

# N-TBG Kit for Specific Market Need



## Opportunity Translated into Success

*RIVN is the thought leader on neonatal TBG testing hosting a workshop at the ISNS – International Society for Neonatal Screening - meeting in Hague Sept 2016.*

*It seeks to promote the importance of importance of N-TBG testing so more countries may reduce false positives obtained by N-T4 testing alone.*

### Executive Summary

In Netherlands at the National Institute of Public Health (RIVN) professionals have incorporated neonatal TBG testing into their protocol as secondary screen for neonate samples with low T4 values (approx. 5%) to discriminate Congenital Hypothyroidism CH (traditional) from TBG-deficiency leading to better diagnosis, patient management and outcomes.

With approximately 180,000 births per year in Netherlands, RIVN labs measure TBG in about 9,000 samples across their five screening labs. The institute is the global thought-leader on implementing neonatal TBG (N-TBG) and actively works to demonstrate the benefit of decreasing the number of 'false positives' found through N-T4 testing alone, so that other countries may adopt N-TBG testing.

## Challenges

There was no commercial test for neonatal N-TBG and RIVN labs developed its own by adopting a radioimmunoassay kit from Japan preparing the calibrators and controls on 'filter paper'. When the kit was being discontinued, the labs needed a solution. Monobind was approached by its Dutch distributor about adopting its TBG kit for neonates.

Based Monobind's extensive experience with neonatal markers, including its long standing participation in USA CDC proficiency testing program for N-T4 and N-TSH and worldwide distribution footprint, it was well poised to develop a new product for N-TBG.

## What We Did

Monobind collected specific details from RIVN including TBG value range for neonates, assay sensitivity requirements and preferred assay time, so the existing TBG assay could be adapted and recalibrated. It was found RIVN preferred an overnight incubation, so the assay was designed with this total time in mind as well as an option for 2.5 hour duration with rotation during incubation.

Further, the calibrators (and controls, a new component) would be made from whole blood and spotted on filter paper as part a complete CE Marked product.

Pilot lots were created for correlation with RIVN's existing TBG radioimmunoassay method and the results were fantastic as obtained by RIVN.

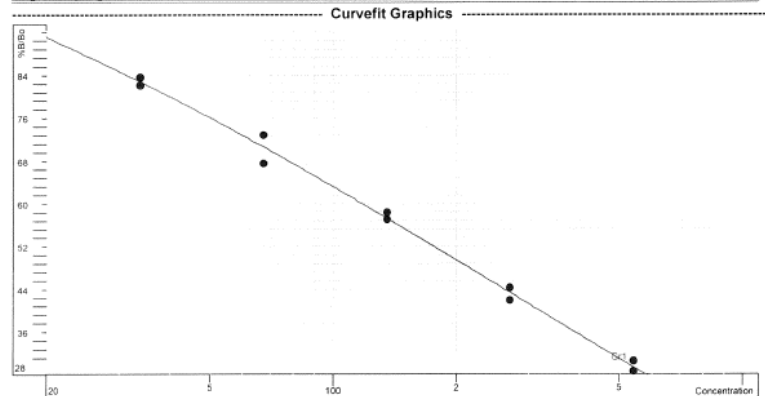
## Expected Values

The mean TBG-concentration in bloodspots in the Netherlands is 166 mol/l blood and that corresponds with the Monobind N-TBG 50% B/B0. Neonates with known TBG-deficiency were properly identified and several hundred samples were assessed in this effort before widespread adoption of Monobind kit.

Below are the initial results provided by RIVN:

TBG							
Measurement file : tbg11052011C.dat				Valid Assay		Measurement date : 12-5-11	
Template file : TBG-B.par						Measurement time : 10:25:25	
Table arranged data							
positie	Sample_ID	Reader_Values-BC	B/B0	nmol/l	nmol/l (2)	%CV	vlag CV
A01	ASB	0.133	0.126				
C01	st-A	3.019	2.938	101	10		2
E01	st-B	2.449	2.494	82	34		1
G01	st-C	2.015	2.174	68	69		5
A02	st-D	1.742	1.704	58	132		2
C02	st-E	1.323	1.254	44	273		4
E02	st-F	0.855	0.909	29	539		4
G02	Low(AC)	2.174	2.288	73	54	54	4
A03	Med(DC)	1.940	1.875	65	96	96	2
C03	High(FC)	1.603	1.555	54	168	168	2
E03	10091	2.883	2.948	97	12	12	2
G03	12617	2.909	2.978	98	11	11	2

vlag CVduplo grenzen: concentratie >10 & %CV > 15%, concentratie <10 nvt



## Conclusion

In concert with Monobind's distributor and the end-user, Monobind was able to solve a critical market need and develop a superior product to better meet neonate testing requirements. Ongoing collaboration and support with customers ensures laboratory success and continued product quality, and remains a cornerstone at Monobind. Since 2011 RIVN has exclusively used Monobind N-TBG kits for its testing purposes.