



June 13, 2016

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

MERIDIAN BIOSCIENCE, INC.
MICHELLE SMITH
SR. DIRECTOR, REGULATORY AFFAIRS AND DESIGN ASSURANCE
3471 RIVER HILLS DRIVE
CINCINNATI OH 45244

Re: K160829

Trade/Device Name: *illumigene* Mycoplasma Direct DNA Amplification Assay

illumigene Mycoplasma Direct External Controls

Regulation Number: 21 CFR 866.3980

Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay

Regulatory Class: II

Product Code: OZX, OOI

Dated: March 24, 2016

Received: March 25, 2016

Dear Ms. Smith:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Steven R. Gitterman -S

Steven Gitterman
Deputy Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160829

Device Name

illumigene Mycoplasma Direct DNA Amplification Assay
illumigene Mycoplasma Direct External Controls

Indications for Use (Describe)

The *illumigene* Mycoplasma Direct 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 swabs obtained from patients suspected of having *Mycoplasma pneumoniae* infection.

The *illumigene* Mycoplasma Direct 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 Direct 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 Direct DNA Amplification Assay may be necessary.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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	illumigene[®] Mycoplasma Direct DNA Amplification Assay	
	Application Reference:	Section 1: General Information
	Attachment Description:	Attachment 007: 510(k) Summary
	Application Date:	June 7, 2016

510(k) Summary

510(k) number: **K160829**

Date of Preparation: June 7, 2016

Owner: **Meridian Bioscience, Inc.**
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Phone: (513) 271-3700
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Contact: **Primary Contact:**
Michelle L. Smith
Senior Director, Regulatory Affairs & Design Assurance

Secondary Contact:
Susan D. Rolih
Executive Vice President, Regulatory and Quality Systems

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

Common Name: *Mycoplasma pneumoniae* DNA Assay System

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

Predicate Device: *illumigene* Mycoplasma DNA Amplification Assay; Catalog 280550
K123423, K152800

	illumigene[®] Mycoplasma Direct DNA Amplification Assay	
	Application Reference:	Section 1: General Information
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	Application Date:	June 7, 2016

Device Description:

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

The *illumigene* Mycoplasma Direct molecular assay utilizes loop-mediated amplification (LAMP) technology to detect *Mycoplasma pneumoniae* in throat swab specimens. The *illumigene* Mycoplasma Direct kit includes *illumigene* Sample Preparation Apparatus II/Negative Control III (SMP PREP II), *illumigene* Mycoplasma Test Devices, and Heat Treatment Tubes. The throat swab is added directly to the SMP PREP II, which contains assay control buffer. Samples processed through SMP PREP II (sample/control mixture) are heat treated to make target and control DNA available for amplification. The heat-treated sample is added to the *illumigene* Mycoplasma 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 (bp) sequence of the *M. pneumoniae* intracellular protease-like gene 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 change in light transmission between Run End and Run Start (S_f:S_i) and compares the ratio to a fixed cut-off value for disposition of results.

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.* 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 and prevent reporting of TEST chamber results. Invalid CONTROL chamber reactions are reported as 'INVALID'. 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.

The *illumigene* Mycoplasma Direct External Control Kit contains a Positive Control reagent for use in routine Quality Control testing; the *illumigene* Sample Preparation Apparatus II/Negative Control III reagent provided with the Mycoplasma Direct Kit serves as the External Negative Control. 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.

	illumigene[®] Mycoplasma Direct DNA Amplification Assay	
	Application Reference:	Section 1: General Information
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	Application Date:	June 7, 2016

Intended Use:

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

The *illumigene* Mycoplasma Direct 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 Direct 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 Direct DNA Amplification Assay may be necessary.

Predicate Device Comparison:

Similarities		
	MODIFIED DEVICE <i>illumigene[®] Mycoplasma Direct DNA Amplification Assay</i>	PREDICATE DEVICE <i>illumigene[®] Mycoplasma DNA Amplification Assay K123423, K152800</i>
Organism Detected	<i>Mycoplasma pneumoniae</i>	<i>Mycoplasma pneumoniae</i>
Target Sequence Detected	The assay targets a 208 base pair (bp) sequence of the <i>Mycoplasma pneumoniae</i> genome. The target DNA sequence is found in the intracellular protease-like protein gene.	The assay targets a 208 base pair (bp) sequence of the <i>Mycoplasma pneumoniae</i> genome. The target DNA sequence is found in the intracellular protease-like protein gene.
Instrumentation	<i>illumipro-10TM</i> Automated Isothermal Amplification and Detection System	<i>illumipro-10TM</i> Automated Isothermal Amplification and Detection System
Amplification and Detection	Self-contained and automated	Self-contained and automated
Amplification Methodology	Loop-Mediated Isothermal Amplification (LAMP)	Loop-Mediated Isothermal Amplification (LAMP)
Reading Method	Visible Light Transmission	Visible Light Transmission
Results Interpretation	Automated; Qualitative	Automated; Qualitative
Testing Time	Less than 60 minutes	Less than 60 minutes
Indications for Use	Professional Use	Professional Use

	illumigene[®] Mycoplasma Direct DNA Amplification Assay	
	Application Reference:	Section 1: General Information
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	Application Date:	June 7, 2016

Similarities		
	MODIFIED DEVICE illumigene[®] Mycoplasma Direct DNA Amplification Assay	PREDICATE DEVICE illumigene[®] Mycoplasma DNA Amplification Assay K123423, K152800
Analytical Sensitivity	<i>M. pneumoniae</i> M129 strain: 200 CFU/mL <i>M. pneumoniae</i> FH strain: 2350 CFU/mL	<i>M. pneumoniae</i> M129 strain: 200 CFU/mL <i>M. pneumoniae</i> FH strain: 2350 CFU/mL
Packaging	Supplied as a kit; 50 tests per kit	Supplied as a kit; 50 tests per kit.

Differences		
	MODIFIED DEVICE illumigene[®] Mycoplasma Direct DNA Amplification Assay	PREDICATE DEVICE illumigene[®] Mycoplasma DNA Amplification Assay K123423, K152800
Intended Use	<p>The <i>illumigene</i> Mycoplasma Direct DNA amplification assay, performed on the <i>illumipro-10TM</i>, is a qualitative in vitro diagnostic test for the direct detection of DNA from <i>Mycoplasma pneumoniae</i> in human throat swabs obtained from patients suspected of having <i>Mycoplasma pneumoniae</i> infection.</p> <p>The <i>illumigene</i> Mycoplasma Direct assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect <i>Mycoplasma pneumoniae</i> by targeting a segment of the <i>Mycoplasma pneumoniae</i> genome.</p> <p>Results from the <i>illumigene</i> Mycoplasma Direct 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 <i>M. pneumoniae</i> may not be detected by this assay. If lower respiratory tract infection due to <i>M.</i></p>	<p>The <i>illumigene</i> Mycoplasma DNA amplification assay, performed on the <i>illumipro-10TM</i>, is a qualitative in vitro diagnostic test for the direct detection of DNA from <i>Mycoplasma pneumoniae</i> in human throat and nasopharyngeal swabs obtained from patients suspected of having <i>Mycoplasma pneumoniae</i> infection.</p> <p>The <i>illumigene</i> Mycoplasma assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect <i>Mycoplasma pneumoniae</i> by targeting a segment of the <i>Mycoplasma pneumoniae</i> genome.</p> <p>Results from the <i>illumigene</i> 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 <i>M. pneumoniae</i> may not be detected by this assay. If lower respiratory tract infection due to <i>M. pneumoniae</i> is suspected, additional laboratory testing using methods other than the <i>illumigene</i> Mycoplasma DNA Amplification Assay may be necessary.</p>

	illumigene[®] Mycoplasma Direct DNA Amplification Assay	
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Differences		
	MODIFIED DEVICE illumigene[®] Mycoplasma Direct DNA Amplification Assay	PREDICATE DEVICE illumigene[®] Mycoplasma DNA Amplification Assay K123423, K152800
	<i>pneumoniae</i> is suspected, additional laboratory testing using methods other than the <i>illumigene</i> Mycoplasma Direct DNA Amplification Assay may be necessary.	<i>illumigene</i> Mycoplasma is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.
Specimen Type	Human throat swab specimens	Human throat swab and nasopharyngeal swab specimens
Swab Types	Rayon, Flocked Nylon, or Polyester	Cotton, Foam, Flocked Nylon, Polyester or Rayon
Transport Media	Transport medium on pledget: Liquid Amies without charcoal or Liquid Stuart	0.85% saline, M4, M4-RT, M5, UTM-RT, or Liquid Amies without charcoal
Sample Preparation	All reagents for sample processing included within the kit.	Manual purification/extraction using Qiagen [®] DSP DNA Minikit, Catalog Number 61304, required.
Reagents/ Components	<ul style="list-style-type: none"> • <i>illumigene</i> Mycoplasma Test Device • <i>illumigene</i> Sample Preparation Apparatus II/ Negative Control III • <i>illumigene</i> Heat Treatment Tubes 	<ul style="list-style-type: none"> • <i>illumigene</i> Mycoplasma Test Device • <i>illumigene</i> Assay Control II • <i>illumigene</i> Reaction Buffer II • Screw-top Microcentrifuge Tubes
Kit Storage	2-27 C	2-8 C

	illumigene[®] Mycoplasma Direct DNA Amplification Assay	
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NON-CLINICAL PERFORMANCE DATA

Analytical Performance:

Precision/Reproducibility:

Blind-coded panels of 10 samples were supplied to three independent laboratories for reproducibility studies. Samples were randomly sorted within each panel to mask sample identities. The panels included contrived manufactured as low positive samples (near the limit of detect, n=3), moderate positive samples (n=3), and high negative samples (n=3). The panel also included one natural negative sample. 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 Direct and eight *illumipro-10* instruments were used in the study. Positive and Negative Controls were tested with each panel. The results are provided in the table below:

Sample Type	Site 1		Site 2		Site 3		Total	
	Percent Agreement		Percent Agreement		Percent Agreement		Percent Agreement	
High Negative	30/30	100.0%	30/30	100.0%	30/30	100.0%	90/90	100.0%
Low Positive	30/30	100.0%	30/30	100.0%	29/30	96.7%	89/90	98.9%
Moderate Positive	30/30	100.0%	30/30	100.0%	30/30	100.0%	90/90	100.0%
Negative	9/10	90.0%	10/10	100.0%	10/10	100.0%	29/30	96.7%
Negative Control	10/10	100.0%	10/10	100.0%	10/10	100.0%	30/30	100.0%
Positive Control	10/10	100.0%	10/10	100.0%	10/10	100.0%	30/30	100.0%

Detection Limit:

Analytical Sensitivity studies were designed to verify the analytical limit of detection (LoD) of *Mycoplasma pneumoniae* with the *illumigene* Mycoplasma Direct assay. The LoD is defined as the lowest concentration of analyte (CFU/mL) that can be distinguished from negative samples with a high degree of probability (95%). Two strains of *M. pneumoniae* (M129 and FH) diluted in a simulated negative throat swab matrix were used to establish the LoD with three kit lots of *illumigene* Mycoplasma Direct. A minimum of three dilutions near the expected LoD in twenty (20) individually prepared replicates were evaluated for each *M. pneumoniae* strain. The overall confirmed analytical LoD by *M. pneumoniae* strain for *illumigene* Mycoplasma Direct is summarized below:

<i>M. pneumoniae</i> Strain	LoD Concentration (CFU/mL)
<i>M. pneumoniae</i> FH (ATCC 15531)	2350
<i>M. pneumoniae</i> M129 (ATCC 29342)	200

The following *M. pneumoniae* strains were tested with *illumigene* Mycoplasma and produced positive reactions at or below stated assay limit of detect of 2350 CFU/mL: PI 1428 (ATCC 29085), MAC (ATCC 15492), M52 (ATCC 15293), Bru (ATCC 15377), M129-B170 (ATCC 29343), Mutant 22 (ATCC 39505) UAB 55612, UAB 56317, UMTB-10G (ATCC 49899). Testing demonstrated that both Type 1 and Type 2 strains are detected with the assay. The same reactivity is expected with the *illumigene* Mycoplasma Direct assay.

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	Attachment Description:	Attachment 007: 510(k) Summary
	Application Date:	June 7, 2016

Analytical Specificity:

Interference Testing:

Potentially interfering substances were tested with simulated negative and contrived low positive (*M. pneumoniae* strains M129 and FH) samples. The following substances, at the saturated solvent/diluent concentrations indicated, do not interfere with **illumigene** Mycoplasma Direct assay:

Acetaminophen (18.1 mg/mL), Albuterol Sulfate (20 mg/mL), Aspirin (9.1 mg/mL), Azithromycin dehydrate (2.0 mg/mL), Cepacol[®] Mouthwash [Alcohol (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 Drops [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)], Mucus (5.0mg/mL), and White Blood Cells (0.5% v/v).

Whole blood was found to produce invalid results at concentrations greater than 2%.

Phenylephrine HCl at concentrations greater than 0.595 mg/mL may produce false negative results with low positive samples.

Robitussin[®] Cough+Congestion Cough Syrup initially produced 1/3 invalid results with Positive Sample P2 that produced acceptable results during repeat testing (1/1 positive). Robitussin[®] Cough+Congestion Cough Syrup is not considered an interferent.

Cross-Reactivity Study:

Crossreactivity studies were previously performed with the **illumigene** Mycoplasma DNA Amplification assay. Positive and negative specimens inoculated with potentially interfering bacterial or fungal organisms to minimum final concentrations of 1.0×10^6 CFU/mL. Viruses were tested at concentrations greater than 1.0×10^5 TCID₅₀/mL or 1.0×10^6 copies/mL. Human DNA was tested at 2.0 ng/test with no crossreactivity observed. Positive specimens contained *M. pneumoniae* concentrations near the limit of detection. None of the following organisms or materials were identified as crossreactive or interfering in the **illumigene** Mycoplasma assay:

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*, *Moraxella catarrhalis*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *Neisseria cinerea*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Nocardia asteroides*, *Peptostreptococcus anaerobius*, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Salmonella paratyphi* (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, Coronavirus, Coxsackievirus, Cytomegalovirus, Epstein Barr virus, Herpes simplex virus 1, Herpes simplex virus 2, Human metapneumovirus, Influenza A, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus, Human DNA.

No crossreactivity is expected with the **illumigene** Mycoplasma Direct assay.

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	Application Date:	June 7, 2016	

Assay cut-off:

The *illumigene* Mycoplasma Direct assay is manufactured with fixed cut-off values. The product is designed with 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-10TM* 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:

The performance characteristics of the *illumigene* Mycoplasma Direct DNA Amplification Assay were established in clinical studies conducted in 2015-2016 at independent clinical test sites representing three geographically distinct regions throughout the United States. Performance characteristics of the assay were compared to a reference molecular in vitro diagnostic method, the *illumigene* Mycoplasma DNA Amplification Assay (Meridian Bioscience, Inc., Cincinnati, OH). A total of 458 prospective, deidentified, throat swab specimens collected under informed consent from symptomatic male and female patients were evaluated. Two samples (0.4%) were excluded from the clinical sample population due to an instrument error during testing (1) or an unacceptable sample type (1) for a total of 456 eligible samples for analysis. There were no invalid results generated by the *illumigene* Mycoplasma Direct assay during the clinical study (0.0%; 95% CI: 0.0 – 0.8%). Performance characteristics of the *illumigene* Mycoplasma Direct assay are summarized below.

<i>illumigene</i> Mycoplasma Direct	<i>illumigene</i> Mycoplasma			
	Positive	Negative	Invalid	Total
Positive	24	10 ^a	0	34
Negative	1 ^b	421	0	422
Invalid	0	0	0	0
Total	25	431	0	456
				95% CI
Positive Percent Agreement	24/25	96.0%	80.5 - 99.3%	
Negative Percent Agreement	421/431	97.7%	95.8 - 98.7%	
Overall Percent Agreement	445/456	97.6%	95.7 - 98.6%	
Invalid Rate	0/456	0.0%	0.0 - 0.8%	

^a 4/10 samples were identified positive by *illumigene* Mycoplasma after testing with an additional frozen sample.

^b Repeat testing by *illumigene* Mycoplasma with the original patient sample and an additional frozen sample produced negative results.

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The eligible study population included throat swab specimens from pediatric, adult, and geriatric patients ranging in age from 3 weeks to 97 years. There was no difference in assay performance based on patient age. The study population included 230 (50.4%) female and 226 (49.6%) male specimens. There was no difference in assay performance based on gender. Prevalence based on patient age is provided below:

Patient Age	Total Positive	Total Samples	Prevalence (%)
0 to 1 Month	0	7	0.0%
2 Months to 2 Years	5	157	3.2%
3 Years to 12 Years	22	147	15.0%
13 Years to 21 Years	5	38	13.2%
22 Years to 65 Years	2	86	2.3%
>65 Years	0	21	0.0%

Expected Values:

The incidence of *Mycoplasma pneumoniae* was established during clinical studies conducted in 2015-2016. The overall prevalence of *M. pneumoniae* in prospective throat swab specimens was 7.5% (34/456).

CONCLUSION

The *illumigene[®]* Mycoplasma Direct DNA amplification assay, performed on the *illumipro-10™*, can be used to detect *Mycoplasma pneumoniae* in human throat swab specimens and is substantially equivalent to the predicate device.