRAF is n is x*) e tumor an is accepta | 2 IHC I IHC FISH FISH) SH6, PMS2) oss of MLH1 and ere is loss of MLH1 tion analysis *) LH1 and PMS2, egative, run MLH1 and normal tissue able for the normal | |
| G=Glob IMML G TC N/A N/A N/A BREA G TC | JNOTHERAPY BIOMAR G A A A A BD-L1 (22C3) IHC ((Keytruda) BD-L1 (E1L3N) BC | RKERS TC N/A (PD-L1 (Tecent) | (28-8) IHC o) (SP142) IHC triq) IHC IHC IHC all tissue specimens specimen)) | | NG CA TC N/A PD (Ke N/A IHC N/A RO N/A AL N/A AL N/A AL N/A RE N/A RE N/A EG N/A EG N/A EG N/A EG N/A EG | -L1 (22C3) IHC eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or ec K (for lung ca) IHC K by FISH ET by FISH T by FISH FR PCR (if neg | Phone ch only G C C C C C C C C C C C C C C C C C C | (w/o interp) TC N/A PD-L1 (28 (Opdivo) N/A PD-L1 (E1 (generic) ROS1 IHC ROS1 by FISH N/A ROS1 by FISH N/A ROS1 by FISH N/A BRAF V60 an ALK FISH) un ALK FISH, and | H) FISH PCR 0 by P | C [IHC] [I | YNi | bal (w/ interp)/TC CH SYNDROM C S MLH1 IHC MSH6 IHC HER2 IHC /A HER2 IHC (if MMR IHC pa PMS2, run BRA /A MMR IHC pa run BRAF V600 promoter metr /A Specimens (pa | equivo nel (ML nel (col AF V600 E nel (if tr) 0 by PCR, ylation a equires siripheral | G TC N/ccal, ru H1, M lon) (iff by PCR domet romote here is , and if analysi eparat blood | CARCII MSH2 MSH2 MSH2 MSH2 MHER2 MHER2 MSH2, MS MSH2, MS MSH3 | E IHC I IHC FISH FISH) SH6, PMS2) DOSS OF MLH1 and Here is loss of MLH1 tion analysis *) LH1 and PMS2, egative, run MLH1 and normal tissue able for the normal | |
| G=Glot IMMU G TC N/# N/# N/# N/# N/# BREA G TC | JNOTHERAPY BIOMAR G A A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) A A A A B B B B B B B B B B B B B B B | RKERS TC N/A (PD-L1 (Opdive N/A (PD-L1 (Tecent Troved) MSH2 PMS2 MSH6 MSH6 Imor and normal for the normals TC PR IHC D p53 IHt in, INPP4B) | (28-8) IHC o) (SP142) IHC triq) IHC IHC IHC all tissue specimens specimen)) | LU G | NG CA TC N/A PD (Ke N/A IHC N/A RO N/A AL N/A AL N/A AL N/A RE N/A RE N/A EG N/A EG N/A EG N/A EG N/A EG | -L1 (22C3) IHC eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or ec K (for lung ca) IHC K by FISH ET by FISH T by FISH FR PCR (if neg | Phone ch only G C C C C C C C C C C C C C C C C C C | (w/o interp) TC PD-L1 (28 (Opdivo) N/A (Opdivo) N/A (generic) ROS1 IHC I, run ROS1 by FISH N/A ROS1 by F N/A BRAF V60 In ALK FISH) | H) FISH PCR 0 by P | IHC [IHC [IF IF IF IF IF IF IF IF | YNi | CH SYNDROM C MLH1 IHC MSH6 IHC HER2 IHC (if MMR IHC pa MR IHC p | equivo nel (ML nel (coo MEH1 pi nel (if tr) b by PCR, nylation a quires s ripheral | G TO G TO | CARCII MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH | 2 IHC I IHC FISH FISH) SH6, PMS2) pass of MLH1 and ere is loss of MLH1 tion analysis *) LH1 and PMS2, egative, run MLH1 and normal tissue able for the normal CCR 2 3, 4 and NRAS | |
| G=Glob IMML G TC N/A N/A N/A BREA G TC | JNOTHERAPY BIOMAR G A PD-L1 (22C3) IHC (Keytruda) PD-L1 (E1L3N) IHC (generic) A PD-L1 SP263 (FDA-app MLH1 IHC MR IHC panel (MLH1, MSH2, MSH6, and PMS2) MSI PCR (requires separate tt (peripheral blood is acceptable ST CARCINOMA G ER IHC | RKERS TC N/A (PD-L1 (Opdive N/A (PD-L1 (Tecent Tecent Toved) MSH2 PMS2 MSH6 Jumor and normal for the normal st TC PR IHC 1 p53 IHc In, INPP4B) | (28-8) IHC o) (SP142) IHC triq) IHC IHC IHC IHC IHC IHC IHC IIHC IIHC | | NG CAITC N/A (PD PD IHC N/A IHC IT IHC N/A AL N/A AL N/A AL N/A AE N/A EG | -L1 (22C3) IHC eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or er K (for lung ca) IHC K by FISH T by FISH T by FISH FR PCR (if neg- gative, run ROS1 FR PCR (if neg- starting) FR PCR (if neg- | Phonoch only G G Q quivoca attive, ru FISH) S1 is nea | (w/o interp) TC PD-L1 (28 (Opdivo) N/A (Opdivo) N/A (generic) ROS1 IHC ROS1 By FISH N/A ROS1 by FISH N/A EGFR by F N/A BRAF V60 In ALK FISH, and ALK FISH, if ALK is gative, run MET FISH In ALK FISH; and | L3N) | C [IHC [Image: | YNO N. N. N. N. N. N. N. | Debal (w/interp)/TOCH SYNDROM CCH SYNDROM CC MHH1 IHC MSH6 IHC HER2 IHC MHR IHC pa MMR IHC pa AMR I | equivo nel (ML nel (col AF V600 B nel (fenc MLH1 pr nel (if th) by PCR, stripheral 2 (FDA-& RAS/NR | G TC N/ocal, rL H1, M lon) (iff by PCR domet romote here is , and if analysi separat blood approv RAS (KR | CARCII MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH | E IHC I IHC FISH FISH) SH6, PMS2) DOSS OF MLH1 and Here is loss of MLH1 tion analysis *) LH1 and PMS2, egative, run MLH1 and normal tissue able for the normal | |
| G=Glot: IMMU G TC N// N// N// N// N// BREA G TC C C C C C C C C C C C C C C C C C C | JNOTHERAPY BIOMAR G A PD-L1 (22C3) IHC (CKeytruda) PD-L1 (E1L3N) IHC (generic) A PD-L1 SP263 (FDA-app MLH1 IHC (MLH1, MSH2, MSH6, and PMS2) MSI PCR (requires separate tr (peripheral blood is acceptable accep | RKERS TC N/A (Opdive N/A (PD-L1 (Tecent Troved) MSH2 MSH2 MSH6 MSH6 | (28-8) IHC o) (SP142) IHC triq) IHC | | NG CAI TC N/A PD (Ke N/A PI H(Ke N/A PI H | -L1 (22C3) IHC eytruda) -L1 (SP142) C (Tecentriq) K (for lung ca) C (if + or equivoca ALK by FISH) S1 IHC (if + or er K (for lung ca) IHC K by FISH T by FISH T by FISH FR PCR (if negressitive, run ROS1 | Phone G G C G G G G G G G G G G G G G G G G | (w/o interp) TC N/A PD-L1 (28 (Opdivo) N/A ROS1 IHC I, run ROS1 by FISH N/A ROS1 by FISH N/A ROS1 by FISH N/A ROS1 by FISH N/A ROS1 by FISH | L3N) | C [IHC [I IF C C C C C C C C C C C C C C C C C C C | N | CH SYNDROM C MHH1 IHC MSH6 IHC HER2 IHC MRI HC PA MMR IHC PA MR IHC | equivo nel (ML nel (col AF V600 B nel (fenc MLH1 pr nel (if th) by PCR, stripheral 2 (FDA-& RAS/NR | G TC N/ocal, rL H1, M lon) (iff by PCR domet romote here is , and if analysi separat blood approv RAS (KR | CARCII MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH2 MSH | 2 IHC I IHC FISH FISH) SH6, PMS2) pass of MLH1 and ere is loss of MLH1 tion analysis *) LH1 and PMS2, egative, run MLH1 and normal tissue able for the normal CCR 2 3, 4 and NRAS | |
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Send: ☐ Reqs (List req #)

 \Box Transport Kits \Box TC Transport Kits \Box RPMI \Box Michels \Box Other Date Needed By:

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.
- 4) 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.