BCM-MEDICAL GENETICS LABORATORIES
WHOLE GENOME LABORATORY

PHONE: 800-411-GENE | FAX: 713-798-2787 | www.bcmgeneticlabs.org

SHIP TO: Medical Genetics Laboratories
Baylor College of Medicine
2450 Holcombe, Grand Blvd. -Receiving Dock
Houston, TX 77021-2024
Phone: 713-798-6555

WHOLE EXOME SEQUENCING PLUS CMA REQUISITION (TEST CODE: 1530)

PATIENT INFORMATION

NAME: _____ _____ ___
LAST NAME FIRST NAME MI

DATE OF BIRTH: ___ / ___ / ___ (MM DD YY)

GENDER (Please select one):
- ☐ FEMALE
- ☐ MALE
- ☐ UNKNOWN

-OR-
PLACE PATIENT STICKER HERE

SAMPLE INFORMATION

DATE OF COLLECTION: ___ / ___ / ___ (MM DD YY)

HOSPITAL#: _____ ACCESSION#: _____

SAMPLE TYPE (Please select one):
- ☐ BLOOD (EDTA & NaHep)
- ☐ FIBROBLAST
- ☐ CORD BLOOD

ETHNIC BACKGROUND (Select all that apply):
- ☐ AFRICAN AMERICAN
- ☐ ASIAN
- ☐ ASHKENAZIC JEWISH
- ☐ EUROPEAN CAUCASIAN
- ☐ HISPANIC
- ☐ NATIVE AMERICAN INDIAN
- ☐ OTHER JEWISH
- ☐ OTHER (Please specify): _____

REPORTING INFORMATION

PHYSICIAN: _____

INSTITUTION: _____

PHONE: _____ FAX: _____

EMAIL (INTERNATIONAL CLIENT REQUIREMENT): _____

ADDITIONAL PROFESSIONAL REPORT RECIPIENTS

NAME: _____

PHONE: _____ FAX: _____

NAME: _____

PHONE: _____ FAX: _____

Whole Exome Sequencing (WES) plus Chromosomal Microarray Analysis (CMA-Comprehensive) (test code 1530) has two components that will be run CONCURRENTLY and reported separately when each test has been completed. Turnaround time for CMA is 14 days and turnaround time for WES is 15 weeks once financial responsibility has been verified.

NOTE: Per our Cancellation Policy, either of these tests can be cancelled before 5 p.m.(central time) the next business day after the sample is received. Cancellation orders received after that time cannot be honored. Tests will be performed, charged, and reports issued. If concurrent testing is not desired, sequential testing may be ordered under the separate test codes, see website for details.

BIOLOGICAL PARENTS SAMPLES are required for WES interpretation of child. Send 10 cc EDTA and 3-5 cc sodium heparin. Be sure to label parental samples with full name and date of birth - DO NOT LABEL WITH CHILD'S NAME.

8995/1505: **MOTHER** (FULL NAME): _____ _____ DOB: ___ / ___ / ___
LAST NAME FIRST NAME (MM DD YY)

☐ ASYMPTOMATIC ☐ SYMPTOMATIC (attach summary of findings)

SAMPLE TYPE: Blood Required DATE OF COLLECTION: ___ / ___ / ___ (MM DD YY) ☐ NOT AVAILABLE ☐ TO BE SENT LATER*

8995/1505: **FATHER** (FULL NAME): _____ _____ DOB: ___ / ___ / ___
LAST NAME FIRST NAME (MM DD YY)

☐ ASYMPTOMATIC ☐ SYMPTOMATIC (attach summary of findings)

SAMPLE TYPE: Blood Required DATE OF COLLECTION: ___ / ___ / ___ (MM DD YY) ☐ NOT AVAILABLE ☐ TO BE SENT LATER*

1506: OTHER RELATIVE OF PATIENT

Prior to submitting samples from a relative other than the parents, please call the lab at (713) 798-6555 to obtain approval.

Approval Received from (Name of MGL Lab Genetic Counselor): _____ DATE: ___ / ___ / ___ (MM DD YY)

Exact Relationship of this individual to the patient: _____

FULL NAME: _____ _____ DOB: ___ / ___ / ___
LAST NAME FIRST NAME (MM DD YY)

☐ ASYMPTOMATIC ☐ SYMPTOMATIC (attach summary of findings - REQUIRED)

SAMPLE TYPE: ☐ BLOOD ☐ SALIVA DATE OF COLLECTION: ___ / ___ / ___ (MM DD YY) ☐ TO BE SENT LATER*

*If parent/other relative samples are to be sent later, please include copy of this requisition form with those samples.

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NAME: _____ LAST NAME _____ FIRST NAME ___ MI DATE OF BIRTH: ___ / ___ / ___ MM DD YY GENDER (Please select one): ☐ FEMALE ☐ MALE ☐ UNKNOWN

CHECKLIST OF ITEMS TO INCLUDE

- ☐ PROBAND SAMPLE (EDTA & NaHep)
- ☐ REQUISITION
- ☐ INDICATION FOR STUDY CHECK LIST
- ☐ SIGNED WES CONSENT FORM
- ☐ CLINICAL NOTE/SUMMARY
- ☐ PEDIGREE
- ☐ MATERNAL SAMPLE (EDTA & NaHep)
- ☐ PATERNAL SAMPLE (EDTA & NaHep)
- ☐ OTHER RELATIVE'S SAMPLE (must be approved by Lab before sending)

REQUIRED - INDICATION FOR STUDY

Please provide the following clinical information regarding the patient to be tested. If answering "yes," please provide additional description as appropriate (e.g., percentiles for growth parameters, type of limb abnormality, etc.). Please also submit a clinic note and pedigree if available. This information is needed to facilitate interpretation of whole exome sequencing results. If the laboratory requires additional information, please indicate the health care provider to be contacted:

NAME: _____ PHONE/PAGER #: _____

	YES (Provide Description)		NO	UNKNOWN
Prematurity	☐		☐	☐
Intrauterine growth restriction	☐		☐	☐
Delayed motor milestones	☐		☐	☐
Delayed speech	☐		☐	☐
Developmental regression	☐		☐	☐
Autism/Autistic spectrum	☐		☐	☐
Intellectual disability	☐		☐	☐
Hearing loss	☐		☐	☐
Hypotonia	☐		☐	☐
Hypertonia/Spasticity	☐		☐	☐
Seizure disorder	☐		☐	☐
Ataxia	☐		☐	☐
Abnormal movements	☐		☐	☐
Dysmorphic features	☐		☐	☐
Short stature	☐		☐	☐
Tall habitus	☐		☐	☐
Microcephaly	☐		☐	☐
Macrocephaly	☐		☐	☐
Hyperextensibility	☐		☐	☐
Joint contractures	☐		☐	☐

INDICATIONS CONTINUED ON PAGE 3

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NAME: _____ LAST NAME _____ FIRST NAME ___ MI DATE OF BIRTH: ___ / ___ / ___ MM DD YY GENDER (Please select one): ☐ FEMALE ☐ MALE ☐ UNKNOWN

REQUIRED - INDICATION FOR STUDY (CONT.)

	YES (Provide Description)		NO	UNKNOWN
Obesity/Overgrowth	☐		☐	☐
Failure to thrive	☐		☐	☐
Structural brain abnormalities	☐		☐	☐
Eye anomalies	☐		☐	☐
Vision loss	☐		☐	☐
Congenital heart disease	☐		☐	☐
Kidney abnormalities	☐		☐	☐
Skeletal abnormalities	☐		☐	☐
Scoliosis	☐		☐	☐
Limb malformation	☐		☐	☐
Skin anomalies	☐		☐	☐
Genital anomalies	☐		☐	☐
Organomegaly	☐		☐	☐
Hemihypertrophy	☐		☐	☐
Cancer/tumor formation	☐		☐	☐
Family history of similar disorder	☐		☐	☐

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WHOLE EXOME SEQUENCING PLUS CMA REQUISITION (TEST CODE: 1530)

INFORMATION AND CONSENT FOR TESTING

Your physician has advised you (or your child) to undergo the genetic test called the Whole Exome Sequencing test (abbreviated WES). The purpose of this document is to provide information about the test. This information is meant to be used as a supplement to your discussion with a health care professional. If you agree to have the WES test, you will be asked to sign the last page of this document, indicating that you understand the information provided and wish to have testing. You will be given a copy of this document for your records.

Description of the Whole Exome Sequencing Test

The Whole Exome Sequencing test is a highly complex test that is newly developed for the identification of changes in an individual's DNA that are causative or related to their medical concerns. The exome refers to the portion of the human genome that contains functionally important sequences of DNA that direct the body to make proteins essential for the body to function properly. These regions of DNA are referred to as exons. It is known that most of the errors that occur in DNA sequences that then lead to genetic disorders are located in the exons. In contrast to current sequencing tests that analyze one gene or small groups of related genes at a time, the Whole Exome Sequencing test will analyze the important regions of tens of thousands of genes at the same time. Therefore, sequencing of the exome is thought to be an efficient method of analyzing a patient's DNA to discover the genetic cause of diseases or disabilities. However, it is possible that even if the WES identifies the underlying genetic cause for the disorder in your family this information may not help in predicting prognosis or change medical management or treatment of disease.

The WES includes a mitochondrial genome screening. Mitochondria are structures within cells that convert the energy from food into a form that cells can use. Although most DNA is packaged in chromosomes within the nucleus, mitochondria also have a small amount of their own DNA. This genetic material is known as mitochondrial DNA or mtDNA. In humans, mitochondrial DNA represents a small fraction of the total DNA in cells. Many genetic conditions are related to changes in particular mitochondrial genes.

Indications for Testing

The decision to undergo the Whole Exome Sequencing test is made by you and your physician. In general, the test is used when your medical history and physical exam findings strongly suggest that there is a genetic cause for your medical issues. The test requires 5-10 cc (about 1-2 teaspoon) of whole blood. You should expect that results of the WES test will be sent to your physician in 15 weeks.

Test Reporting

When your exome sequence is compared to a normal reference sequence, many variations or differences are expected to be found. Based on currently available information in the medical literature and in scientific databases, we will decide whether any of these variations are predicted to be causative or related to your medical condition. The WES test results will be reported to your physician in two parts. Your physician will receive a copy of the focused report for your sample.

The focused report will contain results that may explain the cause of your current medical problems. In addition it may also contain information in the following categories:

Medically Actionable

The focused report may also contain information on genes and diseases that are considered medically actionable because they have clear and immediate medical significance to your health or the health of family members, whether or not they relate to your current symptoms. The American College of Medical Genetics (ACMG) have published guidelines for the reporting of these types of medically actionable or incidental findings (PMID: 23788249). These guidelines include a list of genes, which may be updated periodically, that have been determined to be considered medically actionable and therefore laboratories should seek and report mutations in these genes. In accordance with this recommendation mutations identified in the genes listed in ACMG policy statement will be reported. Additionally, the MGL under the direction of the medical director and other faculty members may determine additional genes meet the same criteria to be considered medically actionable and therefore warrant the same reporting as the genes included in the ACMG list. However, if you chose that you do not want to receive information in genes that are not included in the list you may opt out of this information on the FOCUSED report. However, if the EXPANDED report is requested this information will be included.

Mitochondrial Genome

Proven mutations and large deletions in the mitochondrial genome will also be reported. However, large deletions are rarely seen in blood specimens.

Carrier Status and Pharmacogenetic information

Carrier status for autosomal recessive conditions will include disorders recommended for reproductive screening by professional societies such as ACMG or ACOG (such as cystic fibrosis and Tay-Sachs disease, see FAQ on our website for a complete list). Variants in genes involved in drug metabolism will also be reported. Currently, this is limited to the reporting of pharmacogenetic variants to VKORC1/CYP2C9 (altered warfarin metabolism) and CYP2C19 (altered Plavix metabolism).

See below for options regarding receipt of certain categories of results in the focused report. In addition to the focused report, an expanded report will be available if you and your physician decide to request it.

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INFORMATION AND CONSENT FOR TESTING (cont.)

The patient's sample will have certain findings confirmed by a second methodology (Sanger sequencing) based on the following guidelines.

- Deleterious mutations related to patient phenotype will have Sanger confirmation.
- Variants of unclear clinical significance (VUS) related to phenotype with established autosomal dominant inheritance pattern will have Sanger confirmation when at least one parental sample has been received.
- VUS related to phenotype with established autosomal recessive inheritance will have Sanger sequencing when there are two variant alleles when at least one parental sample has been received.
- VUS related to phenotype with established X-linked inheritance will have Sanger confirmation when at least one appropriate parental sample has been received.
- Medically actionable mutations and carrier status mutations for autosomal recessive conditions recommended for reproductive screening will have Sanger confirmation.
- Mutations identified in the mitochondrial genome will be Sanger confirmed. Mutations reported will be at clinically relevant levels of heteroplasmy. Deletion breakpoints will not be reported.
- As determined by the laboratory, additional confirmation beyond these categories may also be performed.

Once the focused report is received the expanded report can be ordered (no additional charge). The expanded report may contain information on diseases and genes that do not relate to your current condition, or may develop many years from now, or do not have any known link to disease, according to current knowledge. Information included in the expanded report is not Sanger confirmed (unless determined necessary by the laboratory). In discussion with your physician, the expanded report can be ordered for up to 6 months after the focused report is received, for no additional charge. A requisition for ordering the expanded report is available on our website. Please allow 4 weeks for the expanded report. Because medical information continues to advance, it is important to know that the interpretation of the variants is based on information available at the time of testing and may change in the future.

Report Exclusions

The focused and expanded reports will not report findings in genes causing adult onset dementia syndromes for which there is presently no prevention or cure. Heterozygous unclassified variants associated with recessive disorders will not be reported unless a deleterious mutation or a second unclassified variant in the same gene is also detected.

Request for Biological Parental Samples

Biological parental samples are requested to facilitate interpretation of WES results. WES will NOT be performed on the parental samples. The parental samples will be tested by other targeted methods for mutations and/or variants in genes that are highly likely to be causative of disease (related to patient indication for testing) to confirm mode of inheritance, de novo status, etc. These studies will be performed at no additional charge. Additionally, parental status for carrier mutations recommended for reproductive screening will also be reported. A separate parental report will not be issued. The laboratory will decide which mutations/variants will need parental studies based on the following criteria.

- Using Sanger sequencing parental samples will be tested to determine inheritance in the proband for genes related to patient phenotype (mutations and variants of uncertain clinical significance).
- Parental samples will not be run for genes with autosomal recessive inheritance pattern that only have one VUS sequencing change identified related to patient phenotype
- We will not report parental data for medically actionable mutations identified in the proband (child). If such testing is desired it can likely be completed at a later date, for no additional charge, once consent is given to your provider. Once a test order is received it will take several weeks to complete the additional testing.
- We will report parental data for carrier status mutations recommended for reproductive screening.
- Parental inheritance information will not be included for any of the genes reported in the Expanded report.
- Maternal samples will have Sanger sequencing to determine if reported mitochondrial findings are inherited, however maternal level of heteroplasmy will not be reported.
- For other biological relatives submitted, Sanger sequencing will be performed only for changes related to the patient phenotype, as described above (Items 1 and 2).

Potential Risks and Discomforts

(1) It is possible that you could have a mutation in a gene included in the WES test, but the WES test was unable to detect the mutation. Therefore, it is possible that you may be affected with one of the conditions tested by WES, but that the test did not detect the condition.
(2) The WES test does not analyze 100% of the genes in the human genome. There are some genes that cannot be included in the test due to technical reasons.

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INFORMATION AND CONSENT FOR TESTING (cont.)

Potential Risks and Discomforts (cont.)

(3) Results may be unclear or indicate the need for further testing on other family members, usually parents. It is possible, that additional information may come to light during these studies regarding family relationships. For example, data may suggest that family relationships are not as reported, such as non-paternity (the father of the individual is not the biological father).

(4) If you sign the consent form, but you no longer wish to have your sample tested by WES, you can contact your doctor to cancel the test. If testing is complete, but you have not received your results yet, you can inform your doctor that you no longer wish to receive the results. However, if you withdraw consent for testing after 5 p.m. the next business from the day of sample receipt by the laboratory, you will be charged for the full cost of the test.

(5) The cumulative results of WES testing on many samples may be published in the medical literature. These publications will not include any information that will identify you personally.

(6) Due to the fact that many different genes and conditions are being analyzed, there is a risk that you will learn genetic information about yourself or your family that is not directly related to the reason for ordering the WES. This information might relate to diseases with symptoms that may develop in the future in yourself or other family members as well as conditions that have no current treatment. If you have concerns about learning about other diseases unrelated to your current medical problems, please tell you doctor so that the results will not include this information.

Please read the below statements carefully and check the appropriate box and initial. Please note that if neither box is checked the lab will default to the YES/ reporting option.

Initial

1. Carrier Status for Autosomal Recessive Conditions Recommended for Reproductive Carrier Screening

_____ ☐ YES, please report carrier status. By checking this box, I choose to receive information regarding carrier status.

_____ ☐ NO, please do NOT report carrier status. By checking this box, I choose to NOT receive information regarding carrier status.

2. Pharmacogenetic Variants

_____ ☐ YES, please report genes involved in drug metabolism. By checking this box, I choose to receive information regarding drug metabolism. Currently, this is limited to the reporting of pharmacogenetic variants to VKORC1/CYP2C9 (altered warfarin metabolism) and CYP2C19 (altered Plavix metabolism).

_____ ☐ NO, please do NOT report genes involved in drug metabolism. By checking this box, I choose to NOT receive information regarding drug metabolism.

3. Medically Actionable

Mutations in genes included in the ACMG policy statement regarding recommendations for reporting of incidental findings will be reported as medically actionable findings on all focused reports. There is the following option to opt-out of the additional medically actionable information.

_____ ☐ YES, please report mutations in genes that the MGL laboratory has determined is medically actionable (defined as having clear and immediate medical significance to your health or the health of family members).

_____ ☐ NO, please do NOT report mutations in genes that the MGL laboratory has determined are medically actionable. By checking this box, I chose not to receive information regarding MGL determined medically actionable findings. However, I will still receive information regarding mutations in genes included in the ACMG policy statement recommendations and if the expanded report is requested this information WILL BE INCLUDED in that report.

For Samples Submitted From New York State

Specimen Retention: My sample shall be destroyed at the end of the testing process or not more than 60 days after completion of testing. However, I hereby authorize the lab to retain my sample(s) for a longer retention in accordance to the laboratory retention policy for internal laboratory quality assurance studies and possible research testing.

_____
Initial

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INFORMATION AND CONSENT FOR TESTING (cont.)

Due to the complex nature of the WES testing it is recommended that families seek genetic counseling in conjunction with testing.

I hereby authorize the BCM Medical Genetics and Whole Genome Sequencing Laboratories to conduct genetic testing for myself (or my child) for the Whole Exome Sequencing test (WES) as recommended by my physician. (PLEASE INITIAL) _____

Signature: _____ Date: _____

Printed Name: _____

Patient Name: _____ Relationship to Patient: _____

Physician's/Counselor's Signature: _____ Date: _____

Parental/Other Relative Testing Authorization

I hereby authorize the BCM Medical Genetics and Whole Genome Sequencing Laboratories to conduct genetic testing for myself for the purposes of clarifying results for the Whole Exome Sequencing test (WES) that is being performed on my child's blood sample as recommended by my child's physician. I understand that my sample will not be subjected to WES, but will be subjected to targeted testing methodologies (Sanger sequencing). A separate report of these data will not be issued.

Mother Signature: _____ Date: _____

Printed Name: _____

Father Signature: _____ Date: _____

Printed Name: _____

Other Relative's Signature (or Parent/Legal Guardian): _____ Date: _____

Printed Name: _____ Relationship to Patient: _____

SEE NEXT PAGE FOR POTENTIAL RESEARCH OPPORTUNITY

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Additional Studies- RESEARCH

After your results are finalized and reported there may be research studies that you may be eligible for and may be of interest to you. Please read the following statements carefully and check the appropriate box. If the "YES"/contact option is chosen please complete the additional information requested. Please note that if neither box is checked the lab will default to the "NO"/ no contact option.

_____ Initial ☐ YES, the BCM Medical Genetics Laboratories may share my contact information with researchers who have an Institutional Review Board (IRB) approved research study for which I may be eligible for participation. There is no obligation to participate if contacted. No information, other than the contact information below, will be provided to the researcher.

Authorization:

Signature: _____ Date: _____

Printed Name: _____

Patient Name: _____ Relationship to Patient: _____

Contact Information:

Phone #: _____ Alternative Phone #: _____

Address: _____ _____ _____ _____
City State Zip Code

E-mail: _____

Preferred method of contact: ☐ Email ☐ Mail ☐ Phone

_____ Initial ☐ NO, I DO NOT wish to be contacted regarding participation in research studies.

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BILLING INFORMATION

IMPORTANT NOTICE: ONE OF THE THREE FOLLOWING BILLING OPTIONS MUST BE INDICATED BELOW.
PLEASE FORWARD ALL BILLING QUESTIONS TO: MEDGENBILLING@BCM.EDU

PATIENT INFORMATION

PATIENT NAME (LAST,FIRST, MI): _____ PATIENT DATE OF BIRTH (MM/DD/YY): _____

ADDRESS: _____ CITY, STATE, ZIP: _____

PHONE: _____ EMAIL: _____

☐ PAYMENT OPTION 1 - INSTITUTION

BCM-MEDICAL GENETICS LABORATORIES CAN ONLY RUN THIS TEST IF THE INSTITUTION ACCEPTS FINANCIAL RESPONSIBILITY FOR THE FULL PRICE OF THE TEST. PLEASE SIGN AND DATE BELOW THAT YOU ARE AN AGENT OF THE ORDERING INSTITUTION AND CAN ORDER GENETIC TESTING ON ITS BEHALF. TESTING WILL NOT BEGIN WITHOUT THIS SIGNATURE.

PRINTED NAME: _____ SIGNATURE: _____ DATE (MM/YY): _____

INSTITUTION NAME: _____ INSTITUTION CODE: _____

CONTACT NAME: _____ EMAIL (REQUIRED): _____

BILLING ADDRESS: _____ CITY, STATE, ZIP: _____

PHONE: _____ FAX: _____

☐ PAYMENT OPTION 2 - SELF-PAY (PAYMENT MUST ACCOMPANY SAMPLE)

☐ CREDIT CARD (PLEASE SELECT ONE): ◯ AMEX ◯ DISCOVER ◯ MC ◯ VISA

VALID CARD #: _____ EXPIRATION DATE (MM/YY): _____ CVC CODE: _____

CARDHOLDER PRINTED NAME: _____ CARDHOLDER SIGNATURE: _____

☐ CHECK/MONEY ORDER

☐ PAYMENT OPTION 3 - INSURANCE

PROVIDE A LEGIBLE PHOTOCOPY OF THE FRONT & BACK OF THE INSURANCE CARD OR HMO/MEDICAID HMO AUTHORIZATION/REFERRAL.

INSURED MEMBER'S INFORMATION

MEMBER NAME (Last, First, MI): _____ MEMBER DATE OF BIRTH (MM/DD/YY): _____ GENDER: ◯ FEMALE ◯ MALE

MEMBER POLICY #: _____ MEMBER SS #: _____ MEMBER GROUP #: _____

INSURANCE CO. NAME: _____ PHONE: _____

INSURANCE CO. ADDRESS: _____ CITY, STATE, ZIP: _____

ICD9 Diagnosis Code(s) - must be provided or insurance cannot be filed: _____

INSURANCE FINANCIAL POLICY: I UNDERSTAND THAT INSURANCE IS FILED TO BCM-MEDICAL GENETICS LABORATORIES' CONTRACTED CARRIERS AS A CLIENT SERVICE COURTESY. I AM AWARE THAT I AM RESPONSIBLE FOR NON-COVERED SERVICES, DEDUCTIBLES, CO-INSURANCE, CONTRACT EXCLUSIONS, NON-AUTHORIZED SERVICES AND REMAINING BALANCES AFTER INSURANCE REIMBURSEMENT. I AUTHORIZE BCM-MEDICAL GENETICS LABORATORIES TO FURNISH ANY MEDICAL INFORMATION REQUESTED ON MYSELF, OR MY COVERED DEPENDENTS. IN CONSIDERATION OF SERVICES RENDERED, I TRANSFER AND ASSIGN ANY BENEFITS OF INSURANCE TO BCM-MEDICAL GENETICS LABORATORIES.

☐ I have read and agree to all sections of the insurance financial policy above - TESTING WILL NOT BEGIN WITHOUT THIS SIGNATURE

PRINTED NAME: _____ SIGNATURE: _____ DATE (MM/YY): _____

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