

**SPECIAL 510(k): Device Modification
OIR Decision Memorandum**

To: THE FILE

RE: DOCUMENT NUMBER K152800

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

Trade Name: *illumigene* Mycoplasma DNA Amplification Assay
510(k) number: K123423

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use.
3. A description of the device **MODIFICATION(S)**, including sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The submission includes modifications to the assay labeling that include the following:

- A. Addition of Liquid Amies (without charcoal) non-nutritive transport medium as a swab transport media for specimen collection.
- B. Removal of *Moraxella catarrhalis*, *Nocardia asteroides* and Coronavirus as potentially interfering microorganisms in the Limitation and Cross-reactivity/Microbial Interference sections of the package insert.

These labeling changes do not affect the intended use or the instructions for use. There were no modifications to the assay.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, claimed specimen types, and potentially interfering microorganisms.

SIMILARITIES

ITEM	PREDICATE DEVICE: <i>illumigene</i> Mycoplasma DNA Amplification Assay K123423	MODIFIED DEVICE
Intended Use	The <i>illumigene</i> Mycoplasma DNA amplification assay, performed on the <i>illumipro-10</i> TM , is a qualitative <i>in vitro</i> 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. The <i>illumigene</i> Mycoplasma assay utilizes loop- mediated isothermal DNA amplification (LAMP) technology to	Same

	<p>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> <p><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.</p>	
Technology	Loop-mediated amplification (LAMP) technology	Same
Sample Types	Human throat and nasopharyngeal swabs	Same
Target	DNA sequence of the <i>Mycoplasma pneumoniae</i> genome	Same

DIFFERENCES

ITEM	PREDICATE DEVICE: <i>illumigene</i> Mycoplasma DNA Amplification Assay K123423	MODIFIED DEVICE
Claimed Transport Media	0.85% Saline, M4, M4-RT, M5, or UTM-RT	Same, with the addition of Liquid Amies (without charcoal) non-nutritive transport media for specimen collection
Labeling Limitation Pertaining to	Labeling includes the following limitation: "There is potential for a false negative result in the presence of high	Limitation removed

Microbial Interference	concentrations of <i>Moraxella catarrhalis</i> , <i>Nocardia asteroides</i> , or Coronavirus. For these three organisms, a false negative result was observed in only one of seven replicates with samples tested near the Limit of Detection during initial testing that were not confirmed with further testing.”	
Labeling/ Crossreactivity/ Microbial Interference Study Section	Labeling includes the following statement regarding potential microbial interference: “ <i>Moraxella catarrhalis</i> , <i>Nocardia asteroides</i> and Coronavirus produced unexpected results during initial testing that were not confirmed with further testing. For each organism, false-negative results occurred in one of seven replicates tested near the Limit of Detection.”	The statement regarding potential microbial interference is removed from the labeling. <i>Moraxella catarrhalis</i> , <i>Nocardia asteroides</i> and Coronavirus are added to the list of organisms determined to not crossreact or interfere with the <i>illumigene</i> Mycoplasma assay.

5. A **Design Control Activities Summary** which includes:

- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

A description of the Risk Analysis Method, the potential impact of the modification to the device and the results of the analysis were provided. Based on the risk analysis, the following analytical validation studies were performed to substantiate the labeling changes.

- Limit of Detection and Specimen Stability studies were conducted to support the use of Liquid Amies (without charcoal) transport media for swab specimens tested with the *illumigene* Mycoplasma DNA Amplification assay.
- An analytical study was conducted to demonstrate that high concentrations of *Moraxella catarrhalis*, *Nocardia asteroides* and Coronavirus do not negatively affect device performance.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter’s description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.