

STATE OF COLORADO

Bill Ritter, Jr., Governor
James B. Martin, Executive Director

Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

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Dear Health Care Provider,

Beginning May 1, 2008 the Colorado Department of Public Health and Environment Newborn Screening Laboratory will institute new methodology for the screening of cystic fibrosis (CF). Currently, the lab screens for elevated levels of immunoreactive trypsinogen (IRT). If two elevated IRT results are found, the patient is referred for an iontophoretic sweat test, also known as sweat chloride test, for confirmation of cystic fibrosis. Although this protocol has been mostly successful for the past 20 years, it created many false positive and a few false negative results. The former can be a cause of anxiety for parent, the latter can cause delayed diagnosis.

In effort to reduce the number of false positive and false negative results, the lab will add mutation analysis to the CF testing protocol. In the new IRT/IRT/DNA screen, the first screen IRT cutoff will be decreased from 105 to 60; first and second screen specimens will be linked for each newborn; and the second screen will be tested only if the first screen result was greater than 60 (or could not be linked to a viable first screen). Testing for a DNA mutation will occur if both screens have an IRT greater than 60. If one or two mutations are identified or if no mutations are identified but the result on the second specimen is >150, the patient will be referred for sweat chloride testing.

We believe that this new protocol will increase both the specificity and sensitivity of our cystic fibrosis screening. Please do not hesitate to contact us with any questions or concerns.

Sincerely,

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