



# NEONATAL TSH

## Screening Elisa assay

**Enzyme immunoassay  
for the titration of  
Thyroid Stimulating Hormone  
in newborns**



ZenTech

### ORDERING INFORMATION

Code : **E-GP-192A**  
Package Size : 192 tests/kit

Code : **E-GP-480**  
Package Size : 480 tests/kit

Code : **E-GP-2400**  
Package Size : 2400 tests/kit



### Indications

- Determination of Thyroid Stimulating Hormone for the detection of hypothyroidism in newborns
- Elevated results indicate the need for further study to assess congenital hypothyroidism

### Features

- Accurate, sensitive and specific assay
- Reduced incubation time
- Conjugate ready for use
- Standard curve calibrated against the 1st ISNS Reference



### Performance characteristics

- Detection limit : 0.05  $\mu$  I.U./mL
- Measuring range : 6 to 150  $\mu$  I.U./mL

### Kit contents

Reagents	192 tests	Quantity 480 tests	2400 tests
<b>Wells</b>	2 x 96	5 x 96	25 x 96
<b>Calibrators 0-5 &amp; Controls 1-2</b>	1 aluminium pouch	2 aluminium pouches	4 aluminium pouches
<b>TSH conjugate</b>	1 x 25 ml	1 x 55 ml	5 x 55 ml
<b>Extraction buffer</b>	1 x 125 ml	1 x 125 ml	1 x 500 ml
<b>Washing Solution</b>	1 x 35 ml	2 x 35 ml	1 x 500 ml
<b>Chromogenic substrate</b>	1 x 55 ml	1 x 55 ml	1 x 250 ml
<b>Blocking Reagent</b>	1 x 30 ml	2 x 30 ml	1 x 250 ml
<b>Sealing tapes</b>	2 sheets	5 sheets	25 sheets



Zentech s.a.  
Liège Science Park  
Avenue du Pré-Aily,10  
B-4031 Angleur • Belgium  
Tel : +32 (0)4 361 42 32  
Fax : +32 (0)4 367 00 63  
info@zentech.be  
http://www.zentech.be



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**NEONATAL SCREENING**



# NEONATAL TSH

## Screening Elisa assay

### Assay description



The TSH Screening ELISA is an enzyme immunoassay to quantitate human thyroid stimulating hormone (TSH) using dried blood spots.

The TSH Screening ELISA is a sandwich ELISA. The strips are coated with an anti-TSH antibody that capture TSH present in the sample. After incubation and a washing step to remove unbound material, a monoclonal antibody anti-TSH conjugated to horseradish peroxidase (HRP) is added and allowed to bind to TSH.

The following complex is formed : **Mouse anti-TSH \* TSH \* Mouse anti-TSH-HRP conjugate**

After a second incubation and a washing step, the immuno-complex is detected by reduction of 3,3'-5,5'-tetramethylbenzidine (TMB) by HRP. The development of a blue colour is directly proportional to the amount of antigen in the sample or standard. The enzymatic reaction is stopped by addition of sulfuric acid and absorbance at 450 nm is read using an ELISA microtiter plate reader.

## Analytical performances

### Precision

The intra-assay imprecision has been tested with 3 samples containing various amounts of TSH in 24 replicates.

TSH Concentration ( $\mu$ I.U./ml)	Standard Deviation	CV (%)
9.8	0.6	6.04
26.5	1.2	4.60
45.0	2.2	4.91

The inter-assay imprecision has been tested in 9 separated assays with 3 samples containing various amounts of TSH, each sample tested in triplicate.

TSH Concentration ( $\mu$ I.U./ml)	Standard Deviation	CV (%)
12.0	0.6	5.0
20.1	1.1	5.5
38.7	2.1	5.4

### Recovery

Recoveries were performed using samples from the External Quality Control Program CDC. 3 samples were tested in 15 replicates.

Target value ( $\mu$ I.U./ml blood) HCR 50%	Obtained value ( $\mu$ I.U./ml blood)	Recovery (%)
13.9	15.5	111
21.9	25.1	115
43.5	44.4	102

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info@zentech.be  
<http://www.zentech.be>