K091409

510(k) Summary

JUL -6 2010

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Contact:	Larry Pietrelli
Date of Preparation:	July 1, 2010
Device Trade Name:	LightCycler® MRSA Advanced Test
Common Name:	Methicillin-resistant *Staphylococcus aureus* (MRSA) Test
Type of Test:	Nucleic Acid Amplification Test, DNA, Methicillin-resistant *Staphylococcus aureus* (MRSA), qualitative
Classification Name:	Antimicrobial susceptibility powder
Regulation:	866.1640
Procode:	NQX, OOI Nuclei Acid Amplification System, Real Time
Classification Advisory:	Microbiology
Committee:	
Predicate Device:	BD GeneOhm™ MRSA Assay (510(k) numbers K033415/K042357)

TABLE OF CONTENTS

List of Tables

1. DEVICE DESCRIPTION

The LightCycler® MRSA Advanced Test relies on 3 major processes: (1) specimen preparation by mechanical lysis of the bacterial cell walls, (2) PCR amplification of target DNA and detection by specific hybridization probes, and (3) automated result generation after melting peak analysis.

A nasal specimen is collected and transported to the laboratory in either BBL™ CultureSwab™ Liquid Stuart or Copan Venturi Transystem™ Liquid Stuart, BBL™ CultureSwab™ plus Amies gel with charcoal or Copan Venturi Transystem™ plus Amies gel with charcoal or BBL™ CultureSwab™ plus Amies gel without charcoal or Copan Venturi Transystem™ plus Amies gel without charcoal. Swab heads are cut into lysis tubes and subjected to heating to inactivate specimens. Subsequently lysis tubes are transferred in the MagNA Lyser Instrument where mechanical lysis of bacterial cell walls occurs, resulting in crude lysate preparations. After a brief centrifugation step to spin down glass beads and swab fibers, the processed specimen are subjected to PCR analysis using the LightCycler® MRSA Advanced Test.

The processed samples and the amplification mixture containing hot-start Taq polymerase are placed in LightCycler® Capillaries (20µL) in which PCR amplification will occur. Each LightCycler® MRSA Advanced Test reaction contains an internal control, which is designed to control for specimen inhibition, and to monitor reagent integrity. Also present in each LightCycler® MRSA Advanced Test is the AmpErase (uracil-N-glycosylase) enzyme. It recognizes and catalyzes the destruction of DNA strands containing deoxyuridine, but not DNA containing deoxythymidine. Since amplicons produced with the LightCycler® MRSA Advanced Test contain deoxyuridine, potential amplicon contaminants are eliminated during a prolonged heating step performed prior to the start of PCR amplification.

A target sequence in a plasmid is simultaneously amplified in the Positive Control. The Positive Control is intended to monitor for reagent failure and is included into each run. Each run also includes a Negative Control used to detect reagent or environmental contamination by MRSA DNA.

MRSA and Internal Control amplicons are detected by fluorescence using a specific pair of hybridization probes. The probes attach to a specific internal sequence in the amplified fragment and are positioned in a closed proximity to one another. Upon excitation, these bound probes emit a fluorescence signal of a specific wavelength using a process called Fluorescence Resonance Energy Transfer (FRET). The emitted light is measured by the LightCycler® 2.0 Instrument. MRSA or internal control specific amplicons are detected in parallel in two different detection channels and thus can be differentiated.

After completion of the real-time PCR process, a melting peak analysis is performed automatically by the LightCycler® 2.0 Instrument. Single stranded DNA amplicons with bound hybridization probes are subjected to increasing temperatures. When the PCR products reach a specific temperature one of the two bound hybridization probes melts off, resulting in a loss of fluorescence signal. The decrease in the fluorescence signal occurs at a specific temperature and results in melting peaks which are used to identify and distinguish MRSA- and Internal Control-specific amplicons.

After a visual identification of the melting peaks is performed using Tm Bars in the LightCycler® Software, test results are transferred to a dedicated interpretation tool (the Micro Analysis Software) and a report is generated.

2. INTENDED USE

The LightCycler® MRSA Advanced Test is a qualitative in vitro diagnostic test for the direct detection of nasal colonization with methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test is performed on the LightCycler® 2.0 Instrument with nasal swab specimens from patients suspected of colonization, uses swab extraction and mechanical lysis for specimen preparation followed by polymerase chain reaction (PCR) for the amplification of MRSA DNA, and fluorogenic target specific hybridization probes for the detection of the amplified DNA.

The LightCycler® MRSA Advanced Test is not intended to diagnose, guide or monitor treatment for MRSA infections. Concomitant cultures are necessary to recover organisms for epidemiology typing or for further susceptibility testing.

3. SUBSTANTIAL EQUIVALENCE

As indicated in Table 1, the RMS LightCycler® MRSA Advanced Test is substantially equivalent to those characteristics for the predicate device (BD GeneOhm MRSA assay). Both assays have the same intended use, and utilize PCR technology for amplification and detection of MRSA from nasal swabs.

Data as presented in this pre-market notification further support the substantial equivalence.

Table 1: Substantial Equivalence between LightCycler MRSA Advanced Test and Predicate Device

	LightCycler MRSA Advanced Test	**Predicate Device: BD GeneOhm MRSA**
Intended Use	Qualitative in vitro diagnostic test for the direct detection of nasal colonization with Methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings	same
Sample Type	Nasal swab	same
Sample Collection / Transport / Storage	Liquid Stuart swabs, 22 to 25°C for 6 days, 2 to 6°C for 5 days, and 1 month at -25 to -15°C. Amies Gel with charcoal swabs, Amies Gel without charcoal swabs 22 - 25°C for 4 days	Liquid Stuart swabs, 15- 30°C for 36 hours, 2-8°C for up to 5 days
Time to Result	2 hours (16 samples, whole workflow)	60 – 75 minutes (depending on number of samples)
Workflow	multiple manual steps including pipetting, fluid transfer, vortexing, centrifugation and sample heating	same
Lysis	mechanical lysis using glass beads	same
Assay Platform	LightCycler	SmartCycler
Mode of Detection	Nucleic acid amplification (DNA) utilizing real-time PCR	same
DNA Target Sequence	sequence incorporating the insertion site of the SCC*mec* in the *S. aureus orfX* gene	similar but not identical sequence

	LightCycler MRSA Advanced Test	Predicate Device: BD GeneOhm MRSA
Detection Chemistry	paired target-specific hybridization probes using fluorescence resonance energy transfer (FRET)	target-specific hybridization probes (molecular beacon technology)
Result Analysis	based on melting peak analysis	based on analysis of amplification curves
Internal Assay Controls	internal assay control to detect inhibitory specimens and to confirm integrity of reagent in negative samples	same
External Assay Controls	provided: positive control to monitor for reagent integrity	same
External Controls for Whole Workflow	available but not provided (commercial product recommended in PI)	available but not provided (commercial product recommended in PI)
Comparison Performance characteristics	Direct chromogenic culture method Positive agreement: 95.2% Negative agreement: 96.4%	Sensitivity: 92.5%* Specificity: 96.4%* *BD GeneOhm™ MRSA Package Insert using an enriched culture method

4. NON-CLINICAL PERFORMANCE EVALUATION

4.1. Analytical Sensitivity

The analytical sensitivity of the LightCycler® MRSA Advanced Test was determined using 3 strains of MRSA representing the three RE types targeted with this assay (right extremity of the SCC*mec*/*orfX* junction (RE) types 2, 3, and 7). Cultures of these strains were quantified, diluted to values spanning the range of 100 to 400 colony forming units (CFU) per swab, and absorbed onto swabs previously soaked into various transport media. All dilutions around the LOD value were tested in replicates of at least 30. Limit of detection obtained for each strain type and swab type tested represents the lowest number of CFU/swab at which a positive result will be obtained with at least 95% confidence. Results indicate that the LightCycler® MRSA Advanced Test will produce a positive results with 95% confidence for a swab containing 240 CFU.

Table 2: Detection of MRSA in various transport media

Swab Types	CFU/swab
Liquid Stuart transport media	240
Amies gel without charcoal transport media	240
Amies gel with charcoal transport media	240

4.2. Inclusivity

Performance of the LightCycler® MRSA Advanced Test for 137 well characterized MRSA isolates representative of epidemiologic clones in the U.S. is shown in Table 3. The strains were obtained through the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) Program supported under NIAID/NIH Contract No. HHSN272200700055C and from clinical sites. All strains were tested as cultures at a concentration of 10E5 cfu/mL.

All but 1 isolate tested positive with the LightCycler® MRSA Advanced Test (99.3%).

Table 3: MRSA Isolates Representative of Epidemiological Clones Obtained from the Network on Antimicrobial Resistance in Staphylococcus aureus (NARSA) Program and well Characterized Isolates from Clinical Sites

USA type	Number of isolates tested	Isolates with positive results by the LightCycler® MRSA Advanced Test
100	54*	53
200	5	5
300	37	37
400	4	4
500	7	7
600	3	3
700	4	4
800	7	7
1000	7	7
1100	4	4
Not typable/	5	5

unknown		
Total	137	136 (99.3%)

*Of the 54 type USA 100 strains tested, one strain (NRS642) was negative by the LightCycler® MRSA Advanced Test

An additional 1,643 isolates other than those listed in Table 3 were collected in Europe (65%) and in the U.S. (35%) and tested by the LightCycler® MRSA Advanced Test. Of the 1,643 isolates tested, 1,561 (95%) were correctly identified as MRSA while 82 were negative by the LightCycler® MRSA Advanced Test.

4.3. Analytical Specificity

4.3.1. Exclusivity

The specificity of the LightCycler® MRSA Advanced Test was evaluated by testing for cross reactivity to pathogenic microorganisms and to contaminants potentially present in normal nasal microflora. Tested species consisted of 13 viral, 66 bacterial and 7 fungal species as outlined in Table 4. The microorganisms were tested either as cultures in concentrations of 10E6 to 10E7 cfu/mL or as genomic DNA preparations in concentrations of 10 pg/PCR. In addition human DNA in a concentration of 5 ng/reaction was tested. Human DNA and all tested species except for one, were found negative for MRSA with the LightCycler® MRSA Advanced Test.

Table 4: Species Tested for Cross Reactivity with the LightCycler® MRSA Advanced Test

Species	
Staphylococcus aureus (MSSA)	*Haemophilus influenzae*
Staphylococcus cohnii ssp. cohnii	*Haemophilus parainfluenzae*
Staphylococcus epidermidis	Herpes simplex virus 1
Staphylococcus haemolyticus	Human DNA
Staphylococcus hominis	Influenza A (H1N1), A (H3N2)
Staphylococcus intermedius	Influenza B
Staphylococcus lugdunensis	*Issatchenkia orientalis (Candida krusei)*
Staphylococcus pseudointermedius	*Klebsiella pneumoniae ssp. ozeanae*
Staphylococcus saprophyticus	*Kocuria kristinae*
Staphylococcus schleiferi ssp. coagulans	*Kytococcus schroeteri*
Staphylococcus sciuri	*Lactobacillus delbrueckii ssp. delbrueckii*
Staphylococcus simulans	*Legionella pneumophila*
Staphylococcus warneri	*Metapneumovirus*
Staphylococcus xylosus	*Microbacterium testaceum*
Acinetobacter baumannii	*Micrococcus luteus*

Actinobacillus actinomycetemcomitans	*Moraxella catarrhalis*
Actinomyces odontolyticus	*Morganella morganii*
Adenovirus 7A	*Mycobacterium avium*
Aerococcus urinaeequi	*Mycoplasma pneumoniae*
Aspergillus fumigatus	*Mycoplasma salivarium*
Bacteroides fragilis	*Neisseria meningitidis*
Bacteroides uniformis	*Oerskovia jenensis*
Bacteroides vulgatus	Parainfluenza 1
Bordetella bronchioseptica	Parainfluenza 2
Bordetella parapertussis	Parainfluenza 3
Bordetella pertussis	*Parvimonas micra (Peptostreptococcus micros)*
Burkholderia cepacia	*Peptostreptococcus stomatis*
Candida albicans	*Peptostreptococcus anaerobius*
Candida glabrata	*Planococcus maritimus*
Candida parapsilosis	*Proteus mirabilis*
Candida tropicalis	*Proteus vulgaris*
Citrobacter freundii	*Pseudomonas putida*
Coronavirus	*Pseudomonas aeruginosa*
Corynebacterium glutamicum	Respiratory syncytial virus (RSV A, B & A2)
Corynebacterium amycolatum	Rhinovirus
Corynebacterium jeikeium	*Rhodococcus equi*
Cryptococcus neoformans	*Rothia mucilaginosa**
Eikenella corrodens	SARS
Enterococcus faecalis	*Streptococcus agalactiae*
Enterococcus faecium	*Streptococcus pneumoniae*
Enterovirus	*Streptococcus pyogenes*
Escherichia coli	*Streptococcus viridans*
Finegoldia magna (Peptostreptococcus magnus)	*Veillonella atypica*
Haemophilus aphrophilus	

** Initial test results were weakly positive. Retested eight times and all tests were negative for MRSA DNA.*

An absence of cross-reactivity was observed for 98.9% of the organisms tested

In addition, 117 isolates of methicillin-resistant coagulase negative staphylococci, 104 isolates of methicillin-sensitive coagulase negative staphylococci and 100 isolates of methicillin-sensitive *Staphylococcus aureus* obtained from different European clinical centers were tested at

concentrations of 10E4 to 10E5 cfu/reaction. All additional strains tested negative with the LightCycler® MRSA Advanced Test.

5. CLINICAL PERFORMANCE

5.1. Method Comparison

Performance characteristics of the LightCycler® MRSA Advanced Test were determined in a multi-site prospective investigational study at 5 institutions by comparing the LightCycler® MRSA Advanced Test with a second FDA-cleared nucleic acid amplification test (NAAT), direct chromogenic culture, and broth culture (the more sensitive culture method). Subjects included individuals and medical staff at risk for nasal colonization. Each subject was enrolled in the study only one time. Subjects who had received systemic or topical-nasal antibiotics used to treat nasal colonization with MRSA from the day of sample collection and up to one week prior to study enrollment, under 2 years of age, and/or had contraindication to nasal swab collection were excluded from the study. Only those subjects meeting the inclusion and exclusion criteria were enrolled.

A double-headed nasal swab was collected from each subject. One swab head was directly streaked onto a quadrant of a chromogenic agar plate with cefoxitin, and then processed according to the package insert for testing with the LightCycler® MRSA Advanced Test. The remaining quadrants of the chromogenic agar were streaked using a sterile loop. The second swab head was directly streaked onto a separate chromogenic plate with cefoxitin, and then processed for testing with the second FDA-cleared NAAT test (according to the package insert). Thereafter, the second swab head was transferred into Trypticase Soy Broth and incubated for 48 hours at 35-37°C and then subcultured onto a chromogenic plate with cefoxitin. Chromogenic culture plates were incubated at 35-37°C for 20–48 hours. Presumptive MRSA colonies from all culture plates were confirmed by coagulase testing and Gram staining if found after 44-48 hours of incubation. Each participating site performed all tests.

Performance of the LightCycler® MRSA Advanced Test and the second FDA-cleared NAAT test were calculated relative to the direct chromogenic culture, and the broth culture results. Samples

that grew MRSA on direct chromogenic culture from either swab head A and/or swab head B were considered MRSA positive unless otherwise stated.

A total of 1,620 nasal swab specimens were collected from subjects at 5 sites across the United States and tested with the LightCycler® MRSA Advanced Test. Of the 1,620 specimen tested, 1,402 specimens were eligible to be included in statistical analyses[1] The overall number of positive MRSA samples by direct chromogenic culture was 187 (13.3%).

Results obtained in nasal swabs from eligible subjects tested for MRSA using the LightCycler® MRSA Advanced Test compared to direct chromogenic culture, the 2nd FDA-cleared NAAT, and broth culture are shown in Tables 5, 6, and 7, respectively. Included in Table 5 are 1,402 evaluable specimens that had valid LightCycler® MRSA Advanced Test and direct chromogenic culture results. Included in Table 6 are 1,385 specimens with valid results for the LightCycler® MRSA Advanced Test and the second FDA-cleared NAAT test who additionally had concordant direct chromogenic culture results from swab heads A and B. Included in Table 7 are 1,395 evaluable specimens that had valid LightCycler® MRSA Advanced Test and broth culture results.

[1] 218 specimens were not evaluable for statistical analyses: 36 subjects did not meet study inclusion / exclusion criteria, 153 specimens were not tested according to the study protocol, 22 specimens were invalid due to external control failure, and 7 specimens were invalid due to internal control failures. Upon retest these 7 specimens remained invalid due to internal control failure.

Table 5: Comparison of the LightCycler® MRSA Advanced Test With Direct Chromogenic Culture

	Direct chromogenic culture		
LightCycler® MRSA Advanced Test	**Positive**	**Negative**	**Total**
Positive	178	44	222
Negative	9	1,171	1,180
Total	187	1,215	1,402
Positive Percent Agreement (95% exact CI[a])	95.2% (91.1%, 97.8%)		
Negative Percent Agreement (95% exact CI[a])		96.4% (95.2%, 97.4%)	

Note: Included in this summary table are 1,402 evaluable specimens that had valid LightCycler® MRSA Advanced Test and direct chromogenic culture results.

[a] CI = confidence interval

Of the 178 samples with positive results for the LightCycler® MRSA Advanced Test and direct chromogenic culture, the second FDA-cleared NAAT was positive for 175 samples and negative for 3 samples.

For the 44 samples that were positive for the LightCycler® MRSA Advanced Test and negative for direct chromogenic culture, the second FDA-cleared NAAT was positive for 25 samples and negative for 19 samples.

For the 9 samples that were negative for the LightCycler® MRSA Advanced Test and positive for direct chromogenic culture, the second FDA-cleared NAAT was positive for 4 samples and negative for 5 samples.

Of the 1,171 samples with negative results for the LightCycler® MRSA Advanced Test and direct chromogenic culture, the second FDA-cleared NAAT was positive for 76 samples, negative for 1,091 samples, and missing/invalid for 4 samples.

Discrepancy Analysis:

Further investigation (i.e., testing for *mecA* mediated Oxacillin resistance using cefoxitin disk diffusion methodology, *fem*- and *mec*A-specific PCR, and sequencing of SCC*mec* regions) was performed on all samples that gave discordant results between direct chromogenic culture (samples that gave concordant results in swab heads A and B only) and the LightCycler® MRSA Advanced Test LightCycler® MRSA Advanced Test or between direct chromogenic culture (samples that gave concordant results in swab A and B only) and the second FDA-cleared NAAT.

- Discrepancy analysis confirmed the presence of MRSA in 30 of 44 samples in which the LightCycler® MRSA Advanced Test gave a positive result but direct chromogenic culture was negative.
- The presence of MRSA was confirmed in 4 of 9 samples in which the LightCycler® MRSA Advanced Test gave a negative result but direct chromogenic culture was positive.
- The presence of MRSA was confirmed in 13 of 76 samples in which the second FDA-cleared NAAT gave a positive result but the LightCycler® MRSA Advanced Test and the direct chromogenic culture gave a negative result.

Table 6: Comparison of the LightCycler® MRSA Advanced Test with the Second FDA-Cleared NAAT

	The Second FDA-Cleared NAAT		
LightCycler® MRSA Advanced Test	**Positive**	**Negative**	**Total**
Positive	195	20	215
Negative	77	1,093	1,170
Total	272	1,113	1,385
Positive Percent Agreement (95% exact CI[a])	71.7% (65.9%, 77.0%)		
Negative Percent Agreement (95% exact CI[a])		98.2% (97.2%, 98.9%)	

Note: Included in this summary are 1,385 specimens with valid results for the LightCycler® MRSA Advanced Test and the second FDA-cleared NAAT test who additionally had concordant direct chromogenic culture results from swab heads A and B

[a]CI = confidence interval.

Of the 195 samples with positive results for the LightCycler® MRSA Advanced Test and the second FDA-cleared NAAT, direct chromogenic culture was positive for 171 samples and negative for 24 samples (MRSA was confirmed in 20 of these 24 samples from discrepancy analysis).

For the 20 samples that were positive for the LightCycler® MRSA Advanced Test and negative for the second FDA-cleared NAAT, direct chromogenic culture was positive for 1 sample and negative for 19 samples (MRSA was confirmed in 10 of these 19 samples from discrepancy analysis).

For the 77 samples that were negative for the LightCycler® MRSA Advanced Test and positive for the second FDA-cleared NAAT, direct chromogenic culture was positive for 1 sample and negative for 76 samples (MRSA was confirmed in 13 of these 76 samples from discrepancy analysis).

Of the 1,093 samples with negative results for the LightCycler® MRSA Advanced Test and the second FDA-cleared NAAT, direct chromogenic culture was positive for 4 samples (MRSA was confirmed in all 4 samples from discrepancy analysis) and negative for 1,089 samples.

Table 7: Comparison of the LightCycler® MRSA Advanced Test with Broth Culture

	Broth Culture		
LightCycler® MRSA Advanced Test	**Positive**	**Negative**	**Total**
Positive	184	38	222
Negative	21	1,152	1,173
Total	205	1,190	1,395
Positive Percent Agreement (95% exact CI[a])	89.8% (84.8%, 93.5%)		
Negative Percent Agreement (95% exact CI[a])		96.8% (95.6%, 97.7%)	

Note: A total of 1,395/1,402 evaluable specimens that had valid LightCycler® MRSA Advanced Test and broth culture results are included in this summary table. Broth culture results were missing/invalid for 7/1,402 evaluable specimens.

[a]CI = confidence interval.

5.2. Reproducibility

A panel of specimens with varying concentrations of MRSA and methicillin-sensitive *Staphylococcus epidermidis* (MSSE) were tested. Two operators at each of 3 sites performed one run each per day for 5 days on three reagent lots (4 specimens x 3 replicates x 5 days x 3 sites x 3 lots x 2 operators). A 12-member panel was used that was composed of specimens of Methicillin-resistant Staphylococcus aureus (MRSA) strain ATCC 43300 diluted to the concentrations shown in Table 8. Methicillin-sensitive Staphylococcus epidermidis (MSSE) ATCC strain 14990 was included in each panel member at a constant level to achieve an

appropriate sample matrix. The panel included negative member, below the LOD (20 CFU/swab expected to yield a positivity rate of between 30 to 70%), weak positive (300 CFU/swab), and positive (800 CFU/swab). The negative panel member yield negative results from a low of 99% to 100% , the below LOD panel member positivity rate range from a low of 42% to 47%, the weak positive panel member positivity rate range from a low of 99% to 100%, and the positive panel member positivity rate range from a low of 99% to 100% depending on the site.

Table 8: Summary of Reproducibility Results

MRSA CFU/swab	Sample Type	Tm Mean (°C)	Tm Standard Deviation	Tm CV (%)	Lot to Lot			Site to Site			Day to Day		
					Lot	No./No. Tested	%	Site	No./No. Tested	%	Day	No./No. Tested	%
0	Negative	n/a	n/a	n/a	1	90/90	100%	1	90/90	100%	1	53/54**	98%
					2	90/90	100%	2	89/90**	99%	2	54/54	100%
					3	89/90**	99%	3	90/90	100%	3	54/54	100%
											4	54/54	100%
											5	54/54	100%
20*	Below LOD	59.56	0.22	0.4	1	52/90	58%	1	38/90	42%	1	25/54	46%
					2	30/90	33%	2	41/90	46%	2	26/54	48%
					3	39/90	43%	3	42/90	47%	3	22/54	41%
											4	25/54	46%
											5	23/54	43%
300	Weak Positive	59.48	0.20	0.3	1	90/90	100%	1	89/90	99%	1	53/54	98%
					2	89/90	99%	2	90/90	100%	2	54/54	100%
					3	90/90	100%	3	90/90	100%	3	54/54	100%
											4	54/54	100%
											5	54/54	100%
800	Positive	59.43	0.21	0.3	1	90/90	100%	1	90/90	100%	1	53/54**	98%
					2	90/90	100%	2	89/90**	99%	2	54/54	100%
					3	89/90**	99%	3	90/90	100%	3	54/54	100%
											4	54/54	100%
											5	54/54	100%

*Note: *Concentration that produces approximately 30%–70% positive results.*

***There was an apparent transposition of one positive and one negative sample positioned adjacent to each other in the same run. Excluding these samples from the analysis results for lot to lot, site to site, and day to day reproducibility would be 100%.*

6. CONCLUSION

The results of the non-clinical analytical and clinical performance studies summarized above demonstrate that the device is as safe and as effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Larry Pietrelli
Director, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, California 94588-2722

JUL 0 6 2010

Re: K091409

Trade/Device Name:	LightCycler® MRSA Advanced Test
Regulation Number:	21 CFR §866.1640
Regulation Name:	Antimicrobial susceptibility test powder
Regulatory Class:	Class II
Product Code:	NQX,OOI
Dated:	June 11, 2010
Received:	June 14, 2010

Dear Mr. Pietrelli:

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.

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.

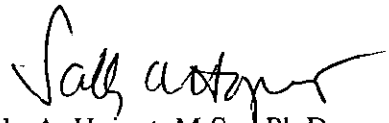
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091409

Device Name: LightCycler® MRSA Advanced Test

Indications for Use:

The LightCycler® MRSA Advanced Test is a qualitative *in vitro* diagnostic test for the direct detection of nasal colonization with methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test is performed on the LightCycler® 2.0 Instrument with nasal swab specimens from patients suspected of colonization, uses swab extraction and mechanical lysis for specimen preparation followed by polymerase chain reaction (PCR) for the amplification of MRSA DNA, and fluorogenic target specific hybridization probes for the detection of the amplified DNA.

The LightCycler® MRSA Advanced Test is not intended to diagnose, guide or monitor treatment for MRSA infections. Concomitant cultures are necessary to recover organisms for epidemiology typing or for further susceptibility testing.

Prescription Use X Part 21 CRF 801 Subpart D)	AND/OR	Over-the Counter Use (21 CRF 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE

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

Division Sign-Off

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Device Evaluation and Safety

510(k) K091409

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____