

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

July 15, 2015

Brad Arington, Associate Director, Regulatory
THERANOS, INC.
1701 PAGE MILL ROAD
PALO ALTO, CA 94304 US

Re: CW150009
CLIA Parent(s): k143236
Applicant: THERANOS, INC.
Device: Theranos Herpes Simplex Virus-1(HSV-1) IgG Assay
Dated: June 29, 2015
Received: June 30, 2015
CLIA Effective Date: July 15, 2015

Waiver Granted Notification

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your application for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. We are pleased to inform you that your test system(s) as identified below is waived:

Test System/Analyte(s): (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved or cleared by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page <http://www.fda.gov/cdrh/clia>. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. FDA reserves the right to re-evaluate and re-categorize this test based upon additional information received.

If you have any questions regarding this complexity categorization, please contact Stephen Lovell at 301-796-6968.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Parent Number : k143236

Test System : Theranos anti-HSV-1 IgG Assay {Fingerstick Whole Blood Only}
Analyte : Herpes simplex I and/or II antibodies
Complexity : WAIVED
