



NOTICE

Date: September 2, 2009

Dear Valued Clients:

Foundation Laboratory is pleased to announce that effective September 1st, 2009 our Cystic Fibrosis assay will be providing more extensive results. Osmetech Molecular Diagnostics, manufacturer of CF platform recently received FDA clearance of their eSensor® CF Genotyping Test. In addition to its use as a carrier screening test for adults of reproductive age, the assay has the additional benefit of being used as an aid in CF screening for newborns and confirmatory diagnostic testing for newborns and children.

Reporting format: As a genotyping test, the assay uses the terms “Wild-type”, “Heterozygote” and “Homozygous” for each of the ACOG and the ACMG-recommended 23 mutations. An additional benefit of the eSensor® CF Genotyping Test is that it can also provide you with the result for the poly-T variant 5/7/9T regardless of the R117H status.

In the earlier version of the assay, “Wild-type” result would have been called "Negative/Non-carrier" and the “Carrier/Heterozygous OR Carrier/Mutant/Homozygous” results would have been called "Positive/Carrier".

Possible Final Results:

1. Wild-Type/Non-Carrier
2. Carrier/Heterozygous : carries a mutation on one of its alleles (Carrier)
3. Carrier/Mutant/Homozygous: carries mutation for both copies of its alleles (Patient with CF)

The specimen requirement:

- No change in specimen requirements. As before blood should be collected in EDTA (as the anticoagulant) lavender-top tubes.

For supplies and other needs please make sure to contact your Foundation Laboratory representative.

Sincerely;

J. Kermani, MSMT (ASCP, NCA), Ph.D.
Director of Technical Operations