



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

April 16, 2015

Duane Poorman, Official Correspondent  
Now Diagnostics  
1200 Stewart Place  
Springdale, AR 72764 US

Re: CR150129  
CLIA Parent(s): k033297  
Applicant: Now Diagnostics  
Device: ADEXUSDx hCG Test  
Dated: March 19, 2015  
Received: March 20, 2015  
CLIA Effective Date: April 16, 2015

### **Categorization Notification**

Regulations codified at 42 CFR 493.17 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

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

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 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.

If you have any questions regarding this complexity categorization, please contact Denise Johnson Lyles at 301-796-6169.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez".

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

**Parent Number : k033297**

Test System : Now Diagnostics, Inc., ADEXUSDx hCG Test  
Analyte : hCG, serum, qualitative  
Complexity : MODERATE

Test System : Now Diagnostics, Inc., ADEXUSDx hCG Test  
Analyte : hCG, whole blood, qualitative  
Complexity : MODERATE

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