BAYLOR GENETICS
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Houston, TX 77021

CLIENT MEMO

Date: May 31, 2017

Dear Valued Clients,

Effective July 5, 2017, in a continuing effort to optimize our offerings, the following changes will be made to the prenatal Chromosomal Microarray Analysis (CMA) tests.

Our reporting policy for prenatal CMA has been updated, as shown in the detailed summary on page two. The major changes include:

- Parental studies will be performed reflexively when necessary to help clarify the significance of the fetal results; for all other fetal findings, parental studies will be available on a fee-for-service basis.
- Moving forward, uniparental disomy (UPD) studies for all chromosomes will be available on a fee-for-service basis.

We have made updates to our requisition and consent forms. The major changes include:

- Reflex testing options are now available.
- The consent form has been updated to include options for receiving information about medically actionable findings.

The above changes apply to the following prenatal CMA tests:

- Targeted CMA - Prenatal - Amniotic Fluid (TC 8656)/ CVS (TC 8657)
- Expanded CMA - Prenatal - Amniotic Fluid (TC 8670)/ CVS (TC 8671)
- Targeted CMA Limited Karyotype - Prenatal - Amniotic Fluid (TC 8673)/CVS (TC 8672)
- Expanded CMA and Limited Karyotype - Prenatal - Amniotic Fluid (TC 8675)/ CVS (TC 8676)

Please direct any questions to 1-800-411-GENE or email us at genetictest@bmgl.com. Also, we highly encourage you to visit our website at www.BMGL.com for additional information on our test offerings and to download the most recent version of the requisition(s) on July 5, 2017.

Sincerely,

Alan Pourpak, PhD, MBA
AVP, Product Management and R&D

Detailed Summary of Prenatal CMA Procedures and Reporting Guidelines:

- Parental samples (5 cc whole blood in EDTA tubes) are required.
- Signed CMA consent is recommended.
- Maternal cell contamination studies will be performed in all cases when a maternal blood sample is provided.
- When interpretation requires parental studies, these will be performed automatically to help clarify the significance of the fetal results.
- Parental studies will not be performed automatically for the following fetal results but are available on a fee-for-service basis:
    - Heterozygous gains and losses in genes associated with autosomal recessive disorders
    - Heterozygous gains and losses in a female fetus of genes associated with X-linked recessive disorders
    - Heterozygous gains and losses classified as likely benign
    - Gains and losses suggestive of an unbalanced rearrangement that require parental studies by FISH or chromosome analysis to assess for parental balanced rearrangements
    - Gains and losses associated with well-characterized deletion/duplication syndromes (i.e., DiGeorge syndrome, Williams Syndrome, Prader-Willi syndrome)
- The following copy number changes will not be reported based on information available at reporting:
    - Gains and losses less than 1000 kb (1Mb) without any genes in the region
    - Gains and losses less than 500kb with genes but no known clinical relevance
    - Gains of KAL1, 15q11.2 BP1-BP2, NPHP1, STS
    - Gains and losses in the mitochondrial genome
    - Gains and losses in AZFa & AZFb
    - Gains and losses associated with adult-onset disorders[1] for which treatment is unavailable
- Additional testing recommendations for absence of heterozygosity (AOH) detected on prenatal CMA:
    - Baylor Genetics will alert the client of any pertinent AOH result and UPD testing recommendations. UPD is available as a pass through service, payable by the client to the other laboratory according to that lab's policies. If UPD testing is elected within 14 days of the notification, Baylor Genetics will provide fetal cultures to the client's choice of outside lab; additional forms may be needed. Parental EDTA blood or extracted DNA samples are required for fetal UPD analysis. Baylor Genetics will work with your office to ensure parental samples are available if specimens were sent as controls for other studies. The turnaround time for UPD analysis is between 3-4 weeks, not including culture time, and results will be reported in an updated CMA report.

[1] Gains and losses associated with medically actionable findings for select genes will be reported as noted in the consent form.