Meridian Bioscience, Inc. Inspired Science. Trusted Solutions.®	*illumigene*® Mycoplasma DNA Amplification Assay Request for Additional Information	
	Application Reference:	Section 2
	Attachment Description:	510(k) Summary
	Application Date:	May 30, 2013 [1]

510(k) Summary

510(k) number: K123423 **Date of Preparation:** May 30, 2013

Owner:
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Contact:
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Jackie Godbey
Regulatory Affairs & Design Assurance Associate

Secondary Contact:
Michelle Smith
Sr. Director, Regulatory Affairs & Design Assurance

Trade Name: ***illumigene***® Mycoplasma DNA Amplification Assay
illumigene® Mycoplasma External Controls

Classification Name: Respiratory viral panel multiplex nucleic acid assay (21 CFR 866.3980, Product Code OZX)

Predicate Device: K120267, FilmArray® Respiratory Panel (RP); Catalog RFIT-ASY-0001

Device Description:

The ***illumigene*** Molecular Diagnostic Test System is comprised of the ***illumigene***® Mycoplasma DNA Amplification Assay Test Kit, the ***illumigene***® Mycoplasma External Control Kit and the ***illumipro-10***™ Automated Isothermal Amplification and Detection System.

The ***illumigene*** Mycoplasma assay utilizes loop-mediated isothermal amplification (LAMP) technology to detect the presence of *Mycoplasma pneumoniae* in human respiratory specimens (throat and nasopharyngeal swab specimens). Each ***illumigene*** Mycoplasma assay is completed using an ***illumigene*** Assay Control Reagent containing Control material, an ***illumigene*** Reaction Buffer, an ***illumigene*** Mycoplasma Test Device and microcentrifuge tubes. Respiratory specimens are combined with the ***illumigene*** Assay Control Reagent. The Specimen/Control sample is manually extracted and purified using a commercially available extraction kit (Qiagen, QIAamp® DSP DNA Mini Kit). Extracted DNA is heat-treated. Target and Control DNA are made available for isothermal amplification via heat-treatment. The heat-treated Specimen/Control sample is added to the ***illumigene*** Reaction Buffer. DNA amplification occurs in the ***illumigene*** Test Device.

The ***illumipro-10*** heats each ***illumigene*** Mycoplasma Test Device containing prepared Sample and Control material, facilitating amplification of target DNA. When *M. pneumoniae* is present in the specimen, a 208 base pair sequence of the *M. pneumoniae* genome is amplified and magnesium pyrophosphate is generated. Magnesium pyrophosphate forms a precipitate in the reaction mixture.

The ***illumipro-10*** monitors the absorbance characteristics of the reaction solutions at the assay Run Start ($Signal_{initial}$, S_i) and at the assay Run End ($Signal_{final}$, S_f). The ***illumipro-10***™ calculates the ratio of the Run End (Signal final or S_f) reads with the Run Start (Signal Initial or S_i) reads and compares the ratio to an established cut-off value. The ***illumipro-10*** performs this ratio calculation to both the TEST chamber and the CONTROL chamber.

Fixed cut-off values for the CONTROL chamber are used to determine validity. CONTROL chamber S_f:S_i ratios less than 90% are considered valid and allow for reporting of TEST chamber results (POSITIVE, NEGATIVE). CONTROL chamber S_f:S_i ratios greater than or equal to 90% are considered invalid. Results are reported as 'INVALID'; Test chamber results are not reported. More stringent cut-off criteria are applied to the Control chamber reaction to ensure amplification is not inhibited, reagents are performing as intended and that sample processing was performed appropriately.

Fixed cut-off values for the TEST chamber are used to report sample results. TEST chamber S_f:S_i ratios less than 82% are reported as 'POSITIVE'; TEST chamber S_f:S_i ratios greater than or equal to 82% are reported as 'NEGATIVE'. Numerical values are not reported.

The ***illumi**gene* Mycoplasma External Controls Kit contains a Positive and Negative Control Reagent. External Control reagents are provided to aid the user in detection of reagent deterioration, adverse environmental or test conditions, or variance in operator performance that may lead to test errors. External Control reagents are provided for use in routine Quality Control testing.

***illumi**pro-10*™ Automated Isothermal Amplification and Detection System:

The ***illumi**pro-10*™ heats each ***illumi**gene* Mycoplasma Test Device containing prepared samples and Control Reagent, facilitating amplification of target DNA. When *Mycoplasma pneumoniae* is present in the respiratory swab sample, a conserved sequence of the *M. pneumoniae* is amplified and magnesium pyrophosphate is generated. Magnesium pyrophosphate forms a precipitate in the reaction mixture. The ***illumi**pro-10* detects the change in light transmission through the reaction mixture created by the precipitating magnesium pyrophosphate. The ***illumi**pro-10* reports sample results as INVALID, POSITIVE or NEGATIVE based on the detected change in light transmission.

The ***illumi**pro-10*™ System Description was reviewed in previous submission, K100818, K110012, K112125, K121044 and K122019. No system or software changes were made for the ***illumi**gene* Mycoplasma assay.

Intended Use:

The ***illumi**gene* Mycoplasma DNA amplification assay, performed on the ***illumi**pro-10*™, is a qualitative in vitro diagnostic test for the direct detection of DNA from *Mycoplasma pneumoniae* in human throat and nasopharyngeal swabs obtained from patients suspected of having *Mycoplasma pneumoniae* infection.

The ***illumi**gene* Mycoplasma assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Mycoplasma pneumoniae* by targeting a segment of the *Mycoplasma pneumoniae* genome.

Results from the ***illumi**gene* Mycoplasma DNA amplification assay should be used in conjunction with clinical presentation, other laboratory findings, and epidemiological risk factors as an aid in the diagnosis of Mycoplasma infection and should not be used as the sole basis for treatment or other patient management. Positive results do not rule out co-infection with other organisms and negative results in persons with respiratory tract infections may be due to pathogens not detected by this assay. Lower respiratory tract infections due to *M. pneumoniae* may not be detected by this assay. If lower respiratory tract infection due to *M. pneumoniae* is suspected, additional laboratory testing using methods other than the ***illumi**gene* Mycoplasma DNA Amplification Assay may be necessary.

***illumi**gene* Mycoplasma is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

Predicate Device Comparison:

Similarities		
Item	**DEVICE** ***illumigene*® Mycoplasma**	**PREDICATE** **FilmArray® Respiratory Panel (RP) System** **K120267**
Intended Use	Qualitative	Qualitative
Indications for Use	Professional Use	Professional Use
Assay Target	*Mycoplasma pneumoniae* genome	*Mycoplasma pneumoniae* DNA, Toxin Gene
Specimen Types	Nasopharyngeal Swab	Nasopharyngeal Swab
Detection	Self contained and automated	Self contained and automated
Differences		
Item	**DEVICE** ***illumigene*® Mycoplasma**	**PREDICATE** **FilmArray® Respiratory Panel (RP) System** **K120267**
Specimen Type	Nasopharyngeal Swab Throat Swab	Nasopharyngeal Swab
Test Format	DNA Amplification Assay; Loop-Mediated Isothermal Amplification (LAMP)	Multiplex PCR Amplification Assay
Reagents/Components	The ***illumigene*** Mycoplasma DNA Amplification Assay Kit contains ***illumigene*** Assay Control II, ***illumigene*** Reaction Buffer II, ***illumigene*** Mycoplasma Test Device and Screw-top Tubes. External Control materials are provided separately in the ***illumigene*** Mycoplasma External Control Kit. The *illumipro-10* is provided separately.	The FilmArray Respiratory Panel (RP) Assay Kit contains FilmArray RP pouch, Sample Buffer, Hydration Solution, transfer pipettes and Sample Loading Syringes (with attached cannula). The FilmArray Instrument with Loading Station is provided separately.
External Controls	External Positive and Negative Controls for the ***illumigene*** Mycoplasma Assay are provided in the ***illumigene*** Mycoplasma External Control Kit. The External Positive Control Reagent contains tris-buffered solution containing non-infectious Plasmid DNA (*M. pneumoniae* and *S. aureus* inserts) with azide (0.09%) as a preservative. The External Negative Control Reagent contains tris-buffered solution containing non-infectious Plasmid DNA (*S. aureus* insert) with azide (0.09%) as a preservative.	The FilmArray Respiratory Panel (RP) Assay does not require external controls. External Controls are not indicated or available for the FilmArray Respiratory Panel (RP) Assay.

Differences *(continued)*

Item	DEVICE *illumigene*® Mycoplasma	PREDICATE FilmArray® Respiratory Panel (RP) System K120267
Amplification Technology and Target Sequence Detected	Assay performed with the ***illumipro-10***™ instrument, utilizes loop-mediated isothermal amplification (LAMP) technology for the detection of 208 base pair (bp) sequence of the *Mycoplasma pneumoniae* genome. The ***illumipro-10***™ detects changes in reaction solution absorbance by visible light transmission.	Assay performed with the FilmArray Instrument, utilizes freeze-dried reagents to perform nucleic acid purification, reverse transcription, and nested multiplex PCR with DNA melt analysis for the detection of multiple respiratory pathogens including detection of a specific *Mycoplasma pneumoniae* toxin gene sequence.
Instrumentation	***illumipro-10***™ Automated Isothermal Amplification and Detection System	FilmArray® Instrument
Reading Method	Visible Light Transmission	Fluorescence Emissions
Interpretation of Results	Results of the ***illumigene*** Mycoplasma Assay are interpreted by the ***illumipro-10*** and reported as INVALID, POSITIVE and NEGATIVE based on change in light transmission of the reaction mixtures. EMPTY WELL is reported when an ***illumigene*** Test Device is not detected by the ***illumipro-10*** or when questionable Signal Initial (S_i) transmission is detected.	Results of the FilmArray Respiratory Panel (RP) Assay report are interpreted by the FilmArray Instrument for *M. pneumoniae* and reported as Detected, Not Detected or Invalid.
Performance Characteristics	**Prospective Specimens** **Nasopharyngeal Swabs** Sensitivity: 100.0% [95% CI: 51.0% - 100.0%] Specificity: 100.0% [95% CI: 92.6% - 100.0%] **Throat Swabs** Sensitivity: 100.0% [95% CI: 67.6% - 100.0%] Specificity: 100.0% [95% CI: 91.8% - 100.0%] **Retrospective Specimens** **Nasopharyngeal Swabs** PPA: 94.4% [95% CI: 81.9% - 98.5%] NPA: 95.6% [95% CI: 89.1% - 98.3%] **Throat Swabs** PPA: 84.6% [95% CI: 66.5% - 93.9%] NPA: 98.5% [95% CI: 92.0% - 99.7%]	**Prospective Samples** **Nasopharyngeal Swabs** Sensitivity: 100.0% [95% CI:39.8 – 100%] Specificity: 100.0% [95% CI: 99.7 – 100%] **Throat Swab** - Not Evaluated **Retrospective Samples** **Nasopharyngeal Swabs** PPA: 84.4% [95% CI: 73.1 – 92.2%] NPA: 89.2% [95% CI: 79.1 – 95.6%] **Throat Swab** - Not Evaluated

NON-CLINICAL PERFORMANCE DATA:

Analytical Performance:

Precision/Reproducibility:

Blind-coded panels of 10 samples were supplied to three independent laboratories. Samples were randomly sorted within each panel to mask sample identities. The panels included contrived samples manufactured as low positive samples (i.e. limit of detection, n = 3) and high negative samples (n = 3). The panels also included contrived positive (n = 3) samples and natural negative samples (n = 1). Testing was performed by different operators at each site on the same day (intra-assay variability) for five days (inter-assay variability). Three lots of ***illumigene*** Mycoplasma and five ***illumipro-10*** instruments were used in this study. Positive and Negative Controls were tested each day of testing. The results are given in the table below:

	Site 1		Site 2		Site 3		Total	
Sample Type	**Percent agreement**		**Percent agreement**		**Percent agreement**		**Percent agreement**	
Negative	10/10	100%	10/10	100%	10/10	100%	30/30	100%
High Negative	30/30	100%	30/30	100%	30/30	100%	90/90	100%
Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%
Positive	29/30	96.7%	30/30	100%	29/30	96.7%	88/90	97.8%
Negative Control	10/10	100%	10/10	100%	10/10	100%	30/30	100%
Positive Control	10/10	100%	10/10	100%	10/10	100%	30/30	100%

Detection Limit:

Analytical Sensitivity studies were designed to determine, within 95% confidence intervals, the analytical limit of detection (LoD) of *Mycoplasma pneumoniae*. The LoD is the lowest number of colony-forming units (CFUs) per test aliquot that can be distinguished from negative samples with a high degree of probability (95%). Two *M. pneumoniae* strains, FH (ATCC 15531) and M129, were evaluated for analytical Limit of Detection. Culture confirmed stock concentrations were serially diluted into negative matrix (rayon swabs inoculated with normal nasal flora screened negative for *M. pneumoniae* and M4 non-nutritive Transport Medium) and tested in the ***illumigene*** Mycoplasma assay. Meridian utilized a simulated negative matrix for analytical studies. Each dilution evaluated in the ***illumigene*** Mycoplasma assay was done so using individually prepared replicates. Not all prepared dilutions were tested in the ***illumigene*** Mycoplasma assay; testing for select dilutions was discontinued when replicate testing did not meet criteria established for limit of detection (e.g. more than 1 negative replicate obtained). The lowest dilution producing positive results in at least 19 of 20 replicates was identified as the assay limit of detection.

Testing was performed using three lots of ***illumigene*** Mycoplasma and six ***illumipro-10*** instruments. External Positive and Negative Controls were tested each day throughout the study. The Limit of Detection for the assay was reported as 88 CFU/Test (2350 CFU/mL) for FH (ATCC 15531) and 7.5 CFU/Test (200 CFU/mL) for M129.

The following *M. pneumoniae* strains were tested and produced positive reactions at or below stated assay limit of detection of 88 CFU/Test (2350 CFU/mL) with ***illumigene*** Mycoplasma: PI1428, MAC (ATCC 15492), M52, Bru, M129-B170, Mutant 22, UAB 55612, UAB 56317, UMTB-10G (*M. pneumoniae* and *M. genitalium*).

Analytical Specificity:

Interference Testing:

Interfering substance testing was performed to assess the potential impact of non-microbial contaminants expected to be present in samples collected for *Mycoplasma pneumoniae* testing on ***illumigene*** Mycoplasma test results. Potentially interfering substances were tested with simulated negative and contrived positive (*M. pneumoniae* strains M129 and FH) samples. Potentially interfering substances were added to M4 medium with rayon swabs (Negative Sample) and to M4 medium with polyester swabs (Contrived Positive Sample) at final concentrations of 0.5% V/V or greater and tested.

The following biological substances, at the saturated solvent/diluents concentrations indicated do not interfere with the ***illumigene*** Mycoplasma test results: Mucus (5.0 mg/mL), White blood cells (0.5% v/v), Whole blood (5% v/v).

The following chemical substances, at the saturated solvent/diluents concentrations indicated do not interfere with test results: Acetaminophen (18.1 mg/mL), Albuterol Sulfate (20 mg/mL), Aspirin (9.1 mg/mL), Azithromycin dehydrate (2.0 mg/mL), Cepacol® Mouthwash [Ethanol, denatured (1.4% v/v), Cetylpyridinium chloride (0.005% v/v)], Contac® Cold + Flu Tablets [Acetaminophen (14.8 mg/mL), Chlorpheniramine maleate (0.06 mg/mL), Phenylephrine HCl (0.15 mg/mL)], Diphenhydramine HCl (2.6 mg/mL), Erythromycin (20.0 mg/mL), HALLS® Cough [Menthol (0.06 mg/mL)], Ibuprofen (12.7 mg/mL), Phenylephrine HCl (0.595 mg/mL), Prednisone (20.0 mg/mL), Robitussin® Cough+Chest Congestion Cough Syrup [Dextromethorphan HBr (0.20 mg/mL), Guaifenesin (2.0 mg/mL)], Saline Nasal Spray [Sodium chloride (0.65 mg/mL)].

Phenylephrine HCl found in nasal decongestants produced false negative results at concentrations above 0.595 mg/mL during *M. pneumoniae* strain M129 Limit of Detection replicate testing.

Cross-Reactivity Study:

Potentially cross-reacting microorganisms expected to be present in respiratory specimens (throat swab, nasopharyngeal swab or bronchoalveolar lavage specimens) were added to negative and contrived positive samples. Negative samples were prepared with M4 transport medium inoculated with nasal flora on rayon swabs. The contrived positive sample was prepared by spiking confirmed negative sample matrix (M4 transport medium inoculated with nasal flora on polyester swabs) with *Mycoplasma pneumoniae,* FH strain, at concentrations at or near the determined limit of detection for the strain. Dilution Controls were prepared by adding a sterile saline solution in place of the potentially cross-reactive organisms. Each inoculated sample was tested in triplicate.

Potentially cross-reactive (or interfering) microorganisms were at minimum concentrations of 1.0×10^6 CFU/mL for bacteria/fungi or concentrations greater than 1.0×10^5 $TCID_{50}$/mL or 1.0×10^8 copies/mL for viruses; Human DNA was tested at 2.0ng/test.

None of the following organisms reacted or interfered with ***illumigene*** Mycoplasma: *Acinetobacter baumannii, Acinetobacter calcoaceticus, Actinomyces odontolyticus, Bacillus subtilis, Bacteroides fragilis, Bordetella parapertussis, Bordetella pertussis, Burkholderia cepacia, Candida albicans, Candida glabrata, Candida parapsilosis, Chlamydia pneumoniae, Citrobacter freundii, Clostridium difficile, Corynebacterium diphtheriae, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Escherichia coli (ESBL), Fusobacterium nucleatum, Haemophilus ducreyi, Haemophilus influenzae, Haemophilus parainfluenzae, Helicobacter pylori, Klebsiella pneumoniae, Klebsiella pneumoniae (KPC), Legionella pneumophila, Listeria monocytogenes, Mycoplasma genitalium, Mycoplasma hominis, Neisseria cinerea, Neisseria gonorrhoeae, Neisseria meningitidis, Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella paratyphi A (Group A), Salmonella typhimurium (Group B), Serratia liquefaciens, Staphylococcus*

aureus, Staphylococcus epidermidis, Streptococcus agalactiae (Group B), Streptococcus anginosus (Group F), Streptococcus bovis (Group D), Streptococcus canis (Group G), Streptococcus equisimilis, Streptococcus mitis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Ureaplasma urealyticum, Adenovirus, Coxsackievirus, Cytomegalovirus, Epstein Barr virus, Herpes simplex virus 1, Herpes simplex virus 2, Influenza A, Influenza B, Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus, Human DNA.

Original replicate testing for *Moraxella catarrhalis, Nocardia asteroides* and Coronavirus produced one of three false-negative results when tested with the *Mycoplasma pneumoniae* FH strain, Limit of Detection sample. Four additional replicates were tested for each organism with expected results obtained. In all cases, the original unexpected results were not confirmed through supplemental testing.

Assay Cut-Off:

The ***illumigene*** Mycoplasma is manufactured with fixed cut-off values. The product is designed around a pre-selected cut-off value and amplification reagent concentrations are optimized to ensure appropriate reactions are obtained. Development optimization includes evaluation of characterized positive and negative clinical specimens. Amplification reagent concentrations are adjusted during design as needed to ensure ***illumigene*** results are aligned with clinical specimen reported results.

Cut-off values applied in the following manner:

The ***illumipro-10***™ calculates the ratio of the Run End (Signal final or S_f) reads with the Run Start (Signal Initial or S_i) reads and compares the ratio to an established cut-off value. The ***illumipro-10*** performs this ratio calculation to both the TEST chamber and the CONTROL chamber.

Fixed cut-off values for the CONTROL chamber are used to determine validity. CONTROL chamber S_f:S_i ratios less than 90% are considered valid and allow for reporting of TEST chamber results (POSITIVE, NEGATIVE). CONTROL chamber S_f:S_i ratios greater than or equal to 90% are considered invalid. Results are reported as 'INVALID'; Test chamber results are not reported. More stringent cut-off criteria are applied to the Control chamber reaction to ensure amplification is not inhibited, reagents are performing as intended and that sample processing was performed appropriately.

Fixed cut-off values for the TEST chamber are used to report sample results. TEST chamber S_f:S_i ratios less than 82% are reported as 'POSITIVE'; TEST chamber S_f:S_i ratios greater than or equal to 82% are reported as 'NEGATIVE'. Numerical values are not reported.

CLINICAL PERFORMANCE DATA:

Clinical Studies:

Clinical Sensitivity:

Clinical trials for the ***illumigene*** Mycoplasma DNA Amplification Assay, including the ***illumipro-10*** Automated Isothermal amplification and detection system, were conducted from February to September 2012.

A total of 334 qualified throat and nasopharyngeal (NP) swab specimens, collected from patients suspected of *Mycoplasma pneumoniae* infection were evaluated with the test device to establish performance characteristics. Specimens were leftover deidentified specimens submitted to the testing laboratories for routine *M. pneumoniae* testing. Specimens included in performance evaluation were prospective (never frozen) and retrospective (frozen prior to ***illumigene*** testing). The performance of ***illumigene*** was compared to a Composite Reference Method

that included *M. pneumoniae* bacterial culture with identification and a validated real-time PCR assay followed by bi-directional sequencing for positive specimens. Specimens producing positive *Mycoplasma pneumoniae* results from either the bacterial culture or real-time PCR and bi-directional sequencing were considered positive. Specimens negative for both culture and PCR were considered negative. A total of 12 specimens were excluded from the clinical sample population because culture results were inconclusive and PCR negative, making final disposition of patient status unavailable. A total of 103 (30.8%) prospective samples and 219 retrospective (65.6%) were tested with 1 initial invalid result (0.30%).

Tables 1-2 summarize performance characteristics. Statistical analysis of Specimen Type performance data was performed with no significant difference between swab types identified.

Data indicates performance is optimal when specimens are collected and tested prospectively.

Table 1. *illumigene* Mycoplasma Assay Performance: Nasopharyngeal Swab Specimens

Specimen Description	Positive Specimens			Negative Specimens			Invalid Results
	illumigene vs. Comparator	% Sensitivity or PPA	95% CI	*illumigene* vs. Comparator	% Specificity or NPA	95% CI	
Composite Reference Method							
Prospective	4/4	% Sensitivity **100.0%**	51.0 – 100.0%	48/48	% Specificity **100%**	92.6 – 100.0%	0
Retrospective	34/36	PPA **94.4%**	81.9 – 98.5%	86/90	NPA **95.6%**	89.1 – 98.3%	0
PCR with Bi-Directional Sequencing							
Prospective	4/4	% Sensitivity **100.0%**	51.0 – 100.0%	48/48	% Specificity **100%**	92.6 – 100.0%	0
Retrospective	34/36	PPA **94.4%**	81.9 – 98.5%	86/90	NPA **95.6%**	89.1 – 98.3%	0

Table 2. *illumigene* Mycoplasma Assay Performance: Throat Swab Specimens

Specimen Description	Positive Specimens			Negative Specimens			Invalid Results
	illumigene vs. Comparator	% Sensitivity or PPA	95% CI	*illumigene* vs. Comparator	% Specificity or NPA	95% CI	
Composite Reference Method							
Prospective	8/8	**% Sensitivity 100.0%**	67.6 – 100.0%	43/43	**% Specificity 100.0%**	91.8 – 100.0%	0
Retrospective	22/26[a]	**PPA 84.6%**	66.5 – 93.9%	66/67	**NPA 98.5%**	92.0 – 99.7%	1
PCR with Bi-Directional Sequencing							
Prospective	8/8	**% Sensitivity 100.0%**	67.6 – 100.0%	43/43	**% Specificity 100.0%**	91.8 – 100.0%	0
Retrospective	21/21[b]	**PPA 100.0%**	84.5 – 100.0%	70/72	**NPA 97.2%**	90.4 – 99.2%	1

a. Four specimens originally identified by culture as positive were not confirmed by either the *illumigene* assay or the independent PCR method. Results suggest sample degradation during storage.

b. One specimen originally identified by the *illumigene* assay and culture as positive was negative by the independent PCR method. This specimen is classified as a false positive relative to PCR.

Age information was known for 83.5% (269/322) of the patients included in the performance analysis. Seven (2.6%) patients tested were between 0 - 28 days of age; 38 (14.1%) patients were between 29 days and up to 2 years of age; 139 (51.7%) patients were between 2 and up to 12 years of age; 61 (22.7%) patients were between 12 and up to 18 years of age; and 9 (3.3%) patients were between18 and up to 21 years of age. The remaining 15 (5.6%) study patients were 21 years or older. No performance differences were noted based on chronological age.

The study population included 90 (27.9%) female patients and 91 (28.3%) male patients. Gender was unknown for 141 (43.8%) of the study participants. In the specimens for which patient gender was known, no performance differences were noted based on gender.

Clinical performance of the ***illumi***gene Mycoplasma DNA Amplification Assay was assessed by the testing of deidentified nasopharyngeal and throat swab specimens lacking clinical information; accordingly, the number of patients with *M. pneumoniae* pneumonia included in the clinical studies is unknown and performance for this group cannot be described separately.

Expected values/Reference range:

Overall incidence of *Mycoplasma pneumoniae* in prospectively collected and tested specimens during the 2012 clinical study was 11.7% (12/103).

CONCLUSIONS

The ***illumi****gene*® Mycoplasma DNA amplification assay, performed on the ***illumi****pro-10*™, can be used to detect *Mycoplasma pneumoniae* in human throat and nasopharyngeal swabs obtained from patients suspected of having *Mycoplasma pneumoniae* respiratory infection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JACQUELINE C. GODBEY
REGULATORY AFFAIRS AND DESIGN ASSURANCE ASSOCIATE
MERIDIAN BIOSCIENCE, INC.
3471 RIVER HILLS DRIVE
CINCINNATI OH 45244

June 5, 2013

Re: K123423
Trade/Device Name: ***illumigene***® Mycoplasma DNA Amplification Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OZX, OOI
Dated: May 22, 2013
Received: May 23, 2013

Dear Ms. Godbey:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat Ph.D., M.Sc
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Meridian Bioscience, Inc. Inspired Science. Trusted Solutions.®	*illumigene*® Mycoplasma DNA Amplification Assay	
	Application Reference:	Section 3
	Attachment Description:	Indications for Use Form
	Application Date:	May 30, 2012

Indication(s) for Use Form

510(k) Number: K123423

Device Name: ***illumigene***® Mycoplasma DNA Amplification Assay

Indications for Use:

The ***illumigene*** Mycoplasma DNA amplification assay, performed on the ***illumipro-10***™, is a qualitative in vitro diagnostic test for the direct detection of DNA from *Mycoplasma pneumoniae* in human throat and nasopharyngeal swabs obtained from patients suspected of having *Mycoplasma pneumoniae* infection.

The ***illumigene*** Mycoplasma assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Mycoplasma pneumoniae* by targeting a segment of the *Mycoplasma pneumoniae* genome.

Results from the ***illumigene*** Mycoplasma DNA amplification assay should be used in conjunction with clinical presentation, other laboratory findings, and epidemiological risk factors as an aid in the diagnosis of Mycoplasma infection and should not be used as the sole basis for treatment or other patient management. Positive results do not rule out co-infection with other organisms and negative results in persons with respiratory tract infections may be due to pathogens not detected by this assay. Lower respiratory tract infections due to *M. pneumoniae* may not be detected by this assay. If lower respiratory tract infection due to *M. pneumoniae* is suspected, additional laboratory testing using methods other than the ***illumigene*** Mycoplasma DNA Amplification Assay may be necessary.

illumigene Mycoplasma is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

Prescription Use ___X____ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

John Hobson -S
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