

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
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Device

Trade Name	Procleix [®] Plasmodium Quality Control
Common Name	N/A
Classification Name	Assayed Quality Control Material for Clinical Microbiology Assays
Regulation Number	21CFR 866.3920
Product Code	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	QTM
Predicate 510(k) Number	BK220746

1. Device Description

The single-use Procleix Plasmodium Quality Control is intended for use as an external assayed quality control material to monitor the performance of the qualitative detection of RNA from *Plasmodium falciparum* with the Procleix Plasmodium Assay performed on the Procleix Panther System. The Procleix Plasmodium Quality Control is designed to assist in monitoring of assay performance by providing an independent reference standard. 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 Plasmodium Quality Control consists of one negative and one positive control. Each of the component is a filled individual vial with volume of 1.2 mL of material, packaged and sold separately.

2. Intended Use/Indications for Use

Procleix[®] Plasmodium 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 *Plasmodium falciparum* with the Procleix Plasmodium Assay. This product is intended to be used solely with the Procleix Plasmodium Assay, a licensed donor screening assay performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device.

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 [®] Plasmodium Quality Control	Predicate Device: BK220746 Procleix [®] WNV/Babesia Quality Control
Intended Use	Procleix [®] Plasmodium 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 <i>Plasmodium falciparum</i> with the Procleix Plasmodium Assay. This product is intended to be used solely with the Procleix Plasmodium Assay, a licensed donor screening assay, 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 <i>Babesia microti</i> 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)	24 months at -15° to -35°C Single-use only; discard after use.	Same
Directions for Use	Process as a sample	Same

	Subject Device: Procleix® Plasmodium Quality Control	Predicate Device: BK220746 Procleix® WNV/Babesia Quality Control
Assay Steps Monitored	Reverse transcription, amplification, detection	Same

Table 2. General Device Characteristic Differences

	Subject Device: Procleix® Plasmodium Quality Control	Predicate Device: BK220746 Procleix® WNV/Babesia Quality Control
Physical Format	Colorless liquid 2 vials, 1.2 mL each: <ul style="list-style-type: none"> • 1 vial of positive control • 1 vial of negative control 	Colorless liquid 3 vials, 1.0 mL each: <ul style="list-style-type: none"> • 2 vials of positive control • 1 vial of negative control
Composition	<ul style="list-style-type: none"> • <u>Procleix Plasmodium Positive Quality Control</u>: A HEPES buffered solution containing detergent and RNA transcript • <u>Procleix Plasmodium Negative Quality Control</u>: A HEPES buffered solution containing detergent 	<ul style="list-style-type: none"> • <u>Procleix WNV Positive Quality Control</u>: A HEPES buffered solution containing detergent and a WNV RNA transcript • <u>Procleix Babesia Positive Quality Control</u>: A HEPES buffered solution containing detergent and a Babesia RNA transcript • <u>Procleix WNV/Babesia Negative Quality Control</u>: A HEPES buffered solution containing detergent
Number of Targets Monitored	One	Multiple
Assay Target Analyte	<i>Plasmodium falciparum</i>	<i>Babesia</i> species (<i>B. microti</i> , <i>B. duncani</i> , <i>B. divergens</i> , and <i>B. venatorum</i>) and West Nile Virus
Licensed Donor Screening Assays	Procleix Plasmodium Assay	Procleix Babesia Assay and Procleix WNV Assay

4. NON-CLINICAL PERFORMANCE EVALUATION

A summary of nonclinical performance testing associated with the Procleix Plasmodium Quality Controls is as follows:

4.1. Reproducibility

Two studies were performed to evaluate the reproducibility of the Procleix Plasmodium Positive and Negative Quality Controls (PQCs). The first reproducibility study was a multisite study using two independent reagent lots of the Procleix Plasmodium Assay with two unique lots of the PQCs. Testing was conducted by two operators each at three sites using three replicates for twelve days for a total of 216 tests for each PQC. The data obtained were analyzed for the components of Signal to cutoff (S/CO) variation between-run, within-run, between-days, between-instruments, and between operators. The second reproducibility study was a single site study to demonstrate the lot-to-lot reproducibility of the Positive and Negative PQCs. This study was performed using three additional independent reagent lots of the Procleix Plasmodium Assay with three unique lots of the PQCs. Testing was conducted by two operators using three replicates for six days for a total of 108 tests for each PQC. As shown in Tables 3 and 4, the results demonstrated a low variability in S/CO for the Plasmodium Positive Control, as evidenced by a % coefficient of variation (CV) of less than 10%. For the Plasmodium Negative Control, the S/CO values were < 0.02, the %CV values observed appear artificially high due to the low analyte S/CO values observed.

Table 3. Reproducibility of Procleix Plasmodium Quality Controls tested with Procleix Plasmodium Assay

Panel	Mean S/CO	Between-Run SD	Between-Run %CV	Within Run SD	Within Run %CV	Between-Days SD	Between-Days %CV	Between-Instruments SD	Between-Instruments %CV	Between-Operators SD	Between-Operators %CV	Total SD	Total %CV
Plasmodium Negative Control	0.02	0.01	30.57	0.02	112.48	0.00	0.00	0.03	168.16	0.00	0.00	0.03	204.61
Plasmodium Positive Control	12.27	0.00	0.00	0.42	3.39	0.00	0.00	0.38	3.06	0.00	0.00	0.56	4.57

S/CO = Signal to cutoff; SD = Standard Deviation (SD reported as 0 due to rounding of a low non-zero value); CV = Coefficient of variation

Table 4. Lot-to-Lot reproducibility of Procleix Plasmodium Quality Controls tested with Procleix Plasmodium Assay on the Procleix Panther Instrument

Panel	Mean S/CO	Within Run SD	Within Run %CV	Between-Days SD	Between-Days %CV	Between-Operators SD	Between-Operators %CV	Between-Lots SD	Between-Lots %CV	Total SD	Total %CV
Plasmodium Negative Control	0.00	0.01	537.47	0.00	0.00	0.00	0.00	0.00	0.00	0.01	537.47
Plasmodium Positive Control	12.46	0.39	3.16	0.00	0.00	0.00	0.00	0.00	0.00	0.39	3.16

S/CO = Signal to cutoff; SD = Standard Deviation (SD reported as 0 due to rounding of a low non-zero value); CV = Coefficient of variation

5.0 Conclusion

The Procleix Plasmodium 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 RNA from *Plasmodium falciparum* with the Procleix Plasmodium Assay. It is comprised of single use vials that have an expiration date of 24 months when stored at -15°C to -35°C. The new Procleix Plasmodium Quality Control has the same technology, similar intended use, and the data presented demonstrates that the device is as safe, as effective, and performs as well as the predicate device.