

ANDREW M. CUOMO Governor HOWARD A. ZUCKER, M.D., J.D. Commissioner SALLY DRESLIN, M.S., R.N. Executive Deputy Commissioner

December 31, 2015

RE: Changes to the New York Newborn Screening Program's cut-off values for the neonatal 17α-hydroxyprogesterone (17-OHP) kit for congenital adrenal hyperplasia (CAH) screening for specimens from babies collected less than 24 hours after birth and specimens from babies collected 14 days or more after birth.

Dear Health Care Provider,

Please be advised that for specimens received and tested as of January 4, 2016, the cutoff values for the neonatal 17-OHP kit will change for babies whose specimens were collected less than 24 hours after birth. In addition, the cut-offs for 14 to 40 day old infants and over 40 day old infants will be replaced with the multi-tiered cut-offs currently in use for the four different weight categories for specimens collected 24 hours to less than 14 days after birth, but taking into account the infant's possible weight gain. These changes will reduce the number of congenital adrenal hyperplasia (CAH) referrals for babies in these categories. New cut-off values have been assigned based on our evaluation of the kit over the past five years. <u>Referral and borderline cut-offs have **NOT** been changed for specimens from babies collected between 24 hours and less than 14 days after birth.</u>

The tables below indicate these changes.

New Referral values (ng/ml) for babies whose specimens are collected less than 24 hours
after birth

Birth Weight (g)	Repeat Specimen Requested As Soon As Possible	Referral (REF)*
<u>< 1000</u>	< 250	<u>≥ 250</u>
1001-1750	< 160	<u>> 160</u>
1751-2250	< 135	<u>≥</u> 135
≥ 2251	< 120	≥ 120

24 hours and less than 14 days after birth					
Birth Weight (g)	Normal Range	Borderline (BL)**	Referral (REF)*		
<u>≤1000</u>	< 106	106-148	<u>≥ 149</u>		
1001-1750	< 69	69-116	≥ 117		

35-78

35-63

Referral and Borderline values (ng/ml) for babies whose specimens are collected between 24 hours and less than 14 days after birth

*REF: Referral level - an evaluation and diagnosis is required.

< 35

< 35

**BL: Borderline level - below referral level, but above normal value; a repeat specimen is required.

Referral and Borderline values (ng/ml) for babies whose specimens are collected 14 days or more after birth

The laboratory with make a conservative estimation of the weight of the infant when the specimen was collected based on the birth weight and the age of the infant. This will be accomplished by adding 25 grams to the birth weight for each day of the baby's life. The cut-offs for borderline and referral values from the table above will then be used.

Please be advised that if the specimen is collected when the baby is less than 24 hours old, a second filter paper specimen taken at 24 hours or more of age is required by the program irrespective of 17α -hydroxyprogesterone findings. In addition, a repeat specimen must be submitted if the test value is within the borderline level.

As always, we will monitor test results over time and may adjust cut-offs based on long term studies. You will be informed if there are any additional changes.

Thank you for your cooperation in making New York State's Newborn Screening Program the best it can be. Questions can be directed to our main telephone number 518-473-7552.

Sincerely,

1751-2250

> 2251

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Norma P. Tavakoli Ph.D. Director, Immunoassay Laboratory

Michele Caggana, Sc.D., FACMG Director, Newborn Screening Program

<u>> 79</u>

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