

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 thyroid stimulating hormone (TSH) kit for congenital hypothyroidism (CH) screening for specimens from babies collected less than 24 hours after birth and changes to CH algorithm pertaining to low birth weight infants.

Dear Health Care Provider,

Please be advised that for specimens received and tested as of January 4, 2016, the emergency referral cut-off values for the TSH kit will change for babies whose specimens were collected *less than 24 hours after birth*. The cut-off value will be increased from $100 \,\mu\text{U/ml}$ to $150 \,\mu\text{U/ml}$. Please note: irrespective of TSH findings, a second filter paper specimen taken at *greater than 24 hours of age* is required by the program if the initial specimen was collected *less than 24 hours after birth*.

The emergency TSH cut-off for specimens collected 24 hours or more after birth remains 100 μU/ml.

Additionally, low birth weight infants (less than 2500g) whose specimens are collected 1 to 30 days after birth and who have two or more borderline (BL) thyroxine (T4) results, will no longer be referred. Instead, their T4 results will be reported as borderline and an additional specimen will be requested and must be submitted. A repeat borderline result from an infant 30 days or older will be referred.

These changes will reduce the number of CH referrals for babies in these categories. New cut-off values have been assigned based on our evaluation of the kit over the past several years.

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,

Norma Justal

Norma P. Tavakoli Ph.D. Director, Immunoassay Laboratory Michele Caggana, Sc.D., FACMG Director, Newborn Screening Program