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