PREVENTION GENETICS

PREVENTIONGENETICS USE ONLY

Test information is available on our website:
www.PreventionGenetics.com

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

NEONATAL CRISIS PANEL
TEST REQUISITION FORM

ORDERING CHECKLIST (required)

☐ Patient and family members (if provided) specimen
☐ Relevant medical records and family health history information (i.e. clinic notes, prior genetic testing, pedigree)

PERSON COMPLETING FORM	CONTACT (PHONE OR EMAIL)	DATE OF REQUEST
		____ / ____ / ____ MONTH / DAY / YEAR

PATIENT INFORMATION

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH
			____ / ____ / ____ MONTH / DAY / YEAR

PATIENT ID	SPECIMEN COLLECTION DATE	SEX
	MONTH ____ / DAY ____ / YEAR ____	☐ Male ☐ Female ☐ Other

SPECIMEN SOURCE

☐ Whole Blood ☐ Extracted DNA, Source ____ ☐ Saliva
☐ Direct Amniotic Fluid ☐ Cultured Cells, Source ____ ☐ Other ____
☐ Direct CVS ☐ Tissue, Source ____

REASON FOR TEST

☐ Diagnosis / Affected
☐ Presymptomatic / At Risk
☐ Carrier Testing

____ SPECIFY KARYOTYPE

GEOANCESTRY / ETHNICITY

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?

☐ NO ☐ YES, PG ID# ____

HAS PATIENT'S RELATIVE BEEN TESTED PREVIOUSLY AT PreventionGenetics?

☐ NO ☐ YES, Name ____ DOB ____
Relationship to Patient ____
or, PG ID# ____

BLOOD TRANSFUSION

☐ NO
☐ Within Last 30 Days, Date and Type
____ / ____ / ____ MONTH / DAY / YEAR
TYPE ____

BONE MARROW TRANSPLANT

☐ NO
☐ YES, Date
____ / ____ / ____ MONTH / DAY / YEAR

ONGOING PREGNANCY

☐ NO
☐ YES

Prenatal Healthcare Statement required for fetal testing of ongoing pregnancies.

OTHER RELEVANT CLINICAL INFORMATION We **require** the inclusion of detailed clinical notes/completion of the clinical data checklist and a pedigree. The ability to interpret variants directly correlates with the quality of clinical information provided.

PATIENT TEST SELECTION

☐ **PATIENT ONLY** Test Code 7383
Neonatal Crisis Panel of patient.

☐ **PATIENT PLUS** Test Code 7500
Neonatal Crisis Panel of patient and targeted testing of parents. Both biological parents required.

☐ **FAMILY - DUO, TRIO, ETC** Test Codes 7383 / 7382
Neonatal Crisis Panel or patient and family members.
☐ Patient's Form
☐ Additional Family Member Form

This test includes >1,100 genes. Reports will consist of two different sections: variants in genes known to be associated with phenotype and variants in genes possibly associated with phenotype. The report will not include all the observed variants in the Neonatal Crisis Panel.

When possible, a preliminary report may be issued. This will only occur for cases with a clearly positive outcome, and for which the sequencing data meet our internal pre-determined quality metrics. In such cases, the preliminary report will be issued prior to Sanger confirmation of the reported variants. Once Sanger results have been completed, a final report will be issued with any updates and information regarding other identified variants that might be relevant to the patient's condition. Please note in order to offer the fastest possible turnaround time for this test, results of copy number variant (CNV) analysis may be reported at a later date than the results of the sequencing portion of the test. While this panel is exome based, we will **NOT** be reporting secondary findings in other genes outside of those tested on the panel.

ADDITIONAL FAMILY MEMBERS (Patient Plus or PGxome Family Only)

List family members' information. Biological parent samples are required for Patient Plus and recommended for Family testing. If family member(s) tested as part of the Family option desire their own test report, please complete a separate Neonatal Crisis requisition form for each individual. Reports for family member(s) incur an additional $990 charge per individual.

NAME (LAST, FIRST)	DATE OF BIRTH	SAMPLE TYPE	RELATIONSHIP TO PROBAND	AFFECTED?	REPORT REQUESTED?
	____ / ____ / ____ MONTH / DAY / YEAR				☐ NO ☐ YES
	____ / ____ / ____ MONTH / DAY / YEAR				☐ NO ☐ YES
	____ / ____ / ____ MONTH / DAY / YEAR				☐ NO ☐ YES

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CLINICAL INFORMATION

A copy of clinic records is required. Clinical information is critical for best interpretation of data. Other relevant medical records, genetic testing results, and/or family medical health history (pedigree) are encouraged to be included. Patient clinical information can also be sent via Face2Gene by sharing with our lab.

PRIMARY INDICATION

- ☐ Developmental Delay
- ☐ Dysmorphic Features
- ☐ Multiple Congenital Anomalies
- ☐ Neurological
- ☐ Neuromuscular
- ☐ Other _____

ADDITIONAL CLINICAL INFORMATION *(optional - check all that apply)*

PERINATAL HISTORY
- ☐ Cystic Hygroma
- ☐ Hydrops Fetalis
- ☐ Increased Nuchal Translucency (NT)
- ☐ Intrauterine Growth Restriction (IUGR)
- ☐ Oligohydramnios
- ☐ Polyhydramnios
- ☐ Prematurity
- ☐ Other _____

GROWTH AND DEVELOPMENT
- ☐ Failure to Thrive
- ☐ Fine Motor Delay
- ☐ Gross Motor Delay
- ☐ Overgrowth
- ☐ Short Stature
- ☐ Other _____

COGNITION AND BEHAVIOR
- ☐ ADHD
- ☐ Autism
- ☐ Global Developmental Delay
- ☐ Intellectual Disability
  - ☐ Mild
  - ☐ Moderate
  - ☐ Severe
- ☐ Learning Disability
- ☐ Obsessive-Compulsive Disorder
- ☐ Speech Delay
- ☐ Other _____

MUSCULOSKELETAL
- ☐ Club Foot / Feet
- ☐ Contractures
- ☐ Diaphragmatic Hernia
- ☐ Joint Hypermobility
- ☐ Kyphosis
- ☐ Limb Anomaly
- ☐ Pes Planus
- ☐ Polydactyly
- ☐ Pterygium
- ☐ Scoliosis
- ☐ Syndactyly
- ☐ Vertebral Anomaly
- ☐ Other _____

CARDIOVASCULAR
- ☐ Arrhythmia
- ☐ ASD
- ☐ Cardiomyopathy
- ☐ Coarctation of Aorta
- ☐ Tetralogy of Fallot
- ☐ VSD
- ☐ Other _____

SKIN, HAIR, AND NAILS
- ☐ Hyperpigmentation (describe) _____
- ☐ Hypopigmentation (describe) _____
- ☐ Unusual Scarring
- ☐ Connective Tissue Abnormality (describe) _____
- ☐ Ichthyosis
- ☐ Rash
- ☐ Blistering
- ☐ Lipoma (or other skin tumors)
- ☐ Hair Abnormality (describe) _____
- ☐ Nail Abnormality (describe) _____
- ☐ Other _____

HEMATOLOGIC AND IMMUNOLOGIC
- ☐ Anemia
- ☐ Thrombocytopenia
- ☐ Neutropenia
- ☐ Pancytopenia
- ☐ Immunodeficiency
- ☐ Other _____

NEUROLOGICAL AND MUSCULAR
- ☐ Ataxia
- ☐ Chorea
- ☐ Seizures / Epilepsy
- ☐ Encephalopathy
- ☐ Hypotonia
- ☐ Hypertonia
- ☐ Spasticity
- ☐ Dystonia
- ☐ Muscle Weakness / Atrophy
- ☐ Exercise Intolerance
- ☐ Structural Brain Abnormalities / Abnormal Brain Imaging (describe) _____
- ☐ Other _____

CRANIOFACIAL
INCLUDING HEARING & VISION
- ☐ Cleft Lip
- ☐ Cleft Palate
- ☐ Craniosynostosis
- ☐ Dysmorphic Features (describe) _____
- ☐ Ear Malformation (describe) _____
- ☐ Microcephaly
- ☐ Macrocephaly
- ☐ Cataracts
- ☐ Coloboma (of eye)
- ☐ Chronic Progressive External Ophthalmoplegia
- ☐ Ptosis
- ☐ Abnormal Vision (describe) _____
- ☐ Optic Atrophy
- ☐ Retinitis Pigmentosa
- ☐ Abnormal Eye Movement
- ☐ Abnormal Hearing (describe) _____
- ☐ Other _____

GASTROINTESTINAL
- ☐ Gastroschisis
- ☐ Omphalocele
- ☐ Pyloric Stenosis
- ☐ Anal Atresia
- ☐ Tracheoesophageal Fistula
- ☐ Chronic Diarrhea
- ☐ Chronic Constipation
- ☐ Gastroesophageal Reflux
- ☐ Recurrent Vomiting
- ☐ Hirschsprung Disease
- ☐ Chronic Intestinal Pseudoobstruction
- ☐ Other _____

GENITOURINARY
- ☐ Ambiguous Genitalia
- ☐ Cryptochidism
- ☐ Hydronephrosis
- ☐ Hypospadias
- ☐ Kidney Malformation
- ☐ Renal Agenesis or Dysgenesis
- ☐ Renal Tubulopathy
- ☐ Other _____

ENDOCRINE
- ☐ Diabetes Mellitus
  - ☐ Type I
  - ☐ Type II
- ☐ Hypothyroidism
- ☐ Hyperthyroidism
- ☐ Hypoglycemia
- ☐ Hypoparathyroidism
- ☐ Hyperparathyroidism
- ☐ Other _____

METABOLIC
- ☐ Abnormal Acylcarnitine Profile (describe) _____
- ☐ Abnormal CPK
- ☐ Abnormal Urine Organic Acids (describe) _____
- ☐ Abnormal Plasma Amino Acids (describe) _____
- ☐ Hyperammonemia
- ☐ Ketosis
- ☐ Lactic Acidosis
- ☐ Metabolic Acidemia
- ☐ Other _____

CANCER / TUMORS
- ☐ Tumor (describe) _____
  - ☐ Age of Onset _____
- ☐ Other _____

ADDITIONAL TESTING
ATTACH COPIES OF RESULTS, IF AVAILABLE
- ☐ Chromosomes (Karyotype), result: _____
- ☐ Chromosomal Microarray (CMA), result: _____
- ☐ Newborn Screening, result: _____
- ☐ Other Molecular Studies, results: _____

FAMILY HISTORY
ATTACH PEDIGREE, IF AVAILABLE
- ☐ Consanguinity, degree of relationship: _____

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PROVIDER / LABORATORY CONTACT INFORMATION

Our preferred method of report transmission is secure email (via ZixCorp).
Please provide an email address when possible. If you have additional specific reporting requests, indicate them below.

PROVIDER INFORMATION

INSTITUTION

ADDRESS (City, State, Country and Postal Code)

REQUESTING PHYSICIAN (First, Last, Degree)		REQUESTING GENETIC COUNSELOR OR ALLIED PROVIDER (First, Last, Degree)	
PHONE NUMBER	NPI#	PHONE NUMBER	NPI#
EMAIL		EMAIL	

TEST REPORTING INSTRUCTIONS
Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP ☐ *Use above email address*

☐ DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.
☐ DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____-_____

TEST REPORTING INSTRUCTIONS
Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP ☐ *Use above email address*

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☐ DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____-_____

SENDOUT LABORATORY COMPLETE ONLY IF REPORT IS NEEDED

INSTITUTION / CONTACT

ADDRESS (City, State, Country and Postal Code)

PHONE NUMBER	NPI# (Where Applicable)
EMAIL	

TEST REPORTING INSTRUCTIONS
Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP ☐ *Use above email address*

☐ DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.
☐ DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____-_____

OTHER

INSTITUTION / CONTACT

ADDRESS (City, State, Country and Postal Code)

PHONE NUMBER	NPI# (Where Applicable)
EMAIL	

TEST REPORTING INSTRUCTIONS
Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP ☐ *Use above email address*

☐ DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.
☐ DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____-_____

As the ordering Healthcare Provider, I confirm I have obtained the patient's informed consent, either verbally or in writing, to perform this test. I further confirm the patient has been appropriately counseled and understands the risks, benefits, and limitations of this genetic testing and the implications of the results.

PREVENTION GENETICS

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PREVENTIONGENETICS USE ONLY

BILLING - PLEASE SELECT INSTITUTIONAL OR SELF-PAY WITH OPTION TO SUBMIT TO INSURANCE

PATIENT TESTING WILL BE DELAYED UNTIL ALL OF THE BILLING REQUIREMENTS HAVE BEEN MET. PLEASE PRINT CLEARLY.

If the patient's specimen is collected in New York, a New York State Non-Permitted Laboratory Test Request approval letter (where applicable) and Genetic Testing Healthcare Provider Statement (see website) must be included before testing will proceed.

INSTITUTIONAL BILLING

BILLING INSTITUTION		PO NUMBER	
CONTACT	PHONE NUMBER	EMAIL	
ADDRESS	CITY	STATE	ZIP
BILLING ACCOUNT NUMBER ☐ UPDATED INFO		COPY OF TEST REPORT(S) FOR BILLING	
EMAIL INVOICE VIA ZIXCORP (PROVIDE EMAIL ADDRESS)		☐ EMAIL (VIA ZIXCORP) _____	
		☐ OTHER (PLEASE SPECIFY) _____	

SELF-PAY **THIS SECTION MUST BE FILLED OUT COMPLETELY**

RESPONSIBLE PARTY'S NAME *(MUST BE 18 YEARS OR OLDER)*	PHONE NUMBER	EMAIL	
ADDRESS	CITY	STATE	ZIP

ACCEPTANCE of financial responsibility for genetic testing ***PREVENTIONGENETICS CANNOT PROCEED WITH TESTING OF THE SPECIMEN WITHOUT A SIGNATURE BELOW.***

My signature indicates that I accept financial responsibility for all fees associated with this genetic testing order.

SIGNATURE OF RESPONSIBLE PARTY _____ PRINTED NAME OF RESPONSIBLE PARTY _____ DATE _____

COMPLETE THE FOLLOWING FOR CREDIT CARD PAYMENT	CREDIT CARD NUMBER (VISA, DISCOVER, OR MASTERCARD ONLY)	EXPIRATION DATE	3-DIGIT SECURITY CODE

My signature authorizes PreventionGenetics to charge my credit card for services for which I am responsible.

SIGNATURE _____ DATE _____

☐ SUBMIT CLAIM TO INSURANCE (OPTIONAL)

POLICYHOLDER'S NAME (REQUIRED)		PLEASE INDICATE THE TYPE OF INSURANCE ☐ PRIVATE ☐ MEDICARE ☐ WI MEDICAID *We only accept WI Medicaid*	
PRIMARY INSURANCE COMPANY NAME (REQUIRED)			☐ *ATTACH A COPY OF INSURANCE CARD both sides*
INSURANCE COMPANY ADDRESS - CLAIMS		CITY	STATE / ZIP
ICD-10 CODES (REQUIRED)	POLICY ID#	GROUP #	AUTHORIZATION #

PLEASE ATTACH THE FOLLOWING DOCUMENTATION *PreventionGenetics cannot proceed with testing of the specimen until all information is received.*

- ☐ NPI # of Requesting Physician _____
- ☐ *MEDICARE – signed ABN Form completed IN FULL*
- ☐ *AUTHORIZATION NUMBER* or letter of agreement from Insurance Company (if available). If not included, we will routinely perform pre-verification prior to initiating testing and will relay information to ordering provider.
- ☐ *Relevant Medical Records addressing medical necessity and/or Letter of Medical Necessity*
- ☐ ***SHARE RESULTS*** of benefits investigation with patient directly via email provided above

or FAX # (_____) _____-_____

AUTHORIZATION to assign benefits and accept financial responsibility for my account

PREVENTIONGENETICS CANNOT PROCEED WITH TESTING OF THE SPECIMEN WITHOUT A SIGNATURE BELOW.

I authorize PreventionGenetics to release information received including, without limitation, medical information, which includes laboratory test results, such as genetic tests results, to my health plan/insurance carrier and its Authorized Representatives. I further authorize insurance payments directly to PreventionGenetics for the services rendered. I understand my health plan/insurance/Medicare/Medicaid carrier may not approve and reimburse my medical genetic services in full due to usual and customary rate limits, benefit exclusions, coverage limits, lack of authorization, medical necessity or otherwise. I understand I am financially responsible for fees not paid in full by my insurer, co-payments, and policy deductibles except where my liability is limited by contract or State and Federal law. I agree to help PreventionGenetics resolve any insurance claim issues. My signature indicates I accept financial responsibility for all fees associated with this genetic testing order.

☐ Proceed with testing once all required information has been sent, *regardless of benefit investigation* (to avoid testing being placed ON HOLD pending pre-authorization, if needed). Option does NOT apply for Medicaid.

SIGNATURE OF RESPONSIBLE PARTY _____ PRINTED NAME OF RESPONSIBLE PARTY _____ DATE _____

PREFERRED SPECIMEN REQUIREMENTS

PLEASE CONTACT US WITH ADDITIONAL SPECIMEN REQUIREMENT QUESTIONS.

WHOLE BLOOD

Collect 3 ml - 5 ml of whole blood in EDTA (purple top tube) or ACD (yellow top tube), minimum 1 ml for small infants.

DNA

Send in screw cap tube at least 5 µg -10 µg of purified DNA at a concentration of at least 20 ng/µL for NGS and Sanger tests and at least 5 µg of purified DNA at a concentration of at least 100 ng/µL for gene-centric aCGH, MLPA, and CMA tests, minimum 2 µg for limited specimens. Indicate concentration on tube label. For requests requiring more than one test, send an additional 5 µg DNA per test ordered when possible.

SALIVA

Oragene™ or GeneFiX™ Saliva Collection kit used according to manufacturer instructions.

FETAL (CVS / AMNIOCYTES) AND OTHER CELL CULTURES

Culture and send at least two, T25 flasks of confluent cells. For sequencing or gene-centric aCGH panels, two flasks are often sufficient; however, some panels may require additional flasks (dependent on size of genes, amount of Sanger sequencing required, etc.). Multiple test requests may also require additional flasks. Please contact us for details. We strongly recommend maintaining a back-up culture. Fetal cell cultures are available at PreventionGenetics from direct amniotic fluid, chorionic villi, products of conception (POC), or other tissue via Test Code #995 (cost $250). Collect 10 ml - 20 ml of direct amniotic fluid or 5 mg - 10 mg cleaned CVS tissue (~15-20 cleaned villi) or 2mm x 2mm x 2mm fresh tissue. CPT code 88235 for amniotic fluid/chorionic villi or 88233 for POC or tissue specimens.

	TEST METHOD	WHOLE BLOOD	DNA	SALIVA	CELL CULTURES	FRESH, FROZEN TISSUE	OCD-100 BUCCAL SWAB	DIRECT AMNIOTIC FLUID/CVS	OTHER
SEQUENCING	NextGen (NGS)	★	★	★	★	★	■	■ C	–
	PGxome® / PGxome Custom Panels	★	★ B	★	★ B	★	■	–	–
	Sanger	★	★	★	★	★	■	■ C	Semen D
DEL / DUP	Gene-centric aCGH	★	★	■	■	★	–	■ C	–
	MLPA	★	★ A	ONLY TEST #1941	★ A	–	■	–	–
	Chromosomal Microarray (CMA)	★	★	■	★	★	–	■	–

EXCEPTIONS

A - Cell cultures and DNA extracted from CVS and amniocytes not accepted for MLPA; DNA extracted from saliva (except test #1941) also not accepted.

B - Cell cultures and DNA extracted from CVS and amniocytes acceptable for PGxome for non-ongoing pregnancies only.

C - Direct prenatal specimen types most appropriate for targeted prenatal familial variant testing (Test Code #990), and strongly discouraged for full gene and panel tests. Back-up culture highly recommended.

D - Semen: Collect 1-2 vials and flash freeze. Vials to be sent frozen (preferably on dry ice). Contact us for details.

KEY

★ PREFERRED

■ ACCEPTED

– NOT ACCEPTED

FRESH, FROZEN TISSUE

Collect 2mm x 2mm x 2mm tissue and flash freeze. Tissue to be sent frozen (preferably dry ice). If cell culture is desired, tissue should not be frozen. Contact us for additional details.

OCD-100 BUCCAL SWAB

OCD-100 Buccal Swab used according to manufacturer instructions. Buccal swabs are most appropriate for targeted, known variant testing.

DIRECT AMNIOTIC FLUID / CHORIONIC VILLI

Collect 10 ml -20 ml of direct amniotic fluid or 5 mg -10 mg cleaned CVS tissue (~15-20 cleaned villi). We strongly recommend maintaining a local back-up culture. Fetal cell cultures available (Test Code #995, $250).

SHIPPING AND HANDLING INSTRUCTIONS

Label all specimen containers with the patient's name, date of birth and/or ID number. At least two identifiers should be listed on specimen containers. Specimen deliveries are accepted Monday-Saturday for all specimen types except cell cultures, direct amniotic fluid, or direct chorionic villi. Cell culture deliveries are routinely accepted Monday-Thursday and require advance notice of arrival. If a Friday or Saturday delivery is necessary, contact us to make arrangements. Saturday delivery should be avoided when possible as prenatal specimens are not processed over the weekend. Holiday schedules will be posted on our website at least one week prior to major holidays.

BLOOD

DO NOT FREEZE. During hot weather, include a frozen ice pack in the shipping container. Place a paper towel or other thin material between the ice pack and the blood tube. In cold weather include an unfrozen ice pack in the shipping container as insulation. At room temperature, blood specimen is stable for up to 48 hours. If refrigerated, blood specimen is stable for up to one week.

DNA

DNA may be shipped at room temperature. Label the tube with the composition of the solute, DNA concentration as well as the patient's name, date of birth, and/or ID number. We only accept genomic DNA for testing. We do not accept products of whole genome amplification reactions or other amplification reactions.

CELL CULTURES, DIRECT AF/CVS, AND POC

Send specimens overnight in an insulated, shatterproof container. Direct AF/CVS, POC, or tissue specimens can be sent in saline or culture media at room temperature for culturing at PreventionGenetics (Test Code #995, $250).

PRENATAL TESTING

Please sign Prenatal Healthcare Provider's Statement for ongoing pregnancies and contact us in advance regarding prenatal test requests. When possible, ship prenatal samples to arrive at PreventionGenetics no later than Thursday.

DNA GENOTYPING PANEL

For quality control purposes, the Prevention Genetics DNA Genotyping Panel is performed on all clinical specimens. Genotyping results are not included in test reports.

DNA BANKING

DNA Banking has a reduced price of $98 for patients if clinical testing is also being performed at PreventionGenetics. Visit our website at www.PGDNABank.com for more information. FOr questions about PGDNABanking, contact us at (715) 387-0484, ext. 151, or email: dnabanking@preventiongenetics.com.

CONTACT US

For additional questions or concerns, contact a Client Service Representatives at (715) 387-0484, ext. 0, or our Genetic Counseling Team at option 2, or email: clinicaldnatesting@preventiongenetics.com.

MAILING ADDRESS

PreventionGenetics - Diagnostic Lab
3800 S. Business Park Avenue
Marshfield, Wisconsin 54449 USA

TESTING KITS

Clinical testing kits with prepaid return shipping are available for U.S. Clients. Clinical testing kits are provided to International clients without the return postage. Submit requests through our website or contact a Client Service Representatives at (715) 387-0484, ext. 0.