

Newborn
Screening Test

Congenital Hypothyroidism Screening
TSH test for Newborns

FREND TSH Neo

Quantitative assay for
Neonatal Thyroid Stimulating Hormone

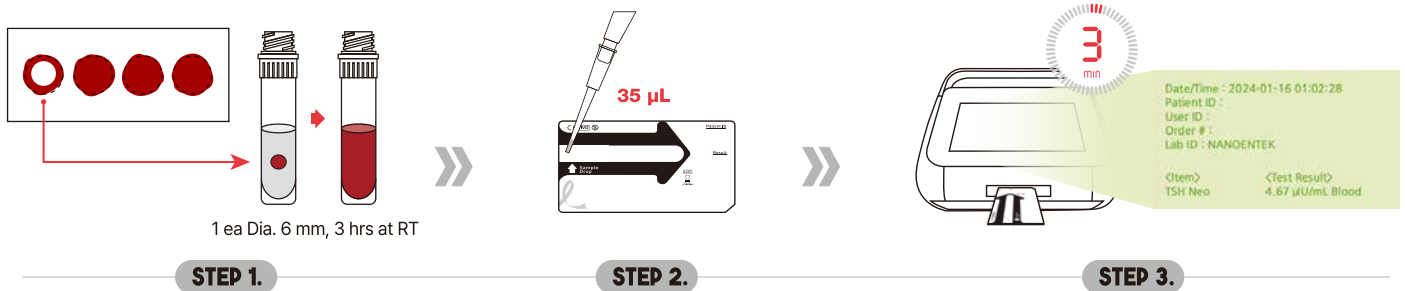
IVD



The FREND TSH Neo is an assay that uses dried blood spot specimens to aid in the **in-house screening** of newborns for congenital hypothyroidism.

Congenital hypothyroidism is a deficiency of thyroid hormone present at birth. If left untreated, severe consequences can arise, including growth failure and permanent intellectual disability. The FREND TSH Neo immunoassay uses Dried Blood Spot (DBS) samples to provide consistent, secure, and sensitive quantitative measurement of TSH levels in neonates. Screening thyroid function is essential to help prevent mental impairment in newborns.

Test Procedures



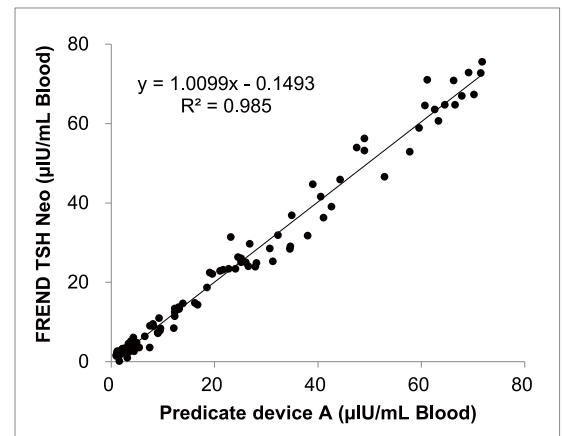
Punch a single 6 mm sample from DBS paper and place it in a dilution tube for 3 hours at RT.

Load 35 µL of the samples on the cartridge.

Insert the cartridge and get the results.

Clinical Performance

The FREND TSH Neo was compared to predicate device A following guidelines (CLSI document EP09-A3). With sample principle, a total of 111 clinical samples tested on both devices and showed a result of high correlation between FREND TSH Neo and the comparator.



Specifications

Item	Specification
Assay method	Fluorescence immunoassay
Sample type	Dried blood spot samples
Measuring range	1.35 ~ 60.00 µIU/mL Blood
Sample volume	35 µL
Time to result	Pretreatment: 3 hrs Cartridge reaction: < 3min
Quantity	20 tests / kit
Storage condition	2 ~ 8 °C

Ordering Information

Product	Cat. no
FREND™ System	F10, F20 (FREND 2.0)
FREND TSH Neo	FRTHN 020

