Grifols Diagnostic Solutions Inc.
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5.0 510(K) SUMMARY

510(k) Owner's Name	Grifols Diagnostic Solutions Inc.
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510(k) Summary Preparation Date	18JUL22

5.1 Device Identification

Trade Name	Procleix® WNV/Babesia Quality Control
Common Name	N/A
Classification Name	Assayed External Control Material For Microbiology Nucleic Acid Amplification (Nat) Assays (21CFR 866.3920, Product Code QTM)

5.2 Device Substantial Equivalence

Predicate Trade Name	BioFire RP2.1/RP2.1*plus* Control Panel M441
Predicate Common Name	BioFire RP2.1/RP2.1plus Control
Predicate Classification Name	Assayed External Control Material For Microbiology Nucleic Acid Amplification (Nat) Assays (21CFR 866.3920, Product Code PMN)
Predicate 510(k) Number	K202196

5.3 Device Description

The Procleix WNV/Babesia Quality Control is designed to assist in the monitoring of assay performance by providing an independent reference standard. Frequent testing of independent quality control samples provides a means of monitoring the performance of laboratory assays. Routine use of controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic errors.

Table 5-1. WNV/Babesia Quality Control Reagents

Each Procleix WNV/Babesia Quality Control is available individually. Store at -15° to -35°C		
Reagent Name	**Number of vials/ Volume per vial**	**Part Number**
Procleix WNV Positive Quality Control *A HEPES buffered solution containing detergent and a WNV RNA transcript.*	30 x 1 mL	9052693
Procleix Babesia Positive Quality Control *A HEPES buffered solution containing detergent and a Babesia RNA transcript.*	30 x 1 mL	9052692
Procleix WNV/Babesia Negative Quality Control *A HEPES buffered solution containing detergent.*	30 x 1 mL	9052691

5.4 Device Intended Use

Procleix WNV/Babesia Quality Control, a set of quality controls, is intended for use as an external assayed quality control material to monitor the performance of the qualitative detection of RNA from Babesia *microti* and West Nile Virus (WNV) with the Procleix Babesia Assay and Procleix WNV Assay respectively performed on the Procleix Panther System. This product is intended to be used solely with the Procleix Babesia Assay or Procleix WNV Assay, licensed donor screening assays performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device.

5.5 Comparison with Predicate Device

Table 5-2. General Device Characteristic Similarities

	Subject Device: Procleix® WNV/Babesia Quality Control	**Predicate Device: K202196** BioFire RP2.1/RP2.1*plus* Control Panel M441
Intended Use	Same: External quality control to measure performance of *in vitro* nucleic acid procedures for the qualitative detection of specific RNA. Procleix WNV/Babesia Quality Control, a set of quality controls, is intended for use as an external assayed quality control material to monitor the performance of the qualitative detection of RNA from Babesia *microti* and West Nile Virus (WNV) with the Procleix Babesia Assay and Procleix WNV Assay respectively performed on the Procleix Panther System. This product is intended to be used solely with the Procleix Babesia Assay or Procleix WNV Assay, licensed donor screening assays performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device.	BioFire RP2.1/RP2.1*plus* Control Panel M441 is intended for use as an external positive and negative assayed quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1- 2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* on the BioFire Respiratory Panel 2.1 (RP2.1) and BioFire Respiratory Panel 2.1*plus* (RP2.1*plus*) assays performed on the BioFire FilmArray 2.0 and Torch systems. BioFire RP2.1/RP2.1*plus* Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BioFire RP2.1 assay and BioFire RP2.1*plus* assay. This product is not intended to replace manufacturer internal controls provided with the device
Storage (unopened)	Same: -35° to -15°C Single-use only; discard after use.	-25° to -15°C Single-use only; discard after use.

	Subject Device: Procleix® WNV/Babesia Quality Control	**Predicate Device: K202196** BioFire RP2.1/RP2.1*plus* Control Panel M441
Physical Format	Same: Colorless liquid 3 vials, 1 mL each: • 2 vials of positive control • 1 vial of negative control	Colorless liquid 12 single use tubes, 300µL each: • 6 tubes of BioFire RP2.1/RP2.1*plus* Positive • 6 tubes of BioFire RP2.1/RP2.1*plus* Negative
Composition	Same: Synthetic RNA transcripts • Procleix WNV Positive Quality Control: A HEPES buffered solution containing detergent and a WNV RNA transcript • Procleix Babesia Positive Quality Control: A HEPES buffered solution containing detergent and a Babesia RNA transcript • Procleix WNV/Babesia Negative Quality Control: A HEPES buffered solution containing detergent	Synthetic RNA transcripts • BioFire RP2.1/RP2.1*plus* Positive control: Synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. • BioFire RP2.1/RP2.1*plus* Negative control: Buffers and preservatives
Directions for Use	Same: Process as sample	Process like patient sample
Assay Steps Monitored	Reverse transcription, amplification, detection	Reverse transcription, amplification, detection, identification
Number of Targets Monitored	Same	Multiple
Energy Source	Same	N/A

Table 5-3. General Device Characteristic Differences

	Subject Device: Procleix® WNV/Babesia Quality Control	**Predicate Device: K202196** BioFire RP2.1/RP2.1*plus* Control Panel M441
Test System	Procleix Panther System	BioFire RP2.1 assay and BioFire RP2.1*plus* assay
Assay Target Analyte	Babesia species (*B. microti, B. duncani, B. divergens,* and *B. venatorum*) and West Nile Virus	Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1- 2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*

5.6 Conclusion

The Procleix WNV/Babesia Quality Control are *in vitro* transcript-based quality control reagents used to monitor the performance of *in vitro* nucleic acid procedures for the qualitative detection of WNV and Babesia. It is comprised of single use vials that have an expiration date of 24 months when stored at -35ºC to -15ºC.

The Procleix WNV/Babesia Quality Control demonstrates substantial equivalence to BioFire RP2.1/RP2.1*plus* Control Panel M441 as they are derived from similar technology, are comparably composed, and share an intended use. The differences between the Procleix WNV/Babesia Quality Control and the predicate device are due to the individual product platform and do not impact safety or effectiveness.