

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

K093383

**B. Purpose for Submission:**

Clearance of bioMérieux's NucliSENS EasyQ System

**C. Manufacturer and Instrument Name:**

bioMérieux's NucliSENS EasyQ System. The primary instrument is bioMérieux's NucliSENS EasyQ Analyzer with Director software.

**D. Type of Test or Tests Performed:**

Real-Time PCR; see K063261 for more details on Enterovirus analyte.

**E. System Descriptions:**

1. Device Description:

The *NucliSENS EasyQ* Analyzer is the primary component of the *NucliSENS EasyQ System*. This system was used in K063261, the original *NucliSENS EasyQ® Enterovirus v1.1*, 510(k) submission. The instrumentation and software components of that system as currently configured are:

Instrumentation:

- *NucliSENS EasyQ* Analyzer
- *NucliSENS miniMAG*
- *NucliSENS EasyQ* Incubator II (updated from version I)

Software:

- *NucliSENS EasyQ Director 2.6* (updated from 2.5)
- *NucliSENS EasyQ Assay Protocol*

2. Principles of Operation:

**Sample Processing:** This step uses the NucliSENS miniMAG, a stand-alone device for semiautomated nucleic extraction. During sample processing, viral particles are lysed and the RNA is captured onto magnetic silica particles. The silica is washed to remove contaminants and the RNA is eluted. The eluted RNA is pipetted into a reaction vessel along with the amplification/detection reagents.

Sample preparation utilizes equipment and reagents that are components of the general NucliSens platform. Specifically, the specimen is lysed in NucliSens lysis buffer (containing guanidinium isothiocyanate) to release the RNA. IC RNA from e.g., the EasyQ Enterovirus kit is then added to the lysed sample. The NucliSens magnetic extraction reagents and equipment are then used to capture total RNA on magnetic silica particles. Unwanted specimen components are removed by washing. Purified and concentrated RNA is eluted.

Real-time Amplification/Detection: Eluted RNA and amplification reagents are added to the amplification reaction vessels (organized in 8-well strip units up to a total of 96 samples). After a brief denaturation step in the NucliSens EasyQ incubator II, the target RNAs are amplified in the NucliSens EasyQ Analyzer. The user interfaces with the Analyzer through the NucliSens EasyQ Director software which controls the Analyzer. The Director software is loaded on the EasyQ Computer which is connected to the Analyzer; the computer system includes a monitor, printer, keyboard and mouse as peripheral devices.

The Analyzer performs an isothermal amplification reaction and detects amplified RNA in real time through the use of two differentially labeled molecular beacons (one for the target, one for an internal control sequence). Upon binding to their target, each beacon produces a fluorescent signal used to detect the amplified RNA or DNA.

The NucliSENS EasyQ analyzer is dedicated to read fluorescence from reaction tubes in a controlled environment. The analyzer contains a plate carrier that keeps the samples at the required temperature for the assay. The reader uses an optical system, based on direct and focused illumination to prevent cross talk and give accurate readings. Filters control the wavelength of the illumination for both excitation and emission of the molecular beacon used in the assay. Filters are automatically selected by the assay protocol. The system uses different filters to measure particular labels (dyes).

Once a tray of sample tubes has been loaded into the NucliSENS EasyQ analyzer, the analyzer moves the first tube into position over the light source. The analyzer then directs the light source upward through the bottom of the sample tube. The light causes the molecular beacons to emit light. Through the use of a mirror, the emitted light is directed through an optical filter to a photo multiplier tube where the fluorescence reading is taken. The next sample is then moved into position and the process is repeated. The intensity of the emitted light is measured for each sample.

Director software receives fluorescence readings from the Analyzer and executes the calculation engine that is part of the assay protocol software. The EasyQ Enterovirus v1.1 Assay Protocol software receives the reaction data and uses a validated algorithm to interpret the kinetics and intensity of fluorescence signals which result from each amplification reaction. After interpretation by the assay

protocol software, results for each test are reported back to Director as one of 3 possible reaction outcomes: positive, negative, or invalid. Director does not have any knowledge of the actual calculation. Director then presents the qualitative result to the user by printing, on screen and by export file.

3. Modes of Operation:

Batch or Random access through tube strip (Analyzer)

4. Specimen Identification:

Entered by user (Analyzer)

5. Specimen Sampling and Handling:

Specimens are processed according to assay instructions.

6. Calibration:

The analyzer contains an autocalibration function that reads the fluorescence from the reference materials on the plate carrier. The reading is compared to the value in the system memory. The measured value can differ from the memory value.

7. Quality Control:

Quality control is addressed for each separately cleared specific assay to be run on the instrument.

8. Software:

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

Yes  or No

**F. Regulatory Information:**

1. Regulation section:

862.2570 Instrumentation for clinical multiplex test systems

2. Classification:

Class II

3. Product code:

OOI (Real Time Nucleic Acid Amplification System) for NucliSENS EasyQ Analyzer

JJH (Clinical Sample Concentrator) for NucliSENS miniMAG

JTQ (Bath, Incubators/Water, All) for NucliSENS EasyQ Incubator II

4. Panel:

Clinical Chemistry (75)

**G. Intended Use:**

1. Indication(s) for Use:

NucliSENS EasyQ Analyzer and NucliSENS EasyQ Director 2.6 Software

*In vitro* diagnostic medical device.

The *NucliSENS EasyQ Analyzer* and the accompanying *NucliSENS EasyQ Director* software are intended for *in vitro* diagnostic use in conjunction with FDA-cleared or approved *NucliSENS* assay protocols. The user shall be a properly trained laboratory technician familiar with performing nucleic acid assays. The analyzer is intended to measure fluorescent readings from molecular beacon probes binding to amplified RNA or DNA in samples containing *NucliSENS EasyQ* assay reagents while controlling the temperature of the samples. The *NucliSENS EasyQ Director* software is intended to control instrument operations and organize the assays to be performed. In addition, the software is intended to automatically calculate results for each test request based on raw measurement data, the data reduction algorithm specified for the assay, and the batch parameters of the reagents used for the test.

2. Special Conditions for Use Statement(s):

Prescription use only

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the SDS Software version 1.4 (K082562)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Multiplex Capable	Able to measure and sort multiple signals generated by an assay from a clinical sample	Able to measure and sort multiple signals generated by an assay from a clinical sample

Differences		
Item	Device	Predicate
Technology	Real-Time NASBA (nucleic acid based sequence amplification)	Real-Time PCR (polymerase chain reaction)
Indications for Use	<p>The NucliSENS EasyQ Analyzer and the accompanying NucliSENS EasyQ Director software are intended for in vitro diagnostic use in conjunction with FDA cleared NucliSENS assay protocols. The user shall be a properly trained laboratory technician familiar with performing nucleic acid assays.</p> <p>The analyzer is intended to measure fluorescent readings from molecular beacon probes binding to amplified RNA or DNA in samples containing NucliSENS EasyQ assay reagents while controlling the temperature of the samples.</p> <p>The NucliSENS EasyQ Director software is intended to control instrument operations and organize the assays to be performed. In addition, the software is intended to automatically calculate results for each test request based on raw measurement data, the data reduction algorithm specified for the assay, and the batch parameters of the reagents used for the test.</p>	<p>The Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the SDS Software version 1.4 is a real-time nucleic acid amplification and detection system that measures nucleic acid signals from reverse transcribed RNA and converts them to comparative quantitative readouts using fluorescent detection of dual-labeled hydrolysis probes. The 7500 Fast Dx is to be used only by technologists trained in laboratory techniques, procedures and on use of the analyzer.</p>

**I. Special Control/Guidance Document Referenced (if applicable):**

Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077819.htm>

## **J. Performance Characteristics:**

All assay analytical and clinical testing was reviewed in K063261. This submission is linked to the assay data presented there.

### 1. Analytical Performance:

#### *a. Accuracy:*

Accuracy was assessed during the clearance of the assay (K063261) and will be addressed for each assay to be run on this system.

#### *b. Precision/Reproducibility:*

Precision/Reproducibility was assessed during the clearance of the assay (K063261) and will be addressed for each assay to be run on this system.

#### *c. Linearity:*

N/A since the Enterovirus assay is not quantitative.

#### *d. Carryover:*

Carryover was assessed during the clearance of the assay (K063261) and will be addressed for each assay to be run on this system.

#### *e. Interfering Substances:*

Interfering Substances were assessed during the clearance of the assay (K063261) and will be addressed for each assay to be run on this system.

### 2. Other Supportive Instrument Performance Data Not Covered Above:

## **K. Proposed Labeling:**

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

## **L. Conclusion:**

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