

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: k030860

B. Analyte: T4

C. Type of Test: Microwell EIA for the quantitation of Thyroxine in neonates.

D. Applicant: Monobind, Inc

E. Proprietary and Established Names: AccuBind™ Neo-Natal T4 Microplate EIA

F. Regulatory Information:

1. Regulation section: 21 CFR 862.1700
2. Classification: Class II
3. Product Code: KLI
4. Panel: 75

G. Intended Use:

1. Intended use(s): This test is intended for the quantitative determination of Thyroxine (T4) in blood specimens dried on filter paper for screening newborns for congenital (neonatal) hypothyroidism.
2. Indication(s) for use: This test is intended for the quantitative determination of Thyroxine (T4) in blood specimens dried on filter paper for screening newborns for congenital (neonatal) hypothyroidism.
3. Special condition for use statement(s): none stated
4. Special instrument Requirements: Microplate reader capable of absorbance readings at 450nm and 620nm

H. Device Description: Monobind's Neo-Natal T4 EIA is a solid phase Enzyme Immunoassay system. Calibrators and controls are included in the test kit. Calibrators, controls and patient samples are dried onto supplied filter paper. Values are established using dried blood references for calibrators. Since measurement is not done via irradiation no radioactive waste is collected.

I. Substantial Equivalence Information:

1. Predicate device name(s): Delfia Neonatal Thyroxine Kit

2. Predicate K number(s): k943416

<u>Comparison with predicate:</u>		
Item	Device	Predicate
Intended for the quantitative determination of Thyroxine (T4) in blood specimens dried on filter paper for screening newborns for congenital (neonatal) hypothyroidism.	Yes	Yes
Uses filter paper to blot and dry sample	Yes	Yes
EIA Assay	Yes	No
Uses radioactive labeled T4 as indicator	No	Yes
Includes calibrators and controls	Yes	Yes

J. Standard/Guidance Document Referenced (if applicable): None Stated

K. Test Principle: The methodology used in the Monobind T4 is EIA (Enzyme Immunoassay)

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility: The within and between run assays of the Neonatal T4 Microplate EIA test system were determined by analysis on three different levels of dried blood controls. The number, mean values, standard deviation and coefficient of variation for each control are listed below. This data represents ten experiments run in duplicate over a ten day period.

Within Assay Precision (values in ug/dL)

Sample	N	X	S.D.	C.V.
Low	20	2.4	0.26	10.7%
Normal	20	8.1	0.37	4.6%
High	20	21.1	1.69	8.02%

Between Assay Precision (values in ug/dL)

Sample	N	X	S.D.	C.V.
Low	10	2.5	0.26	10.5%
Normal	10	8.2	0.47	5.8%
High	10	21.0	1.51	7.2%

b. Linearity/ assay reportable range:

Two individual blood units were drawn from apparently normal, healthy subjects. The blood samples were stripped of T4 by washing red cells twice with 50 mM PBS. The serum collected was supplemented with T4/T3 stripped human serum. Hematocrit was adjusted to 0.52. An aliquot of T4 '0' blood sample was spiked with 100 µg/dL of Thyroxine. This stock was used for making further dilutions. All the diluted preparations were spotted on the S&S 903 filter paper and dried. The blood dots taken from those were assayed according to Monobind product insert 2625-300 for Neo-T4 EIA. The summarized results are given here below:

Sample I.D.	Concentration (µg/dL)		% Recovery
	Expected (E)	Observed (O)	O/E*100
A	0.0	0.0	100.0
B	0.312	0.253	81.1
C	0.625	0.671	107.4
D	1.250	1.313	105.1
E	2.500	2.484	99.4
F	5.000	4.906	98.1
G	10.000	10.330	103.3
H	20.000	20.920	104.6
I	30.000	28.780	95.9
J	40.000	41.200	103.0
K	50.000	48.110	96.2
L	60.000	55.000	91.6
M	70.000	59.000	84.2
N	80.000	64.000	80.0
O	90.000	61.000	67.8
P	100.000	61.000	61.0

Based on the above study Monobind Neo-T4 was observed to be linear from 0.3 µg/dL to 50 µg/dL. Samples (Concentrations) A-B & L-P were deleted from the range.

c. Traceability (controls, calibrators, or method): CDC neonatal control program for monitoring neonatal thyroid assays.

d. Detection limit: Two individual blood units were drawn from apparently normal, healthy subjects. The blood samples were stripped of T4 by washing red cells twice with 50 mM PBS. The serum collected was supplemented with T4/T3 stripped human serum. Hematocrit was adjusted to 0.52. An aliquot of T4 '0' blood sample was spiked with 100 µg/dL of Thyroxine. All the above preparations were spotted on the S&S 903 filter paper and dried. The blood dots taken from those were assayed

according to Monobind product insert 2625-300 for Neo-T4 EIA. Based on the above study Monobind Neo-T4 was observed to be linear from 0.3 µg/dL to 50 µg/dL. This linear limit indicates the assay detection cutoff.

e. Analytical specificity: No apparent effect of increased hemoglobin was seen for the assay. No effects were noted when pure thyroid binding globulin, phenytoin or phenylbutazone were added to samples and assayed.

f. Assay cut-off: Based on 242 specimens taken from healthy infants the normal range for healthy neonates is assigned at 8.2 – 19.7 ug/dL. The results showed a mean of 14.0 ug/dL and a 10% cut off value of 10.3 ug/dL.

2. Comparison studies:

a. Method comparison with predicate device: The Accubind was compared to the Delfia Neonatal Thyroxine Kit. Biological specimens from infants were used. (The values ranged from 0.5ug/dL – 45ug/dL). A total of 370 specimens were used. Least square regression and the correlation coefficient were computed for this comparison with the predicate method. The data obtained is provided below:

Method	Mean(x)	Equation
Monobind EIA “Y”	15.63	$Y=0.6044+0.9413*X$
Predicate RIA (X)	15.96	

b. Matrix comparison: NA

3. Clinical studies:

a. Clinical sensitivity: No Clinical studies were provided to determine clinical sensitivity

b. Clinical specificity: No Clinical studies were provided to determine clinical specificity

c. Other clinical supportive data (when a and b are not applicable):
none stated

4. Clinical cut-off: Based on 242 specimens taken from healthy infants the normal range for healthy neonates is assigned at 8.2 – 19.7 ug/dL. The results showed a mean of 14.0 ug/dL and a 10% cut off value of 10.3 ug/dL.

5. Expected values/Reference range: Based on 242 specimens taken from healthy infants the normal range for healthy neonates is assigned at 8.2 – 19.7 ug/dL. The results showed a mean of 14.0 ug/dL and a 10% cut off value of 10.3 ug/dL. The manufacturer further states: “It is important to keep in mind that any normal range establishment is dependant upon a multiplicity of factors like the specificity of method, the locale, the population tested and the precision of the method in the hands of technicians. For neonatal screening age, weight, and prematurity of the infant play a major role as well. For these reasons each laboratory should depend upon the range of expected values established by the manufacturer only until in house ranges can be determined.”

M. Conclusion: Based upon the information provided, I recommend that the AccuBind™ Neo-Natal T4 Microplate EIA Kit be found substantially equivalent with similar predicate devices as defined in 21 CFR 862.1700.