510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k142821

B. Purpose for Submission:
New device

C. Measurand:
Not applicable- blood collection tube

D. Type of Test:
Not applicable

E. Applicant:
PreAnalytiX GmbH

F. Proprietary and Established Names:
PAXgene Blood DNA Tube

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1675, Blood Specimen Collection Device

2. Classification:
   Class II

3. Product code:
   PJE, Blood/Plasma collection device for DNA testing

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indication(s) for use below

2. Indication(s) for use:
   The PAXgene Blood DNA Tube is intended to collect, anticoagulate, stabilize, transport, and store a venous whole blood sample for preparation of human DNA for use with molecular diagnostic test methods that require DNA.

The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.

3. Special conditions for use statement(s):
   - For prescription use only
   - For *in vitro* diagnostic use
   - The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.
   - The PAXgene Blood DNA Tube is not intended for blood donor screening.
   - The PAXgene Blood DNA Tube has not been validated for the following technologies or samples: next generation sequencing, cytogenetic arrays, FISH assays, somatic mutations such as might be tested for hematological oncology purposes.
   - Endotoxin not controlled. Blood and Blood components collected and processed in the tube are not intended for infusion or introduction into the human body.
   - The PAXgene Blood DNA Tube has not been validated for the collection, stabilization, storage or extraction of microbial DNA from human whole blood samples, and has not been cleared or approved for laboratory tests that detect microbial nucleic acids.
   - The PAXgene Blood DNA Tube has not been validated with DNA extraction methods involving manual precipitation.

4. Special instrument requirements:
   Not applicable

I. Device Description:

The PAXgene Blood DNA Tube is a sterile, single use, plastic, evacuated 13 × 75 mm blood collection tube with a Hemogard closure assembly and a measured quantity of K2EDTA additive. The additive quantity dispensed into each tube is designed to match the nominal blood draw volume of 2.5 mL. The tube is made of polyethylene terephthalate (PET) plastic, which functions to maintain vacuum within the tube. The tube has a unique, 2D barcode on each tube for specimen identification.

J. Substantial Equivalence Information:

Predicate device name	510(k) number
BD Vacutainer Plus EDTA Blood Collection Tube	k972075

Comparison with predicate:

Similarities and differences		
Item	Candidate Device PAXgene Blood DNA Tube	Predicate Device BD Vacutainer Plus EDTA Blood Collection Tube (k972075)
Intended Use	Intended for the collection, anticoagulation, transport and storage of a venous blood sample	Same
Design/Function	Evacuated blood collection tube	Same
Anticoagulant	K_2EDTA	Same
Tube material	Polyethylene terephthalate (PET)	Same
Closure	BD Hemogard™ closure consisting of a rubber stopper plus BD Hemogard™ shield	Same
Tube stopper Lubricant	Silicone	Same
Tube sterility	Sterile	Same
Sterilization method	Gamma irradiation	Same
Injection Molding (Tube/Hemogard Closure)	Injection molded	Same
Shelf Life	12 months	Same
Interior Coating	Spray coated/Dried	Same
Evacuation	Vacuum chamber	Same
Anticoagulant amount	>5.4 mg	5.4 mg
Tube size	13 mm x 75 mm	13 mm x 100 mm / 16 mm x 100
Nominal Blood Draw Volume	2.5 mL	5.0 mL/8.5 mL

K. Standard/Guidance Document Referenced (if applicable):

- ISO 11137-1 First edition 2006-04-15: Sterilization of Health Care Products – Radiation –Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. Amendment 1 (2013).
- ISO 11137-2:2013: Sterilization of Health Care Products - Radiation - Part 2: establishing the sterilization dose.

- CLSI GP34-A, Validation and verification of tubes for venous and capillary blood specimen collection; approved guidance.
- CLSI GP39-A6 (Formerly H01-A6), Tubes and additives for venous blood specimen collection; approved standard-sixth edition.
- CLSI MM13-A, collection, transport, preparation, and storage of specimens for molecular methods; approved guideline.

L. Test Principle:

The PAXgene Blood DNA Tube is intended to be placed inside a tube holder or an adaptor that contains a needle designed to pierce the tube closure and allow blood to flow into the tube. Once the vein has been penetrated (using a standard blood collection needle or a blood collection set), the tube is pushed into the holder, and the blood enters the tube. Once a tube has drawn the appropriate amount of blood, it is disengaged from the holder and inverted 8-10 times to mix the additive with the blood.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Reproducibility:
   A multi-site study was conducted to evaluate the performance of the PAXgene Blood DNA Tube. DNA was isolated and purified from whole blood aliquots using commercially available, automated, silica membrane based DNA isolation kits. 126 subjects were enrolled in the study at the collection site to provide samples for one or more of the assays below. Of the 126 subjects enrolled, 6 were withdrawn due to incomplete or no blood draw. Three lots of candidate tubes were used in this study.

   All subjects participating in the study were tested with a commercially available, FDA cleared Cystic Fibrosis assay and a commercially available, FDA cleared SSO HLA Typing assay. Subjects with viable blood draws numbered 41 through 120 were additionally tested with a commercially available, FDA cleared Thrombophilia Risk assay.

   Site-to-Site Reproducibility:
   Data from 20 subjects with three candidate tubes from the same lot per subject were evaluated for site-to-site reproducibility across three sites (1 candidate tube for each site). For each assay, either a Cystic Fibrosis assay or a SSO HLA assay, if one subject had the same genetic markers detected with tubes tested at all three sites the subject was designated concordant. Otherwise, the subject was designated discordant. The results are summarized below:

Sites	Assay	Samples Tested	Correct calls	Incorrect calls	No-calls	% Correct	95% CI lower bound
A,B,C	CF Assay	20	20	0	0	100%	N/A
A,B,C	SSO* HLA Assay	20	20	0	0	100%	N/A

*For all SSO HLA assay results across all reproducibility studies, in addition to the two-field concordance presented in the 3 tables, probe hit patterns were analyzed and a total of 7 probes out of 14,400 (200 comparisons × 72 probes) were found to be discordant. The overall probe concordance was 99.95% with a 95% CI lower bound of 99.9%.

Lot-to-Lot Variation:
Data from 20 subjects with three candidate tubes per subject (1 tube from each lot) were evaluated for lot-to-lot variation at one site. For each assay, Cystic Fibrosis Assay or SSO HLA assay and for each subject, if the same genotyping results were obtained from specimens collected in candidate tubes from all 3 lots, the subject was designated as concordant. Otherwise, the subject was designated discordant.

Sites	Assay	Samples Tested	Correct calls	Incorrect calls	No-calls	% Correct	95% CI lower bound
A	CF Assay	20	20	0	0	100%	N/A
A	SSO HLA Assay	20	20	0	0	100%	N/A

Tube Performance Evaluation:
For tube performance evaluation with the cystic fibrosis assay and SSO HLA assay, data across the three sites with one control tube and one candidate tube per subject were evaluated. For tube performance evaluation with the Thrombophilia Risk Test, data from 80 subjects at Site D with one control and one candidate tube per subject were evaluated.

Sites	Assay	Samples Tested	Correct calls	Incorrect calls	No-calls	% Correct	95% CI lower bound
A,B,C	CF Assay**	117	116	0	1	99.1%	N/A
A,B,C	SSO HLA Assay***	120	120	0	0	100%	N/A
D	Thrombophila Assay	80	80	0	0	100%	95.4%

**CF Assay results shown were determined after retest. These include 1 sample from Site B showing a result of "No Call" that was not retested. Three previous runs at Site B included up to 38 samples showing a result of "No Call" due to a degraded enzyme in the CF Assay Kit. Run 4 used a new enzyme to perform the test at Site B. The results exclude 3 subjects from Site B where the assay was not repeated for 3 evaluation tubes.

***SSO HLA Assay results shown were determined after retest. These results include 4 samples from Site C that were re-extracted and retested due to a labeling error.

Inter and Intra-lot reproducibility:
Venous whole blood from 12 subjects drawn into 9 candidate tubes from lot 1 and 3 replicate candidate tubes each of lots 2 and 3 per subject. DNA extraction was performed using a commercially available, automated, magnetic bead based DNA isolation kit on one instrument by a single operator. DNA eluate concentration and purity was determined on all DNA samples. The results are summarized below:

DNA purity: All DNA eluates extracted from the proposed tube yielded an A260/A280 ratio range of 1.7-2.0.

DNA concentration: DNA eluates from 179 out of 180 tubes yielded DNA concentration of ≥12.5 ng/µl. The DNA elute from the remaining tube yielded DNA concentration of ≥10 ng/µl.

b. Linearity/assay reportable range:
Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The sponsor performed studies to confirm each of the following stability claims.

Sample stability at 18–25°C:
Venous whole blood was analyzed from 12 consented subjects drawn into 4 candidate and 2 control tubes per subject. Blood collected into 2 control tubes and 1 candidate tube per subject were processed without storage on the day of blood collection. The remaining candidate tube replicates were stored for 3, 7, and 14 days at 18–25°C prior to processing. DNA from each specimen was extracted on one commercially

available, automated, magnetic bead based DNA isolation kit by a single operator. DNA purity, concentration and SSP HLA genotype were assessed on all eluates. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube for all time points were concordant with the results obtained from samples drawn into both the control tube and candidate tube at the time of collection.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7–1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded a concentration of $\geq$ 17.5 ng/uL.

In a separate expanded study, the sponsor analyzed blood from 60 additional subjects into 2 candidate tubes. Blood collected into 1 candidate tube per subject was processed without storage on the day of blood collection. The remaining candidate tube replicates were stored for 14 days at 18–25°C prior to processing. The samples were processed as described above. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube for all time points were concordant with the results obtained from samples obtained using the candidate tube at the time of collection.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7–1.9.

DNA concentration: All DNA eluates extracted from the proposed tube yielded a concentration of $\geq$ 16.7 ng/uL.

Sample stability at 2–8°C:
Venous whole blood was analyzed from each of 12 subjects drawn into 5 candidate and 2 control tubes. Blood was collected into 2 control tubes and 1 of the replicate candidate tubes per subject were processed without storage on the day of blood collection. The remaining candidate tube replicates were stored at 2–8°C for 7, 14, 21 and 28 days prior to processing. DNA from each specimen was extracted on one instrument by a single operator using a commercially available, automated, magnetic bead based DNA isolation kit. DNA purity and concentration and SSP HLA genotype were determined on all eluates. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube for all timepoints were concordant with the results obtained from the samples obtained using both the evaluation tube and the control tube at timepoint 0.

DNA purity: All DNA eluates extracted from the proposed tube met the pre-determined acceptable ratio defined as having an A260/A280 ratio range of 1.7–1.9.

DNA concentration: All DNA eluates extracted from the proposed tube yielded a concentration of ≥ 13.4 ng/uL.

In a separate expanded study, the sponsor collected blood from an additional 60 subjects into 2 candidate tubes tube. Blood was collected into 1 of the candidate tubes per subject was processed without storage on the day of blood collection. The remaining candidate tube was stored for 28 days at 2–8°C prior to processing. The samples were processed as described above. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube after 28 days at 2–8°C were concordant with the results obtained from the samples obtained using the candidate tube at the time of collection.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7-1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded a concentration of ≥ 14.9 ng/uL.

Sample Stability at -20°C

Venous whole blood was analyzed from each of 12 subjects into 14 candidate and 2 control tubes. DNA from each specimen was extracted on 2 commercially available, automated, magnetic bead based DNA isolation kits by 2 operators. Blood collected into 2 control tubes and 1 candidate tube per subject were processed without storage on the day of blood collection. The remaining candidate tube replicates were stored at −20°C prior to processing. After 1 month, 3 months, 6 months, and 12 months of storage, one candidate tube per time point for each subject was thawed, processed, and tested. DNA purity and concentration and SSP HLA genotype were determined on all eluates. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube for the 6 month and 12 month time-points were concordant with the results obtained from the samples obtained using the predicate tube at timepoint 0. Discordant HLA typing results were found between results from candidate tubes for Subjects 4–12 at the 3 month time point and other time points for the same subjects. The discordant results for the 3 month time-points tubes were investigated and determined to be due to a mislabeling of DNA samples for at this time point only. Concordant genotyping results were obtained at all later time points for the specimens from the same subjects.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7–1.9.

DNA concentration: All DNA eluates extracted from the proposed tube met the pre-determined acceptable concentration of ≥ 15.3 ng/uL.

Sample Storage at 35°C

Venous whole blood was analyzed from each of 12 subjects drawn into 5 candidate and 2 control tubes. DNA from each specimen was extracted on 1 commercially available, automated, magnetic bead based DNA isolation kit by 1 operator. Blood collected into 2 control tubes and 1 of the candidate tubes per subject were processed without storage on the day of blood collection. The remaining candidate tube replicates were stored at 35°C for 6, 24, 48 and 72 hours prior to processing. DNA purity, eluate concentration and SSP genotype were determined on all eluates. The results are described below:

Genotyping: All HLA results generated from the samples collected in the candidate tube for all timepoints were concordant with the results obtained from the samples obtained using the control tube and the candidate tube at timepoint 0.

DNA purity: All DNA eluates extracted from the proposed tube yielded a A260/A280 ratio range of 1.7–1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded DNA elutes with concentrations of ≥ 14.1 ng/uL.

Sample stability after freeze/thaw cycles

Venous whole blood was analyzed from each of 12 subjects drawn into 4 candidate and 2 control tubes. DNA from each specimen was extracted by one operator using a commercially available, automated, magnetic bead based DNA isolation kit. Blood collected into 2 control tubes and 1 of the candidate tubes per subject were processed without storage on the day of blood collection. The remaining candidate tubes were frozen at −20°C and processed after 1, 2 or 3 freeze thaw cycles total. DNA purity, concentration and SSP genotype were determined on all eluates. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube for all freeze-thaw conditions were concordant with the results obtained from the samples obtained using the control tube and candidate tubes without freeze/thaw.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7-1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded a DNA concentration of ≥ 16.1 ng/uL.

In an additional separate study, venous whole blood was analyzed from each of 60 subjects drawn into 2 candidate tubes. DNA from each subject was extracted by one operator on 1 commercially available, automated, magnetic bead based DNA isolation kit. Blood collected into 1 candidate tube per subject were processed on the day of collection. The remaining candidate tubes were frozen at −20°C and processed after 1, 2 or 3 freeze thaw cycles total. DNA purity and concentration were determined on all eluates. The results are summarized below:

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7-2.0

DNA concentration: All DNA eluates extracted from the candidate tube yielded a DNA concentration of ≥ 13.1 ng/uL.

Sample Stability Summary:
The results of the studies support the sponsor's claim that the PAXgene Blood DNA tubes are suitable for storage of whole blood for 14 days at 18-25°C, 28 days at 2-8°C, 3 days at 35°C, 12 months at -20°C or when subjected to three freeze-thaw cycles prior to DNA extraction.

Samples stored at -20°C or subjected to freeze thaw cycles yielded sufficient DNA to perform the SSP HLA assay in each study, however, overall the DNA recovery for specimens stored at -20°C or subjected to freeze thaw cycles was decreased compared to samples that were never frozen. The following limitation was added to product labeling:

> "DNA concentrations in eluates extracted from blood specimens which have undergone 1 freeze-thaw cycle have been shown to fall by more than 25%, which subsequent freeze-thaw cycles not seen to further reduce DNA yield. For highest yield, DNA should be extracted from blood collected in the PAXgene Blood DNA Tube prior to freezing. Up to 3 freeze-thaw cycles does not negatively affect DNA quality or performance in molecular diagnostic test methods."

Real time stability studies for PAXgene Blood DNA tubes:
Shelf-life stability study:

Shelf-life stability testing of the proposed tube was evaluated for 13 months at room temperature. The sponsor tested specimens from 15 subjects using tubes and assessed the following endpoints: For the 6 month, and 7 month timepoint, DNA eluates were evaluated for DNA concentration and purity. For the 12 month and 13 month timepoint, DNA eluates were evaluated for DNA concentration and purity and were tested using a SSP HLA typing assay compared to DNA from duplicate control tubes. Stability testing protocols and acceptance criteria were reviewed and found acceptable. Current real-time data supports a shelf-life of 12 months at ambient temperature.

Transport simulation study: Transport stability was assessed using temperature cycling for short durations between high (45°C) and low (-20°C) durations after 6 or 12 months at the recommended storage conditions. Specimens from 15 subjects were evaluated at each time point. Using the cycling profile below:

Condition	Temperature	Duration
Pre-Cycling Storage	25°C ± 3°C	N/A
Extreme High	45°C ± 3°C	5 d
Room temp.	25°C ± 3°C	7–10 d
Extreme Low	−20°C ± 3°C	5 d
Room temp.	25°C ± 3°C	7–10 d
Extreme High	45°C ± 3°C	5 d
Equilibration to room temp. or room temp. storage	25°C ± 3°C	< 1 d – 6 m

Specimens from control tubes were processed immediately after collection, and candidate tubes were processed after temperature cycling. The resulting eluates were evaluated for DNA concentration, purity and SSP HLA genotype assay compared to paired specimens collected in control tubes. Stability testing protocols and acceptance criteria were reviewed and found acceptable.

Current real-time data supports the claimed transport conditions of up to 7 days at 40°C.

d. Detection limit:
Not applicable

e. Analytical specificity:

Short Draw Studies:
Venous whole blood was analyzed from 10 subjects drawn into 10 candidate and 2 control tubes. From each subject, partial-filled candidate tubes were drawn in quadruplicate for each of the two targeted fill volumes (50% and 28% of nominal draw), and duplicate candidate and control tubes were filled to the nominal draw volume. DNA was extracted using 2 commercially available, automated, magnetic bead based DNA isolation kits by two operators. DNA purity, concentration and SSP HLA genotype was evaluated on DNA from tubes collected from each subject: two control tubes and one candidate tube from each of the targeted fill volumes (100%, 50% and 28% of nominal). The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the proposed tube for all short-draw conditions and for the nominal draw were concordant with the

results obtained from the samples obtained using the control tube for the nominal draw.

DNA purity: All DNA eluates extracted from the candidate tube met yielded a A260/A280 ratio range of 1.7-1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded concentrations of ≥ 12.5 ng/uL.

Interference from Endogenous Substances:
The sponsor evaluated the impact of interfering substances by venous whole blood collected from 10 subjects. Per subject, 4 candidate tubes and 4 control tubes were spiked with interferent according to the table below:

Hemoglobin	Bilirubin	Triglycerides	Added Albumin
20 g/dL	20.0 mg/dL	1818 mg/dL	2.74 g/dL

The remaining candidate and control tubes (1 each per subject), received no interferent. The spiked and naïve tubes were processed with 1 commercially available, automated silica membrane based DNA isolation kit and 1 commercially available, automated magnetic bead based DNA isolation kit and the resulting elutes were evaluated. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the tubes with added interferent were concordant with the results obtained from the samples obtained from DNA samples from control and candidate tubes without interferent from the same donor.

DNA purity: All DNA eluates extracted from the candidate tube with and without interferent met the acceptable A260/A280 ratio range of 1.7-1.9.

DNA concentration: All DNA eluates extracted from the candidate tube with and without interferent yielded acceptable concentration of DNA ≥24.0 ng/uL.

2. Comparison studies:
   a. *Method comparison with predicate device:*

Suitability of DNA for Molecular Test Methods

Venous whole blood specimens were analyzed from each of 60 consented subjects drawn into 2 candidate tubes and 2 control tubes. DNA was isolated from all tubes, by 2 operators with 2 instruments using a commercially available automated magnetic bead based DNA isolation kit. DNA purity, concentration and SSP HLA genotype was assess for each eluate. Per subject, two DNA samples from control tubes were processed by different operators with the same instrument and one sample from one

candidate tube processed by one operator were analyzed. The results are summarized below.

Genotyping: All 60 HLA results generated from the samples collected in the candidate tube were concordant with the 120 HLA results obtained from the samples obtained using the control tube.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7–1.9.

DNA concentration: All 120 DNA eluates extracted from the candidate yielded concentration of ≥12.5 ng/uL.

Compatibility with Clinical Sample Concentrator Methods.
Venous whole blood specimens were analyzed from 4 control and 4 candidate tubes from each of 30 subjects. Specimens were extracted on 1 commercially available automated silica membrane based DNA isolation kit and 1 commercially available automated magnetic bead based DNA isolation kit by two operators (A, B) per method using two instruments per automation platform (instrument 1 and 2) as described in the table below.

Isolation of DNA from Control and Evaluation tubes by three methods

Subject	1-15							
Tubes per Subject	4 Control tubes				4 Candidate tubes			
Operator	A		B		A		B	
Method	1	2	1	2	1	2	1	2
Instrument number	#1	#1	#1	#1	#1	#1	#1	#1

Subject	16-30							
Tubes per Subject	4 Control tubes				4 Candidate tubes			
Operator	A		B		A		B	
Protocol	1	2	1	2	1	2	1	2
Instrument number	#2	#2	#2	#2	#2	#2	#2	#2

DNA eluates were assessed for DNA concentration and DNA purity. The results are summarized below:

DNA purity: All 192 DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7-1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded elutes with DNA concentration of ≥12.5 ng/uL.

The following limitation is provided by the sponsor in the device labeling to clarify that this tube has not been validated with manual extraction methodologies:

> "The PAXgene Blood DNA Tube has not been validated with DNA extraction methods involving manual precipitation. "

Additional studies in support of the tubes:

Incomplete tube inversion:

Venous whole blood was analyzed in replicate tubes from each of 10 subjects drawn into 8 control tubes and 8 candidate tubes. DNA from each specimen was extracted on two instruments by two operators using a commercially available, automated, magnetic bead based DNA isolation kit. Per subject, duplicate control and duplicate candidate tubes were not inverted after blood collection , while the three other sets of duplicate control and duplicate candidate tubes were inverted 1, 5, and 8 times. After inversion, tubes were incubated at room temperature (18– 25°C) for 1 day, followed by processing on the first day after blood collection. DNA purity, concentration and SSP HLA genotype were assessed. The results are summarized below:

Genotyping: All HLA results generated from the samples collected in the candidate tube which had been inverted 1x and 8x were concordant with the results obtained from the samples obtained using the control tube which had been inverted 8x.

DNA purity: All DNA eluates extracted from the candidate tube yielded an A260/A280 ratio range of 1.7-1.9.

DNA concentration: All DNA eluates extracted from the candidate tube yielded DNA concentrations of ≥ 15 ng/uL.

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off**:**
   Not applicable

5. Expected values/Reference range:
   Not applicable

N. Proposed Labeling:

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

O. Conclusion:

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