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Grifols Diagnostic Solutions Inc.
10808 Willow Court. San Diego, CA 92127

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21CFR 807.92.

510(k) Owner's Name	Grifols Diagnostic Solutions Inc.
Company Address	10808 Willow Court. San Diego, CA 92127
Phone Numbers	(b) (6)

Device

Trade Name	Procleix® WNV/Babesia Quality Control
Common Name	N/A
Classification Name	Assayed quality control material for clinical microbiology assays
Regulation Number	21CFR 866.3920
Product Code(s)	SDM, QTM
Establishment Registration	3003460312

Predicate Device

Predicate Trade Name	Procleix® WNV/Babesia Quality Control
Predicate Common Name	N/A
Predicate Classification Name	Assayed quality control material for clinical microbiology assays
Regulation Number	21CFR 866.3920
Product Code(s)	QTM
Predicate 510(k) Number	BK220746

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1. Device Description

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* with the Procleix Babesia Assay and RNA from West Nile Virus (WNV), with the Procleix WNV Assay and Procleix UltrioPlex W Assay, performed on the Procleix Panther System. 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. The Procleix WNV/Babesia Quality Control consists of one (1) negative and two (2) positive controls. Each of the components is a filled individual vial with volume of 1.3 mL of material, packaged and sold separately.

2. Intended Use/Indications for 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* with the Procleix Babesia Assay and RNA from West Nile Virus (WNV), with the Procleix WNV Assay and Procleix UltrioPlex W Assay. This product is intended to be used solely with the Procleix Babesia Assay, Procleix WNV Assay, and Procleix UltrioPlex W Assay, licensed donor screening assays, performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device.

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3. Comparison with Predicate Device

Grifols Diagnostic Solutions is claiming Procleix WNV/Babesia Quality Control (BK220746) as the predicate. The tables below compare the similarities and differences between the subject and predicate devices.

Table 1. General Device Characteristic Similarities

	Subject Device: Procleix® WNV/Babesia Quality Control	**Predicate Device: BK220746** Procleix® WNV/Babesia Quality Control
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* with the Procleix Babesia Assay, and West Nile Virus (WNV), with the Procleix WNV Assay and Procleix UltrioPlex W Assay. This product is intended to be used solely with the Procleix Babesia Assay, Procleix WNV Assay, and Procleix UltrioPlex W Assay, licensed donor screening assays, performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device.	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.
Test System	Procleix Panther System	Same
Storage (unopened)	-15° to -35°C Single use only; discard after use.	Same
Physical Format	Colorless liquid 3 vials, 1 mL each: • 2 vials of positive control • 1 vial of negative control	Same
Composition	Synthetic RNA transcripts	

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	Subject Device: Procleix® WNV/Babesia Quality Control	**Predicate Device: BK220746** Procleix® WNV/Babesia Quality Control
	• 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	Same
Directions for Use	Process as sample	Same
Assay Steps Monitored	Reverse transcription, amplification, detection	Same
Number of Targets Monitored	Multiple	Same
Assay Target Analyte	*Babesia* species (*B. microti, B. duncani, B. divergens,* and *B. venatorum*) and West Nile Virus	Same

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Table 2. General Device Characteristic Differences

	Subject Device: Procleix® WNV/Babesia Quality Control	**Predicate Device: BK220746 Procleix® WNV/Babesia Quality Control**
Licensed Donor Screening Assays Intended	Procleix Babesia Assay, Procleix WNV Assay, and Procleix UltrioPlex W Assay	Procleix Babesia Assay and Procleix WNV Assay

4. NON-CLINICAL PERFORMANCE EVALUATION

A summary of nonclinical performance testing associated with the Procleix WNV/ Babesia Quality Control is as follows:

4.1. Reproducibility

A five-day reproducibility study was performed using two Procleix Quality Control (PQC) lots with three independently manufactured Procleix UltrioPlex assay (UPW) reagent lots on two Procleix Panther instruments, which resulted in 240 replicates for each target. One operator performed all 30 runs. The data obtained were analyzed for the components of Signal to cutoff (S/CO) variation between days, between PQC lots, between UPW reagent lots, between Panther instruments, between run, within run and overall variability.
As shown in Table 3a and 3b below, the results demonstrated a low variability in S/CO as evidenced by a % coefficient of variation (CV) of less than 10%. The IC/WNV %CV for HIV/HCV/HBV negative control and WNV negative control is 11%, however, it is below the cutoff for the reactivity (S/CO $\geq$ 1.0).

Table 3a. Repeatability of the PQC tested with UPW on the Procleix Panther instrument

Target	N	Mean S/CO (95% CI)	Repeatability SD	Repeatability %CV
HIV-1 [1]	240	0.22 (0.21-0.22)	0.04	17%
HCV [1]	240	0.25 (0.24-0.25)	0.04	14%
HBV [1]	240	0.18 (0.17-0.18)	0.03	18%
HIV/HCV/ HBV Negative [2]	241	0.27 (0.27-0.28)	0.03	11%
WNV	240	3.76 (3.73-3.79)	0.25	7%
WNV Negative	240	0.27 (0.27-0.27)	0.03	11%

SD = Standard Deviation, CI = Confidence Interval; %CV = percent Coefficient of Variation.
[1] The UPW is a dual kinetic assay and both channels namely, HIV/HCV/HBV and internal control (IC)/WNV are simultaneously reported. The IC/WNV channel reports the target signal detected for WNV positive analyte and the IC signal in a negative sample when tested with Procleix WNV/Babesia Quality Control. The IC/WNV signal in a HIV, HCV, or HBV positive samples is the IC signal.

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[2] One extra replicate was erroneously tested

Table 3b. Reproducibility of PQC tested with UPW on the Procleix Panther instrument

Target	Mean S/CO	Btw - Run SD	Btw - Run %CV	Btw Day SD	Btw Day %CV	Btw UPW-Lot SD	Btw UPW-Lot %CV	Btw PQC-Lot SD	Btw PQC-Lot %CV	Within-Run SD	Within-Run %CV
HIV-1[1]	0.22	0.02	12%	0.01	4%	0.01	7%	0.00	0%	0.02	10%
HCV[1]	0.25	0.01	4%	0.00[2]	2%	0.01	3%	0.00	0%	0.03	13%
HBV[1]	0.18	0.01	6%	0.01	4%	0.02	11%	0.00	0%	0.02	12%
HIV/ HCV/ HBV Negative	0.27	0.01	3%	0.01	2%	0.01	4%	0.00	0%	0.02	9%
WNV	3.76	0.13	4%	0.05	1%	0.03	1%	0.02	1%	0.19	5%
WNV Negative	0.27	0.01	4%	0.00	1%	0.01	5%	0.00	0%	0.03	9%

Btw = Between; SD = Standard Deviation, CI = Confidence Interval, N/A = Not applicable
[1] The UPW is a dual kinetic assay and both channels namely, HIV/HCV/HBV and internal control (IC)/WNV are simultaneously reported. The IC/WNV channel reports the target signal detected for WNV positive analyte and the IC signal in a negative sample when tested with Procleix WNV/Babesia Quality Control. The IC/WNV signal in a HIV, HCV, or HBV positive samples is the IC signal.
[2] The non-negative SDs were rounded to 0.00.

5. 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*. The new Procleix WNV/Babesia Quality Control has the same technology, similar intended use and the data presented demonstrate that the device is as safe, as effective, and performs as well as the predicate device.