March 23, 2020

Hologic, Inc.
Jill Wyland
Director, Regulatory Affairs
10210 Genetic Center Drive
San Diego, California 92121

Re: K200436
Trade/Device Name: Aptima Combo 2 Assay (Panther) - 250 test kit, Aptima Combo 2 Assay (Tigris) - 250 test kit, Aptima Trichomonas Vaginalis (Panther) - 250 test kit, Aptima Trichomonas Vaginalis (Tigris) - 250 test kit
Regulation Number: 21 CFR 866.3120
Regulation Name: Chlamydia Serological Reagents
Regulatory Class: Class I, reserved
Product Code: MKZ, LSL, OUY, QEP
Dated: February 21, 2020
Received: February 24, 2020

Dear Jill Wyland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven Gitterman, M.D., Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) SUMMARY

Aptima Combo 2 Assay (Panther and Tigris System)
Aptima Trichomonas Vaginalis Assay (Panther and Tigris System)

I. SUBMITTER

Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Contact Information:

Jill Wyland
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Date Prepared: February 21, 2020

II. DEVICES

Proprietary Name:	Aptima Combo 2® Assay (Panther System)
Classification Name:	Nucleic Acid Amplification System for Non-Viral Microorganism(s) Sexually Transmitted Infections DNA Probe, Nucleic Acid Amplification, Chlamydia DNA Reagents, Neisseria
Regulation Number:	866.3390
Regulatory Class:	Class II
Product Code:	QEP
Subsequent Product Code:	MKZ, LSL

Proprietary Name:	Aptima Combo 2® Assay (Tigris System)
Classification Name:	DNA Probe, Nucleic Acid Amplification, Chlamydia DNA Reagents, Neisseria
Regulation Number:	866.3390
Regulatory Class:	Class II
Product Code:	MKZ, LSL

Proprietary Name:	Aptima Trichomonas Vaginalis® Assay (Panther System)
Classification Name:	Trichomonas Vaginalis Nucleic Acid Amplification Test System
Regulation Number:	866.3860
Regulatory Class:	Class II
Product Code:	OUY

Proprietary Name:	Aptima Trichomonas Vaginalis® Assay (Tigris System)
Classification Name:	Trichomonas Vaginalis Nucleic Acid Amplification Test System
Regulation Number:	866.3860
Regulatory Class:	Class II
Product Code:	OUY

III. PREDICATE DEVICES

The predicate devices are the following:

- Aptima Combo 2 Assay (Panther System): K190515; cleared 05/23/2019)
- Aptima Combo 2 Assay (Tigris System): K060652; cleared 08/17/2006)
- Aptima Trichomonas Vaginalis Assay (Panther System): K122062; cleared 01/09/2013)
- Aptima Trichomonas Vaginalis Assay (Tigris System): K102911; cleared 04/19/2011)

These predicate devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTIONS

The clearance of this Special 510(k) application will allow the use of a Ready-Made Reagent format for the Aptima Combo 2 assay (AC2) and the Aptima Trichomonas Vaginalis assay (ATV) on the Tigris and Panther systems. The use of Ready-Made Reagent assays does not change the principles of procedure, intended use, or primary technological characteristics.

Description of Ready-Made Reagents

Currently, each of the AC2 and ATV Amplification, Enzyme, and Probe reagents are provided in two parts: a lyophilized reagent (cake form) and a reconstitution solution (liquid form). Per the instructions provided in the respective assay's package inserts, the customers are instructed to prepare the reagents by reconstituting each reagent by combining the bottles of lyophilized reagent with the reconstitution solution and mixing reagents manually prior to placing on the Panther or Tigris system. Hologic developed "Ready Made Reagents" (RMRs), which are liquid

format or pre-reconstituted Amplification, Enzyme, and Probe reagents available for customers to procure in the 250-Test Kit size available for use on both the Tigris and Panther systems.

Changes to the user interface are minimal as the RMRs are identical to the lyophilized reagents once they have been reconstituted at the laboratory. In order to prepare the current format reagents (lyophilized format), the laboratory personnel pairs each reconstitution solution (Amplification, Enzyme, and Probe) with its respective lyophilized reagent. Using the RMR format, the customer eliminates the reconstitution step and is only required to bring the three reagents to room temperature following the same process currently done for the previously reconstituted reagents. All subsequent steps by the operator are unchanged. All assay principles and processing steps on the Panther or Tigris systems remain unchanged. There are no changes to the instrument hardware or software based on this change.

Assay Components

A list of the components that comprise the AC2 assay and the ATV assay master kits for both the RMR format and lyophilized format is provided in **Table 5-01.** Both kits are available for use on either the Panther or Tigris systems. There are no changes to the Aptima Controls Kit, ancillary kits, or collection kits.

Table 5-01: Reagents Required to Perform the AC2 and ATV Assays

Components for Lyophilized Kits	Components for RMR Format Kits
Box 1 (Stored at 2°C to 8°C)	
Amplification Reagent	RMR Amplification Reagent
Enzyme Reagent	RMR Enzyme Reagent
Probe Reagent	RMR Probe Reagent
Target Capture Reagent B	Target Capture Reagent B
Box 2 (Stored at 15°C to 30°C)	
Selection Reagent	Selection Reagent
Target Capture Reagent	Target Capture Reagent
Amplification Reconstitution Solution	
Enzyme Reconstitution Solution	
Probe Reconstitution Solution	

V. INDICATIONS FOR USE

There are not changes to the indications for use / intended use for each assay due to the use of the Ready-Made Reagents.

Intended Use - Aptima Combo 2 (Panther)

The Aptima Combo 2® Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC) to aid in the diagnosis of chlamydial and/or gonococcal disease using the Panther® System as specified.

On the Panther System, the assay may be used to test the following specimens from symptomatic and asymptomatic individuals: clinician-collected endocervical, vaginal, throat, rectal, and male urethral swab specimens, clinician-collected gynecological specimens collected in the PreservCyt® Solution, patient-collected vaginal swab specimens,1 and female and male urine specimens.

[1]Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection Kit has not been evaluated for home use.

Intended Use - Aptima Combo 2 (Tigris)

The Aptima Combo 2® Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the Tigris® DTS® Automated Analyzer or semi-automated instrumentation as specified. The assay may be used to test the following specimens from symptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; patient-collected vaginal swab specimens1; and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens, from both symptomatic and asymptomatic patients, collected in the PreservCyt® Solution.

[1]Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection Kit is not for home use.

Intended Use - Aptima Trichomonas Vaginalis (Panther)

The Aptima Trichomonas vaginalis Assay is an in vitro qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from Trichomonas vaginalis to aid in the diagnosis of trichomoniasis using the Panther System. The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, and specimens collected in PreservCyt Solution.

Intended Use - Aptima Trichomonas Vaginalis (Tigris)

The Aptima Trichomonas vaginalis Assay is an *in vitro* qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis using the Tigris® DTS® System. The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, female urine specimens, and specimens collected in PreservCyt Solution.

VI. COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

A comparison of the four subject devices (RMR assay format) to the predicate devices are summarized in **Table 5-02** through **Table 5-05**. Use of the RMR assay format does not change the principles of procedure, intended use, or primary technological characteristics. The similarities and differences between the subject and predicate devices are further discussed following the last substantial equivalence table. This discussion is the same for each assay.

Table 5-02: Comparison Between Predicate Device and Subject Device - AC2 on Panther

Item	AC2 Assay (Panther) (Predicate Device) K190515	AC2Assay (Panther) (Subject Device)
Technology Principle of Operation	Target Capture (TC), Transcription-Mediated Amplification (TMA), Hybridization Protection Assay (HPA)	Same
Platform	Automated Panther System	Same
Function	Detection and differentiation of rRNA from *Chlamydia trachomatis* and *Neisseria gonorrhoeae*	Same
Organisms Detected	*Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC)	Same
Patient Population	Symptomatic and asymptomatic individuals	Same
Intended Use	The Aptima Combo 2 Assay is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the Panther System as specified On the Panther System, the assay may be used to test the following specimens from symptomatic and asymptomatic individuals: clinician-collected endocervical, vaginal, throat, rectal, and male urethral swab specimens, clinician-collected gynecological specimens collected in the PreservCyt® Solution, patient-collected vaginal swab specimens,[1] and female and male urine specimens. [1]Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection Kits have not been evaluated for home use.	Same

Table 5-03: Comparison Between Predicate Device and Subject Device - AC2 on Tigris

Item	AC2 Assay (Tigris) (Predicate Device) K060652	AC2 Assay (Tigris) (Subject Device)
Technology Principle of Operation	Target Capture (TC), Transcription-Mediated Amplification (TMA), Hybridization Protection Assay (HPA)	Same
Platform	Automated Tigris System	Same
Function	Detection and differentiation of rRNA from *Chlamydia trachomatis* and *Neisseria gonorrhoeae*	Same
Organisms Detected	*Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC)	Same

Item	AC2 Assay (Tigris) (Predicate Device) K060652	AC2 Assay (Tigris) (Subject Device)
Patient Population	Symptomatic and asymptomatic individuals	Same
Intended Use	The Aptima Combo 2® Assay is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the Tigris® DTS® Automated Analyzer. On the Tigris DTS system, the assay may be used to test the following specimens from symptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; patient-collected vaginal swab specimens[1]; and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens, from both symptomatic and asymptomatic patients, collected in the PreservCyt® Solution. [1]Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal and multitest swab specimen collection kits are not for home use.	Same

Table 5-04: Comparison Between Predicate Device and Subject Device - ATV on Panther

Item	ATV Assay (Panther) (Predicate Device) K122062	ATV Assay (Panther) (Subject Device)
Technology Principle of Operation	Target Capture (TC), Transcription-Mediated Amplification (TMA), Hybridization Protection Assay (HPA)	Same
Platform	Automated Panther System	Same
Function	Detection and differentiation of rRNA from *Trichomonas vaginalis*	Same
Organisms Detected	*Trichomonas vaginalis*	Same
Patient Population	Symptomatic and asymptomatic individuals	Same
Intended Use	The Aptima Trichomonas vaginalis Assay is an *in vitro* qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis using the	Same

Item	ATV Assay (Panther) (Predicate Device) K122062	ATV Assay (Panther) (Subject Device)
	Panther System. The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, and specimens collected in PreservCyt Solution.	

Table 5-05: Comparison Between Predicate Device and Subject Device – ATV on Tigris

Item	ATV Assay (Tigris) (Predicate Device) DEN110012; K102911	ATV Assay (Tigris) (Subject Device)
Technology Principle of Operation	Target Capture (TC), Transcription-Mediated Amplification (TMA), Hybridization Protection Assay (HPA)	Same
Platform	Automated Tigris System	Same
Function	Detection and differentiation of rRNA from *Trichomonas vaginalis*	Same
Organisms Detected	*Trichomonas vaginalis*	Same
Patient Population	Symptomatic and asymptomatic individuals	Same
Intended Use	The Aptima Trichomonas vaginalis Assay is an *in vitro* qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis using the Tigris® DTS® System. The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, female urine specimens, and specimens collected in PreservCyt Solution.	Same

Similarities

Each of the subject devices utilize the same technology and principles of operation, mechanisms of action, conditions of use, results interpretation, have identical intended uses, and run on the same automated instrument system as compared to their predicate device. There are no differences in the performance of the assay as a result of the additional RMR format. The availability of the RMR format is a convenience for customers processing high volume of assays. The customer now has the option of procuring the AC2 and ATV assays using the RMR format in the 250-test kit size.

Differences

For the four assays, changes to the user interface are minimal as the RMRs are identical to the lyophilized reagents once they have been reconstituted at the laboratory. In order to prepare the current format of assay reagents (lyophilized format), the laboratory personnel pairs each reconstitution solution (Amplification, Enzyme, and Probe) with its respective lyophilized reagent. Using the RMR format, the customer eliminates the reconstitution step and is only required to bring the three reagents to room temperature following the same process currently done for the previously reconstituted reagents. All subsequent steps by the operator are unchanged. All assay principles and processing on the Panther or Tigris System remain unchanged. Use of the RMR format required new kit packaging and updated package inserts to include the new kit configuration and product handling instructions.

VI. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Brief Description of Non-Clinical Data

The following analytical (non-clinical) studies were conducted to support the clearance of the AC2 RMR assay on the Panther system, AC2 RMR assay on Tigris, ATV RMR on Panther and ATV RMR on Tigris.

Intended Use Study

Aptima Combo 2 Assay (Panther)

A comparison of Intended Use results between the AC2 and AC2 RMR assays on the Panther system showed comparability when negative and positive panels were tested. AC2 panels consisting of a Negative panel, CT positive, GC positive, and CT/GC dual positive panels were run on two Panther instruments. The current AC2 assay was used as the baseline result. The results showed 100% agreement to the expected positivity results for each CT panel, GC Panel and with dual positive panel for both the current AC2 and AC2 RMR assays on Panther.

Aptima Combo 2 Assay (Tigris)

A comparison of Intended Use results between the AC2 and pC2 RMR assays on the Tigris system showed comparability when negative and positive panels were tested. AC2 panels consisting of a Negative panel, CT positive, GC positive, and CT/GC dual positive panels were run on one Tigris instrument. The current AC2 assay was used as the baseline result. The results showed 100% agreement to the expected positivity results for each CT panel, GC Panel and with dual positive panel for both the current AC2 assay and AC2 RMR assay on the Tigris system.

Aptima Trichomonas vaginalis Assay (Panther)

A comparison of Intended Use results between the ATV and ATV RMR assays on the Panther system showed comparability when negative and positive panels were tested. ATV panels consisting of a Negative panel, TV positive, and TV low positive were run on two Panther instruments. The current ATV assay was used as the baseline result. The results showed 100% agreement to the expected positivity results for each TV panel, for both the current ATV and ATV RMR assays on the Panther system.

Aptima Trichomonas vaginalis Assay (Tigris)

A comparison of Intended Use results between ATV and ATV RMR on the Tigris system showed comparability when negative and positive panels were tested. ATV panels consisting of a Negative panel, TV positive, and TV low positive were run on one Tigris instrument. The current ATV assay was used as the baseline result. The results showed 100% agreement to the expected positivity results for each TV panel, for both the current ATV and ATV RMR assays on the Tigris system.

Limit of Detection

Aptima Combo 2 Assay (Panther)

The Limit of Detection (LoD) for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) for AC2 RMR assay was determined to be within ½ log of the LoD for the AC2 assay on the Panther system. The limit of detection (LoD) was estimated for the current AC2 and AC2 RMR assays by using stocks of CT and GC organisms in negative clinical liquid pap specimens

collected in PreservCyt solution (ThinPrep). These panels were tested on two Panther systems using two lots for each reagent format. The equivalency was shown as the results of the lowest concentration ≥ 95% positivity for CT target on the current AC2 assay and for AC2 RMR assay on the Panther was 0.01 IFU/mL. The equivalency for the GC target was equivalent as shown by the lowest concentration ≥ 95% positivity for the current AC2 assay and for the AC2 RMR assay on the Panther was 0.1 cells/mL.

Aptima Combo 2 Assay (Tigris)

The Limit of Detection (LoD) for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) for AC2 RMR assay was determined to be within ½ log of the LoD for the AC2 assay on the Tigris system. The limit of detection (LoD) was estimated for the current AC2 and AC2 RMR assays by using stocks of CT and GC organisms in negative clinical liquid pap specimens collected in PreservCyt solution (ThinPrep). These panels were tested on one Tigris system using two reagent lots for each format. The equivalency was shown as the results of the lowest concentration ≥ 95% positivity for CT target on the current AC2 assay and for AC2 RMR assay on Tigris was 0.01 IFU/mL. The equivalency for the GC target was equivalent as shown by the lowest concentration ≥ 95% positivity for the current AC2 assay and for the AC2 RMR assay on Tigris was 0.1 cells/mL.

Aptima Trichomonas vaginalis Assay (Panther)

The Limit of Detection (LoD) for *Trichomonas vaginalis* for ATV RMR assay was determined to be within ½ log of the LoD for the ATV assay on the Panther System. The limit of detection (LoD) was estimated for the current ATV and ATV RMR assays by using stocks of TV organisms in negative clinical liquid pap specimens collected in PreservCyt solution (ThinPrep). These panels were tested on two Panther Systems using two lots for each reagent format. The equivalency was shown as the results of the lowest concentration ≥ 95% positivity for TV target on the current ATV assay and for the ATV RMR assay on Panther was 0.003 TV/mL.

Aptima Trichomonas vaginalis Assay (Tigris)

The Limit of Detection (LoD) for *Trichomonas vaginalis* for ATV RMR assay was determined to be within ½ log of the LoD for the ATV assay on the Tigris System. The limit of detection

(LoD) was estimated for the current ATV and ATV RMR assays by using stocks of TV organisms in negative clinical liquid pap specimens collected in PreservCyt solution (ThinPrep). These panels were tested on one Tigris System using two reagent lots for each format. The equivalency was shown as the results of the lowest concentration ≥ 95% positivity for TV target on the current ATV assay was 0.003TV/mL and for the ATV RMR assay on Tigris was 0.01 TV/mL.

Clinical Performance Study

Aptima Combo 2 Assay (Panther)

The clinical comparability was determined between the current AC2 assay and the AC2 RMR assay on the Panther system when evaluating clinical positive and negative specimens. Hologic demonstrated comparability using the AC2 assay on Panther as representative of both the ATV and AC2 assays for both the Tigris and Panther systems.

Three hundred (300) remnant clinical swab specimens were evaluated with the current AC2 assay and the AC2 RMR assay using two reagent lots of each assay format and across two Panther systems. The current AC2 assay was used as the reference result. The positive, negative and overall agreement between the AC2 and AC2 RMR assays were calculated for both CT and GC target interpretations.

Table 5-06: CT Target Agreement Results

		AC2		
		+	-	Total
AC2 RMR	+	47	1	48
	-	0	242	242
	Total	47	243	290

Positive agreement (95% CI) = 100% (92.4% - 100%)
Negative agreement (95% CI) = 99.6% (97.7% - 99.9%)
Overall agreement (95% CI) = 99.7% (98.1% - 99.9%)

Table 5-07: GC Target Agreement Results

		AC2		
		+	-	Total
AC2 RMR	+	45	1	46
	-	0	245	245
	Total	45	246	291

Positive agreement (95% CI) = 100% (92.1% - 100%)
Negative agreement (95% CI) = 99.6% (97.7% - 99.9%)
Overall agreement (95% CI) = 99.7% (98.1% - 99.9%)

This study demonstrates that the performance of the current AC2 assay and AC2 RMR assay is comparable when testing clinical specimens on the Panther system.

VIII. CONCLUSIONS

A comparison of the intended use, technological characteristics, and results from the analytical performance studies demonstrate that the AC2 RMR assay and ATV RMR assay on the Panther and Tigris systems performs comparably to their predicate devices and supports a substantial equivalence decision.