510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K122019

B. Purpose for Submission:

To obtain substantial equivalence for the *illumigene*® Group A Streptococcus (Group A Strep) DNA Amplification Assay

C. Measurand:

A segment of *Streptococcus pyogenes* genome (206 base-pair sequence)

D. Type of Test

Qualitative in vitro diagnostic Loop-mediated DNA amplification (LAMP) technology

E. Applicant:

Meridian Bioscience, Inc.

F. Proprietary and Established Names:

illumigene® Group A Streptococcus (GBS) DNA Amplification Assay

illumigene® Group A Strep External Control Kit

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
OYZ-Group A Streptococcus DNA Amplification System; OOI-Real Time Nucleic Acid Amplification System	Class I	21 CFR 866.3740 – *Streptococcus spp*. Serological Reagents	Microbiology (83)

H. Intended Use:

1. Intended use:

   The *illumigene*® Group A *Streptococcus* (Group A Strep) assay, performed on the *illumipro-10*™, is a qualitative in vitro diagnostic test for the detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*) in throat swab specimens.

   The *illumigene* Group A Strep assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Streptococcus pyogenes* by targeting a segment of the *Streptococcus pyogenes* genome. Results from the *illumigene* Group A Strep assay can be used as an aid in the diagnosis of Group A Streptococcal pharyngitis. The assay is not intended to monitor treatment for Group A *Streptococcus* infections. *illumigene* Group A Strep is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

2. Indication(s) for use:

   The *illumigene*® Group A *Streptococcus* (Group A Strep) assay, performed on the *illumipro-10*™, is a qualitative in vitro diagnostic test for the detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*) in throat swab specimens.

   The *illumigene* Group A Strep assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Streptococcus pyogenes* by targeting a segment of the *Streptococcus pyogenes* genome. Results from the *illumigene* Group A Strep assay can be used as an aid in the diagnosis of Group A Streptococcal pharyngitis. The assay is not intended to monitor treatment for Group A *Streptococcus* infections. *illumigene* Group A Strep is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

3. Special conditions for use statement:

   - For professional use
   - The device is not intended for point-of-care use

4. Special instrument requirements:

   illumipro-10™ Automated Isothermal Amplification and Detection System

I. Device Description:

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

The *illumigene* Group A Strep assay utilizes loop-mediated isothermal amplification (LAMP) technology to detect the presence of *Streptococcus pyogenes* (Group A beta-

hemolytic *Streptococcus*) in throat swab specimens. Each *illumigene* Group A Strep assay is completed using an *illumigene* Sample Preparation Apparatus II/Negative Control III containing Control material, an *illumigene* Group A *Streptococcus* Test Device and an *illumigene* Heat Treatment Tube. Samples are diluted in the *illumigene* Sample Preparation Apparatus II and dispensed into an *illumigene* Heat Treatment Tube. Target and Control DNA is made available for isothermal amplification via heat-treatment. DNA amplification occurs in the *illumigene* Test Device.

The *illumipro-10* heats each *illumigene* Group A Strep Test Device containing prepared sample and Control material, facilitating amplification of target DNA. When *S. pyogenes* is present in the throat swab specimen, a 206 base pair sequence of the *S. pyogenes* 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 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'. *Numerical values 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.

The *illumigene* Group A Strep External Control Kit contains a Positive Control Reagent. The External Positive control Reagent is used in conjunction with the *illumigene* Sample Preparation Apparatus II/Negative Control III reagent included in the *illumigene* Group A Strep Kit as part of routine Quality Control testing. 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.

J. Substantial Equivalence Information:

1. Predicate device name:

   GEN-PROBE® Group A *Streptococcus* Direct Test; Catalog 103890

2. Predicate 510(k) number:

   K924715

3. Comparison with predicates:

Similarities		
Item	**DEVICE** (K122019) ***illumi**gene*® **Group A** ***Streptococcus***	**PREDICATE (K924715)** **GEN-PROBE® Group A** ***Streptococcus* Direct**
Intended Use	Qualitative	Qualitative
Test Format	Molecular-based Amplification Assay	Molecular-based Direct Assay
Target	*Streptococcus pyogenes*	*Streptococcus pyogenes*
Specimen Types	Throat Swab	Throat Swab
Detection	Self-contained and automated	Self-contained and automated

Differences		
Item	**DEVICE** ***illumi**gene*® **Group A** ***Streptococcus***	**PREDICATE** **GEN-PROBE® Group A *Streptococcus* Direct** **K924715**
Test Format	DNA Amplification Assay; Loop-Mediated Isothermal Amplification (LAMP)	Nucleic Acid Hybridization
Target Sequences Detected	206 base pair (bp) sequence *S. pyogenes* genome, resident in the pyrogenic exotoxin B	*Streptococcus pyogenes* ribosomal RNA
Reagents/Components	***illumi**gene* Sample Preparation Apparatus II/Negative Control III ***illumi**gene* Group A *Streptococcus* Test Device ***illumi**gene* Heat Treatment Tubes	Lysis Reagent Probe Reagent Hybridization Buffer Selection Reagent Positive Control Negative Control Sealing Cards
Amplification	Self-contained and automated	Not Applicable
Testing Time	Less than 60 minutes	Less than 90 minutes
Instrumentation	***illumipro-10*™** Automated Isothermal Amplification and Detection System	GEN-PROBE® LEADER® Luminometer
Reading Method	Visible Light Transmission	Chemiluminescent Emissions
Performance Characteristics	**Sensitivity: 98.0%** [95% CI: 93.1% - 99.5%] **Specificity: 97.7%** [95% CI: 96.3% - 98.6%]	**Sensitivity: 94.1%** **Specificity: 98.3%**

K. Standard/Guidance Document Referenced (if applicable):

- Clinical and Laboratory Standards Institute. 2008. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline- Second Edition (EP12-A)

- Clinical and Laboratory Standards Institute. 2005. User Verification of Performance for Precision and Trueness; Approved Guideline- Second Edition (EP15-A2)

- Clinical and Laboratory Standards Institute. 2005. Interference Testing in Clinical Chemistry; Approved Guideline- Second Edition (EP7-A2)

L. Test Principle:

The *illumigene* Group A Strep assay is based on loop-mediated isothermal amplification technology (LAMP). Loop-mediated amplification of DNA is accomplished by the use of specially designed primers that provide specific and continuous isothermal amplification. Magnesium-pyrophosphate is produced as a by-product of LAMP amplification. The magnesium-pyrophosphate forms a white precipitate in the reaction solution, giving the reaction solution a turbid appearance. Change in sample absorbance created by precipitation of magnesium pyrophosphate indicates the presence of target DNA and is considered a positive reaction. The absence of target DNA results in no detectable change in sample absorbance and is considered a negative reaction.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. 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* Group A Strep and five *illumipro-10* instruments were used in this study. The results are given in the table below. The Reproducibility Studies are acceptable.

	Site		**Site**		**Site**		**Tota**	
Sample Type	**Percent**		**Percent**		**Percent**		**Percent**	
Negative	10/10	100%	10/10	100%	10/10	100%	30/30	100%
High Negative	29/30	96.7	30/30	100%	28/30	93.3%	87/90	96.7%
Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%
Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%

b. Linearity/assay reportable range:

N/A

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Stability:
Sample storage and hold time studies were performed to characterize *illumigene* Group A Strep assay ranges. Validation studies performed at Meridian were completed using rayon swabs in both Liquid Amies (without charcoal) and Liquid Stuart Transport Medium.

Study results demonstrated that throat swab samples can be held at 21°-27° C for up to 48 hours or at 2°-8° C for up to 7 days prior to testing. Samples diluted in the *illumigene* Sample Preparation Apparatus can be held at 2°-29° C for up to 2 hours prior to heat treatment. Heat-treated samples may be held at 21°-29° C for up to one hour prior to testing. Final testing demonstrated that rayon, polyester and flocked nylon swab types with either Liquid Amies (without charcoal) or Liquid Stuart Transport Medium perform acceptably with the *illumigene* Group A Strep assay. Swab and transport medium types with demonstrated performance in the *illumigene* Group A Strep assay appear in the Package Insert.

d. Detection limit

Studies were designed to determine the analytical limit of detection of *S. pyogenes* in throat swab specimens. Two common strains of *S. pyogenes,* ATCC 12344 and ATCC 19615, were evaluated with the ***illumi****gene* Group A Strep assay. Each strain was spiked into sterile saline and diluted serially. Dilutions were combined with negative matrix (rayon swabs inoculated with normal throat flora screened negative for *S. pyogenes,* and Liquid Amies (without charcoal) Transport Media) prior to testing. A minimum of twenty replicates for each dilution were individually processed and tested to establish limit of detect. Testing was performed using three production lots of *illumigene* Group A Strep 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 400 CFU/Test for ATCC 12344 and 430 CFU/Test for ATCC 19615. The following *S. pyogenes* strains were tested and produced positive reactions at or below stated assay limit of detect of 400 CFU/Test with *illumigene* Group A Strep: ATCC 12384, NCIMB 13285, CCUG 33061, CCUG 33409, CCUG 39158, ATCC 49399, and CCUG 53553.

Limit of Detection studies are acceptable.

e. Analytical specificity:

Interference Studies:

Potentially interfering substances were tested with negative and contrived positive (ATCC 12344, ATCC 19615) samples. Contrived positive samples were prepared near the reported

limit of detection for each strain tested. Negative samples and contrived positive samples were added to the *illumigene* Sample Preparation Apparatus II and inoculated with throat swab matrix (rayon swab inoculated with normal throat flora, screened negative for *Streptococcus pyogenes,* and Liquid Amies Transport Medium). Each inoculated sample was tested in triplicate.

The following biological substances, at the saturated solvent/diluent concentrations indicated, do not interfere with test results: Mucus (5.0mg/mL), Human saliva (10% v/v), and Whole Blood (2.5% v/v). Whole Blood at concentrations greater than 2.5% v/v may interfere with the *illumigene* Group A Strep Assay.

The following chemical substances, at the saturated solvent/diluents concentrations indicated, do not interfere with test results: Acetaminophen (19.5 mg/mL), Aspirin (12.3 mg/mL), Cepacol® Mouthwash, [Cetylopyridinium Chloride (0.005% v/v)], Cepacol® Sore Throat Lozenges [Benzocaine (0.09 mg/mL), Menthol (0.02 mg/mL)], Chloraseptic® Oral Anesthetic/Analgesic [Phenol (0.07% v/v)], Contac® Cold + Flu Tablets [Acetaminophen 16.2 mg/mL), Chlorpheniramine maleate (0.06 mg/mL), Phenylephrine HCl (0.16 mg/mL0], Crest® Complete Toothpaste [Sodium fluoride (0.1 mg/mL)], Diphenhydramine HCl (2.7 mg/mL), HALLS® Cough Drops [Menthol (0.08 mg/mL)], Ibuprofen (15.6 mg/mL), Listerine® Antiseptic Mouthwash [Eucalyptol (0.0092% v/v), Menthol (0.0042% v/v), Methyl salicylate (0.0060% v/v), Thymol (0.0064% v/v), Robitussin® Cough/Chest Congestion Cough Syrup [Dextromethorphan HBr (0.2 mg/mL), Guaifenesin (2.0 mg/mL). Zicam® Oral Mist [Zincum Aceticum 2X, Zincum Gluonicum 1X (0.625% v/v) produced invalid results in all replicates tested.

Interference studies are acceptable.

Cross-Reactivity Studies:

Potentially cross-reacting microorganisms expected to be present in throat swab specimens were added to negative and contrived positive samples. The negative sample was prepared from *S. pyogenes* negative clinical throat swab sample in Liquid Amies (without charcoal) Transport Medium. The contrived positive sample was prepared by spiking sterile saline with *Streptococcus pyogenes* strain ATCC 12344 at approximately 400 CFU/Test, the reported limit of detection for the strain. Potentially cross-reactive microorganisms were added at concentrations of 1.2×10^8 CFU/mL (bacteria and fungi); Human DNA was tested at 0.02 mg/mL. Dilution controls for each sample were prepared by adding sterile saline solution in place of the potentially cross-reactive microorganisms. Each sample was tested in triplicate. No microorganism tested met the definition of interferent or cross-reactive.

None of the following organisms reacted with *illumigene* Group A Strep:

Acinetobacter baumannii, Acinetobacter lwoffii, Aeromonas hydrophila, Arcanobacterium haemolyticum, Bordetella bronchiseptica, Bordetella holmesii, Bordetella parapertussis, Bordetella pertussis, Burkholderia cepacia, Campylobacter jejuni, Candida albicans, Citrobacter freundii, Corynebacterium diphtheria, Corynebacterium pseudodiphtheriticum, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Haemophilus influenza, Klebsiella oxytoca, Klebsiella pneumoniae, Lactococcus lactis, Legionella jordanis, Legionella micdadei, Legionella pneumophila, Listeria monocytogenes, Moraxella

catarrhalis, Morganella morganii, Neisseria gonorrhoeae, Neisseria meningitides, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens, Staphylococcus aureus, Staphylococcus epidermidis, Stenotrophomonas maltophilia, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus bovis, Streptococcus canis, Streptococcus dysgalactiae (subspecies equisimilis), Streptococcus equines, Streptococcus intermedius, Streptococcus mitis, Streptococcus mutans, Streptococcus pneumoniae, Streptococcus salivarius, Streptococcus suis, Streptococcus uberis, Streptococcus sp. Viridans type. *Mycoplasma pneumoniae* was tested at 1.5 x 10^6 CFU/mL with no reaction with the *illumigene* Group A Strep assay.

Cross-reactivity studies are acceptable.

f. Assay cut-off:

The *illumigene* Group A Strep assay has a fixed cut-off based on the measured change in light transmission at the assay endpoint. The *illumipro-10* measures transmission of light through the Test and the Control reactions at the start of the Assay Run (Signal initial) and at the end of the Assay Run (Signal final). The *illumipro-10* calculates that change in transmission between the Signal final: Signal initial and compares the result to a fixed cut-off value. Test results are reported as Positive or Negative based on comparison to the assay cut-off. Fixed cut-off values were based on well characterized clinical specimens.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Clinical trials for the *illumigene* Group A *Streptococcus* (Group A Strep) DNA Amplification Assay, including the *illumipro-10* Automated Isothermal amplification and detection system, were conducted from April to June 2012. Performance characteristics of the assay were determined by comparison to composite bacterial culture method for Group A *Streptococcus*. A total of 798 qualified specimens were evaluated with the test; two specimens produced invalid results and were not included in performance calculations. Overall assay Sensitivity was reported as 98.0% [95% CI: 93.1 – 99.5%]; overall assay Specificity was reported as 97.7% [96.3 – 98.6%].

Compiled clinical study information is described below:

Group A *Streptococcus* Composite Culture	***illumi*gene Group A Strep**		
	Positive	**Negative**	**Total**
Positive	10	2	102
Negative	1	67	694
Total	11	68	796
			95%
Sensitivity	100/102	**98.0%**	93.1 – 99.5%
Specificity	678/694	**97.7%**	96.3 – 98.6%
Correlation	778/796	**97.7%**	96.5 – 98.6%

Three independent clinical test sites located in the Midwestern and Southern regions of the United States participated in the device evaluation. All samples utilized in the study were leftover human specimens, not individually identifiable. All samples included in the study were submitted to the testing laboratory by an ordering physician for Group A *Streptococcus* testing and were presumed from symptomatic patients. No restrictions were placed on age, gender, medications or known pharmaceutical therapies.

Composite culture methods were employed to accommodate reports that Group A *Streptococcus* culture is considered 90-95% sensitive when correct sampling and plating techniques are used. The Composite Culture Method consisted of the Clinical Site Culture Method as performed in standard of care testing and a Reference Culture Method performed by Meridian Bioscience. Site culture testing was performed by direct plating of the throat swab specimen while reference culture testing was performed by plating the swab transport media. Specimens producing positive Group A *Streptococcus* results from either the Site Culture Method or the Reference Culture Method was considered positive. Specimens that generated invalid or false-positive results were further evaluated. Data review for the two initial invalid samples revealed one Control Chamber failure and one suspect Test Chamber reaction. Repeat testing for both specimens produced valid, negative results; repeat testing data was not used in performance characteristic calculations. Discrepant specimens were further evaluated using a laboratory developed molecular assay with an alternate *Streptococcus pyogenes* DNA target. Thirteen of the 16 (81.2%) *illumigene* false-positive specimens were considered positive by the alternate molecular method. One of the two *illumigene* false-negative specimens was negative by the alternate molecular method; the remaining ***illumi****gene* false-negative specimen was not tested. Site performance information was analyzed by Composite Culture Reference Testing and Site Culture Methods. Site performance as compared to Composite Culture Method, is summarized in the first table below.

Site performance as compared to Site Culture Methods is presented in the second table below:

***illumigene* Group A Strep Assay Performance by Site; Composite Culture Method**

Site Identification	Positive Specimens			Negative Specimens			Invalid Specimens	
	illumigene /Composite Culture	% Sensitivity	95% CI	*illumigene* /Composite Culture	% Specificity	95% CI	Invalid /Total	% Invalid
Site 1	47/47	100.0%	92.4 - 100.0%	287/291	98.6%	96.5 - 99.5%	0/338	0.0%
Site 2	28/30	93.3%	78.7 - 98.2%	203/211	96.2%	92.7 - 98.1%	1/242	0.4%
Site 3	25/25	100.0%	86.7 - 100.0%	188/192	97.9%	94.8 - 99.2%	1/218	0.5%
Total	100/102	98.0%	93.1 - 99.5%	678/694	97.7%	96.3 - 98.6%	2/798	0.3%

***illumigene* Group A Strep Assay Performance by Site; Clinical Site Culture Method**

Site Identification	Positive Specimens			Negative Specimens			Invalid Specimens	
	illumigene /Composite Culture	% Sensitivity	95% CI	*illumigene* /Composite Culture	% Specificity	95% CI	Invalid /Total	% Invalid
Site 1	40/40	100.0%	91.2 - 100.0%	287/298	96.3%	93.5 - 97.9%	0/338	0.0%
Site 2	18/18	100.0%	82.4 - 100.0%	205/223	91.9%	87.6 - 94.8%	1/242	0.4%
Site 3	16/16	100.0%	80.6 - 100.0%	188/201	93.5%	89.3 - 96.2%	1/218	0.5%
Total	74/74	100.0%	95.1 - 100.0%	680/722	94.2%	92.2 - 95.7%	2/798	0.3%

Seven of the 102 Composite Culture-positive specimens were positive by Site Culture methods only; 26 of the 102 Composite Culture-positive specimens were positive only by the Reference Culture method; the two *illumigene* false-negative results were positive only by the Reference Culture performed by Meridian Bioscience. Statistical analysis of Site performance data was performed with no significant difference among Sites identified. Clinical performance data was evaluated by patient age and gender. Seventy two (9.0%) patients tested were two years of age or younger; 385 (48.2%) patients were between two and 12 years of age; while 259 (32.5%) patients were greater than 12 and less than 21 years of age. The remaining 82 (10.3%) study patients were greater than 21 years old. Age information was known for all patients included in the performance analysis. No performance differences were noted based on chronological age. The study population included 410 (51.4%) female patients and 386 (48.4%) male patients. Gender was unknown for two (0.2%) of the study participants. No performance differences were noted based on gender.

*b. Clinical specificity**:***

See 3(a) above

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off**:**

   N/A

5. Expected values/Reference range:

   Overall incidence of *Streptococcus pyogenes* in patients tested during the 2012 clinical study was 14.6% (116/796).

N. Instrument Name:

The *illumipro*-10

O. System Descriptions:

1. Modes of Operation:
   The *illumipro-10* is a menu driven laboratory instrument with two independent sample processing blocks: Block A and Block B. Each *illumipro-10* Block is capable of batch processing up to five closed *illumigene* test devices.

   The *illumipro*-10 operates in four basic modes: ASSAY, RESULTS, SERVICE, and SYSTEM. Assay Selection and Sample Amplification occur in the ASSAY mode; Test Results are managed in the RESULTS mode; Basic instrument set-up is performed in the SYSTEM mode; and Optical performance verification is completed in the SERVICE mode.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X____ or No _____

3. Specimen Identification:

   Samples are identified by position. Default Sample Identification is based on Block and Well position (e.g. Block A, Well 1). The user may input Sample Identification information using the keypad, the barcode scanner or the optional external keyboard.

4. Specimen Sampling and Handling:

   Specimen Sampling and Handling is performed external to the *illumipro-10*. Prepared Samples in closed *illumigene* Test Devices are placed in the *illumipro-10* for amplification and detection. The *illumipro-10* has no direct contact with samples. Closed *illumigene* Test Devices are discarded at the end of the assay to reduce the likelihood of contamination of the *illumipro-10* or the workspace.

5. Calibration:

The *illumipro-10* was designed to be a self-monitoring instrument. Calibration by the end user is not required.

6. Quality Control:

Quality Control requirements for the *illumipro-10* are limited to verification of optical performance and routine surface cleaning/decontamination. Optics system verification is performed by the user at installation and at 30 day intervals thereafter. Optics Verification Standards consist of ten red acrylic pieces molded and polished to replicate the dimensions of each *illumigene* Test Device chamber. The verification standards act like a high pass optical filter with the pass wavelength of 650 nm extending into the infrared range. Light transmission through the verification standard is used to confirm proper performance of the optics system. Failed optics verification testing for an instrument block will disable the block until the error is resolved. The *illumipro-10* completes a Power-On Self-Test (POST) at each power-on. POST testing confirms that the Hardware and Software elements of the system are performing as expected. The *illumipro-10* reports an error if POST failures are obtained; the instrument is disabled until the error is resolved.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.