Tuesday, January 19, 2016

To Whom It May Concern:

The Aptima® Trichomonas vaginalis Assay has been validated and FDA-cleared for use with the Tigris® DTS® System to test clinician-collected endocervical or vaginal swabs, urine, and PreservCyt® solution specimens from symptomatic or asymptomatic women.

This letter is to verify that Hologic, Inc. is the sole source of an FDA-cleared amplified assay for determining the presence of *Trichomonas vaginalis* in a test sample. Hologic is the sole source of the kits listed below:

Cat. #302806 Aptima® Trichomonas vaginalis Assay (250 test kit)
U.S. Patent Nos. 5,656,207, 5,658,737, 5,696,251, 5,827,656, 5,840,873, 6,090,591, 6,110,678, 6,245,519, 6,280,952, 6,294,338, 7,070,925, 7,495,093 and 7,632,934.

Cat. #303065 Aptima® Trichomonas vaginalis Assay (100 test kit)
U.S. Patent Nos. 5,656,207, 5,658,737, 5,696,251, 5,827,656, 5,840,873, 6,090,591, 6,110,678, 6,245,519, 6,280,952, 6,294,338, 7,070,925, 7,495,093 and 7,632,934.

Hologic does not sell through dealers or distributors in the U.S. Sales are made directly to the end user only.

Please do not hesitate to contact me personally if you should need further assistance.

Sincerely,

Thomas West
Division President, Diagnostics

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