

MP Biomedicals, LLC

Diagnostics Division
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Quality Control Certificate

ISO 13485
Cert. No. US13/82845

PRODUCT: NEO TSH ELISA KIT

LOT NUMBER: MNHK1704

EXPIRATION DATE: 2017 NOV 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

MTHP1606
MTSHBS1601
MTSHBC1602
MEB1603A
MWB1601
MNHE1604
MED1701
MCS1603
MSS1502

	Value	Control	TSH (uIU/ml)	Range
Max Abs @ 450 nm	1.81	MTSHBC1602-I	13.4	11.6-19.0
		MTSHBC1602-II	25.3	21.6-35.4
		MTSHBC1602-III	60.7	44.4-72.6

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