

MP Biomedicals, LLC

Diagnostics Division
29525 Fountain Parkway
Solon, Ohio 44139
Telephone 440-337-1200
Fax: 440-337-1180

Quality Control Certificate

ISO 13485
Cert. No. US13/82845

PRODUCT: NEO TSH ELISA KIT

LOT NUMBER: MNHK1801

EXPIRATION DATE: 2018 DEC 05

The following components have been tested together for use as an integral unit. For quality control purposes only these components should be used together. Do not intermix other lot numbers.

Components

Lot No.

PLATE
STANDARDS
CONTROLS
ELUTION BUFFER
WASH BUFFER CONC.
ENZYME CONJUGATE
ENZYME DILUENT
COLOR SUBSTRATE
STOPPING SOLUTION

MTHP1705
MTSHBS1701
MTSHBC1701
MEB1702
MWB1701
MNHE1702
MED1701E
MCS1703
MSS1701

	Value	Control	TSH (uIU/ml)	Range
Max Abs @ 450 nm	2.25	MTSHBC1701-I	14.5	10.3-16.7
		MTSHBC1701-II	31.6	22.3-36.5
		MTSHBC1701-III	70.5	51.7-83.3

MP Biomedicals certifies that these products have been manufactured according to good manufacturing practices. This product has been tested and found to meet established specifications and release criteria.

P. Shah

Approved by Quality Control

Human blood products may have been used in product formulation. Each blood donor unit used in the manufacture of these products has been tested by an FDA reviewed method and found to be non-reactive for HIV 1, HIV 2 antibody, and HBsAg. No known test method can offer assurance that products derived from human blood will not be infectious.

GMP No.: 773.10
QER No.: Q13-039