

# STATE OF COLORADO

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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 Colleagues,

On or about December 1, 2009 the CDPHE Newborn Screening Lab will be adjusting the cutoffs for the congenital adrenal hyperplasia assay. This change is necessary due to the assay kit vendor, PerkinElmer Life and Analytical Sciences, reformulating the reagents with a new antibody. The effects of this new antibody are:

1. Reduction of cross-reactivity, commonly found in testing very low birth weight babies, thereby reducing the false positive test results in these cases.
2. Lowering the mean 17- $\alpha$  hydroxy progesterone concentration for all birth weight babies by about half.

As a member of a newborn screening consortium consisting of six other Midwestern states, our lab participated in a study that examined the new formulation and conducted parallel testing against the current formulation to gather enough data, especially with low birth weight babies, in order to determine appropriate cutoffs.

Parallel testing resulted in over 26,000 data points, including over 750 data points representing our lowest birth weight tier of  $\leq 1,299$  gm. After a significant amount of data analysis we have set the cutoff as follows:

Weight Range (gm)	New Cut Off (ng/ml 17-OHP)	Old Cut Off (ng/ml 17-OHP)
$\geq 2200$	<b>35</b>	55
1700 - 2199	<b>58</b>	65
1300 - 1699	<b>75</b>	115
$\leq 1299$	<b>125</b>	135

In addition, the "presumptive positive," or emergency cut off concentration that will trigger immediate notification to the on-call endocrinologist, will change to **150 ng/ml** (from 200 mg/ml).

Sincerely,

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