

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: MNHK1614

EXPIRATION DATE: 2017 MAY 20

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.

<u>Components</u>	<u>Lot No.</u>
PLATE	MTHP1603
STANDARDS	MTSHBS1601
CONTROLS	MTSHBC1602
ELUTION BUFFER	MEB1501
WASH BUFFER CONC.	MWB1503
ENZYME CONJUGATE	MNHE1601
ENZYME DILUENT	MED1601
COLOR SUBSTRATE	MCS1503
STOPPING SOLUTION	MSS1502

	Value	Control	TSH (uIU/ml)	Range
Max Abs @ 450 nm	2.26	MTSHBC1602-I	18.0	11.6-19.0
		MTSHBC1602-II	28.3	21.6-35.4
		MTSHBC1602-III	60.9	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.



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