April 4, 2024

Sebia Inc.
Karen Anderson
Director of Regulatory
1705 Corporate Drive Suite 400
Norcross, Georgia 30093

Re: K232027
Trade/Device Name: CAPI 3 NEONAT Hb, CAPILLARYS 3 DBS Instrument
Regulation Number: 21 CFR 864.7415
Regulation Name: Abnormal hemoglobin assay
Regulatory Class: Class II
Product Code: GKA
Dated: March 4, 2024
Received: March 5, 2024

Dear Karen Anderson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232027

Device Name
CAPI 3 NEONAT Hb
CAPILLARYS 3 DBS instrument

Indications for Use *(Describe)*

The CAPI 3 NEONAT Hb kit is intended as a qualitative screen for the detection of normal hemoglobins (F and A) and abnormal hemoglobins (S, C, E, D and Bart's) in blood from human new-born collected on filter paper. This analysis is performed by capillary electrophoresis with the CAPILLARYS 3 DBS instrument.
The CAPILLARYS 3 DBS instrument is a capillary electrophoresis based automated analyzer which performs a complete hemoglobin profile for the qualitative analysis of hemoglobins (A, F, S, C, D, E and Bart's). The assay is performed on the hemolysate of whole blood samples previously collected on filter paper.
The test result must be interpreted in conjunction with other biological and clinical findings. In case of abnormal hemoglobin presence, it should be confirmed by additional tests as per local recommendations. The device is intended for professional use only.
For In Vitro Diagnostic Use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) SUMMARY (Summary of Safety and Effectiveness)

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

Submitter Name	Sebia. Inc.
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Date Prepared	April 03, 2024
Manufacturing	Sebia Parc Technologique Léonard de Vinci Rue Léonard de Vinci. CP 8010 LISSES. 91008 EVRY Cedex FRANCE Phone: (33) 1 69 89 80 80 Fax: (33) 1 69 89 78 78
Product Name	CAPI 3 NEONAT Hb kit using the CAPILLARYS 3 DBS instrument
Common Name	HEMOGLOBINS BY CAPILLARY ELECTROPHORESIS
Product Regulation No.	21 CFR Part 864.7415 – Abnormal Hemoglobin Assay 21 CFR Part 864.7415 – Abnormal Hemoglobin Assay. Controls (510(k) exempt. FDA docket 2017-N-1129/1610 published December 30. 2019; Class II (special control) devices)
Product Codes	GKA – Abnormal Hemoglobin Quantitation – Class II JCM – Control. Hemoglobin. Abnormal – Class II (special control) devices. 510(k) exempt
Device classification and Panel Classification	Class II. Hematology
Establishment Registration No.	8023024

1. DEVICE DESCRIPTIONS

The CAPI 3 NEONAT Hb kit is intended for the detection of normal hemoglobins (F and A) and abnormal hemoglobins (S, C, E, D and Bart's) in blood from human new-born collected on filter paper. The resulting electrophoregrams are automatically evaluated for pattern abnormalities with identification of normal and pathological patterns.

The CAPILLARYS 3 DBS instrument uses the principle of capillary electrophoresis in free solution which is the most common form of capillary electrophoresis. With this technique. charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation also occurs according to the electrolyte pH and electroosmotic flow.
The CAPILLARYS 3 DBS instrument has silica capillaries functioning in parallel allowing 12 simultaneous analyses. A sample dilution with hemolysing solution is prepared and injected by aspiration at the anodic end of the capillary. A high voltage protein separation is then performed and direct detection of the hemoglobins is made at the cathodic end of the capillary at 415 nm. which is the absorbance wavelength specific to hemoglobins. Before each run. the capillaries are washed with a wash solution and prepared for the next analysis with buffer.
The CAPILLARYS 3 DBS performs all sequences automatically to obtain a complete hemoglobin profile for the qualitative analysis of hemoglobins. The assay is performed on the hemolysate of whole blood samples previously collected on Guthrie filter paper and punched to obtain a paper circle.

By using alkaline pH buffer. normal and abnormal (or variant) hemoglobins are detected in the following order. from cathode to anode: C, A2, E, S, D, F, degraded F, A, degraded A and Bart's. Variants generated by the mutation of the γ chain may appear in different zones of the electrophoretic pattern. The carbonic anhydrase is not visualized on the hemoglobin electrophoretic patterns with capillary electrophoresis.

2. REAGENTS

REAGENTS AND MATERIALS SUPPLIED IN THE CAPI 3 NEONAT Hb KIT

CAPI 3 NEONAT Hb KIT includes:	**PN 2506**
CAPILLARYS HEMOGLOBIN(E) BUFFER (ready to use)	3 vials, 700 mL each
Filters	5 filters
CAPILLARYS 3 DBS MICROPLATES 96 well-microplates (with bar codes)	1 pack of 10 microplates

REAGENTS/SUPPLIES REQUIRED BUT NOT SUPPLIED IN THE CAPI 3 NEONAT Hb KIT

SUPPLIES	SEBIA PRODUCT NUMBER
CAPI 3 NEONAT HEMOLYSING SOLUTION KIT (ready to use)	(PN 2563), 2 vials of 70 mL each and 2 pierceable caps
CAPI 3 NEONAT Hb AF CONTROL (lyophilized)	(PN 4757), 2 vials and one boarding cartridge
CAPILLARYS 3 CAPICLEAN (concentrated solution)	(PN 2060), 1 vial of 25 mL and 1 pierceable cap
CAPILLARYS 3 WASH SOLUTION (stock solution)	(PN 2062), 1 vial of 75 mL

OPITIONAL SUPPLIES

SUPPLIES	SEBIA PRODUCT NUMBER
Hb AFSC CONTROL (lyophilized)	(PN 4792) 1 vial of 0.5 mL

3. INDICATIONS FOR USE

INTENDED USE STATEMENT

The CAPI 3 NEONAT Hb kit is intended as a qualitative screen for the detection of normal hemoglobins (F and A) and abnormal hemoglobins (S, C, E, D and Bart's) in blood from human new-born collected on filter paper. This analysis is performed by capillary electrophoresis with the CAPILLARYS 3 DBS instrument.

The CAPILLARYS 3 DBS instrument is a capillary electrophoresis based automated analyzer which performs a complete hemoglobin profile for the qualitative analysis of hemoglobins (A, F, S, C, D, E and Bart's). The assay is performed on the hemolysate of whole blood samples previously collected on filter paper.

The test result must be interpreted in conjunction with other biological and clinical findings. In case of abnormal hemoglobin presence, it should be confirmed by additional tests as per local recommendations. The device is intended for professional use only.

For In Vitro Diagnostic Use only.

4. SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name	Predicate Device 510(k) number	Regulation No.	Vendor
CAPILLARYS NEONAT Hb	K091283 February 22. 2010	21 CFR Part 864.7415 – Abnormal Hemoglobin Assay	Sebia

5. COMPARISON WITH PREDICATE DEVICE

SIMILARITIES (Table A).

Kit Similarities		
Table A	**Candidate Device** CAPI 3 NEONAT Hb CAPILLARYS 3 DBS instrument	**Predicate Device** CAPILLARYS NEONAT Hb (K091283)
Intended Use	The CAPI 3 NEONAT Hb kit is intended as a qualitative screen for the detection of normal hemoglobins (F and A) and abnormal hemoglobins (S, C, E, D and Bart's) in blood from human new-born collected on filter paper. This analysis is performed by capillary electrophoresis with the CAPILLARYS 3 DBS instrument. The CAPILLARYS 3 DBS instrument is a capillary electrophoresis based automated analyzer which performs a complete hemoglobin profile for the qualitative analysis of hemoglobins (A, F, S, C, D, E and Bart's). The assay is performed on the hemolysate of whole blood samples previously collected on filter paper. The test result must be interpreted in conjunction with other biological and clinical findings. In case of abnormal hemoglobin presence, it should be confirmed by additional tests as per local recommendations. The device is intended for professional use only. *For In Vitro Diagnostic Use only.*	The CAPILLARYS NEONAT Hb kit is designed for the separation of the normal hemoglobins (F and A) in blood samples from human new-borns. and for the detection of the major hemoglobin variants (S, C, E, D and Bart's), by electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 system. The CAPILLARYS NEONAT Hb kit is designed for laboratory use. The CAPILLARYS 2 is an automated analyzer which performs a complete hemoglobin profile for the qualitative analysis of hemoglobins. The assay is performed on the hemolysate of whole blood samples previously collected on filter paper. For *In Vitro* Diagnostic Use only.
Analyte	Hemoglobin detection	Same
Measurement	Qualitative	Same
Sample Matrix	Blood samples from human new-borns collected on filter paper	Same
Technology	Capillary electrophoresis	Same
Instrument Wavelength Measurement	415 nm	Same
Software	PHORESIS	Same

REAGENT SIMILARITIES (Table B).

Reagent similarities		
Table B	**Candidate Device** CAPI 3 NEONAT Hb CAPILLARYS 3 DBS instrument	**Predicate Device** CAPILLARYS NEONAT Hb (K091283)
Buffer	CAPILLARYS HEMOGLOBIN(E) buffer	Same
Hemolysing Solution	CAPILLARYS NNHb hemolysing solution	Same
Controls	Hb AF Control	Same
	Hb AFSC Control	Same

DIFFERENCES (Table C)

Kit Differences		
Table C	**Candidate Device** CAPI 3 NEONAT Hb CAPILLARYS 3 DBS instrument	**Predicate Device** CAPILLARYS NEONAT Hb (K091283)
Dilution Vessel	96 well-microplates	Dilution segments
Punch Size	3.2 mm diameter	3.8 mm diameter
Instrument	CAPILLARYS 3 DBS	CAPILLARYS 2 SYSTEM

6. ANALYTICAL PERFORMANCE DATA

A) Precision

Between capillaries, between lots, between instruments, and between days precision.

Eight (8) different samples were analyzed using the CAPI 3 NEONAT Hb procedure used on the CAPILLARYS 3 DBS instrument. The samples included 6 new-born whole blood samples (with FA, FAS, FAC, FAD, FAE and FA Bart's patterns) and 2 controls.

- For the between capillaries precision, each sample was analyzed once on the 12 capillaries of 1 instrument with 1 reagent lot, through 1 run.
- For the between lots precision, for 3 days, same samples were analyzed once per run over 2 runs (with a minimum of 2 hours between both runs), on 1 instrument with 1 reagent lot per day (total of 3 lots).
- For the between instruments precision, within the same day, same samples were analyzed once per run over 2 runs (with a minimum of 2 hours between both runs), on 3 instruments with 1 reagent lot.
- For the between days precision, every day, for 5 days, same samples were analyzed once per run over 2 runs (with a minimum of 2 hours between both runs) on 1 instrument with 1 reagent lot.

All samples gave 100 % identification pattern concordance between all capillaries, lots, instruments, and days.

		Between capillaries		**Between lots**		**Between instruments**		**Between days**	
	Identification pattern	Result	Total analyses	Result	Total analyses	Result	Total analyses	Result	Total analyses
Sample No. 1	FA	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 2	FAS	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 3	FAC	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 4	FAD	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 5	FAE	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 6	FA Bart's	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 7	AFSC	100% concordance	12	100% concordance	6	100% concordance	6	100% concordance	10
Sample No. 8	FA	100% concordance	12	100% concordance	72	100% concordance	72	100% concordance	120
Total concordance (95% CI. Wilson score method)		**100% (96.2%;100.0%)**	**96**	**100% (96.7%;100.0%)**	**114**	**100% (96.7%;100.0%)**	**114**	**100% (98.0%;100.0%)**	**190**

Precision using controls as per CLSI EP05-A3 general study design

The precision of the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument was evaluated in a study with a study design based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP5-A3 guideline "Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition".

Two (2) different control samples (with FA and AFSC patterns) were analyzed using the CAPI 3 NEONAT Hb procedure used on the CAPILLARYS 3 DBS instrument.

- For the within-laboratory precision, each sample was analyzed once on the 12 capillaries of 1 instrument with 1 lot of reagents, through 2 runs per day during 20 days.

% Hb F

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV
AF	480	69.2	0.40	0.6	0.25	0.4	0.49	0.7	0.68	1.0
AFSC	480	26.0	0.15	0.6	0.07	0.3	0.02	0.1	0.16	0.6

% Hb A

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV
AF	480	30.2	0.40	1.3	0.26	0.9	0.51	1.7	0.70	2.3
AFSC	480	46.6	0.30	0.6	0.23	0.5	0.00	0.0	0.38	0.8

% Hb S

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV
AFSC	480	16.6	0.14	0.8	0.11	0.7	0.00	0.0	0.17	1.0

% Hb C

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV
AFSC	480	10.7	0.08	0.7	0.06	0.6	0.04	0.4	0.11	1.0

- For the between-lots precision, during 5 days, same samples were analyzed 3 times per run over 2 runs (with a minimum of 2 hours between both runs), on 1 instrument with 3 lots of reagents.

% Hb F

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Lots		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AF	90	69.3	0.22	0.3	0.32	0.5	0.00	0.0	0.17	0.2	0.42	0.6
AFSC	90	25.8	0.10	0.4	0.05	0.2	0.04	0.2	0.06	0.2	0.14	0.5

% Hb A

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Lots		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AF	90	30.0	0.21	0.7	0.34	1.1	0.00	0.0	0.16	0.5	0.43	1.4
AFSC	90	47.1	0.41	0.9	0.00	0.0	0.12	0.3	0.17	0.4	0.46	1.0

% Hb S

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Lots		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AFSC	90	16.5	0.24	1.5	0.00	0.0	0.04	0.3	0.10	0.6	0.27	1.6

% Hb C

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Lots		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AFSC	90	10.6	0.14	1.3	0.00	0.0	0.04	0.4	0.13	1.2	0.19	1.8

- For the between-instruments precision, during 5 days, same samples were analyzed 3 times per run over 2 runs (with a minimum of 2 hours between both runs), on 3 instruments with 1 lot of reagents.

% Hb F

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Instruments		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AF	90	69.4	0.33	0.5	0.43	0.6	0.00	0.0	0.45	0.6	0.70	1.0
AFSC	90	25.9	0.11	0.4	0.06	0.2	0.00	0.0	0.09	0.3	0.15	0.6

% Hb A

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Instruments		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AF	90	29.9	0.33	1.1	0.45	1.5	0.00	0.0	0.44	1.5	0.71	2.4
AFSC	90	46.6	0.28	0.6	0.08	0.2	0.05	0.1	0.47	1.0	0.56	1.2

% Hb S

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Instruments		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AFSC	90	16.7	0.15	0.9	0.00	0.0	0.05	0.3	0.23	1.4	0.28	1.7

% Hb C

Control	N	Mean (%)	Within-Run		Between-Run		Between-Day		Between-Instruments		Total	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
AFSC	90	10.8	0.10	1.0	0.05	0.4	0.02	0.2	0.16	1.5	0.20	1.8

All samples gave 100 % identification pattern concordance between all analyses.

B) Analytical Specificity/Interference

Endogenous interference

The common interfering factors with the CAPI 3 NEONAT Hb procedure used on the CAPILLARYS 3 DBS instrument (conjugated bilirubin. unconjugated bilirubin and triglycerides) were evaluated in studies based on the Clinical Laboratory Standards Institute (CLSI - USA) EP7-A2 guideline "Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition" and the Clinical Laboratory Standards Institute (CLSI - USA) EP07. 3rd Edition guideline "Interference Testing in Clinical Chemistry".
The results are summarized below.

No interference with the CAPI 3 NEONAT Hb procedure used on the CAPILLARYS 3 DBS instrument was detected due to the new-born whole blood sample's high concentration of the following interfering factors tested at levels up to the concentrations listed below:

Endogenous interfering factor	Concentration
Conjugated bilirubin	40 mg/dL
Unconjugated bilirubin	40 mg/dL
Triglycerides	1500 mg/dL

C) Qualitative Method Comparison with Predicate Device

Qualitative method comparison – Internal study

The concordance study of the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP12-A2 guideline "User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition". sections 9. Comparison of Methods and 10. Data Analysis.

NOTE: The analyzed samples were provided by 5 laboratories in France. Thailand and Panama. All the samples followed the same guidelines in regard to sample integrity and were prepared according to the instructions for use of each technique.

One hundred and thirty-eight (138) different new-born whole blood samples (71 normal samples and 67 pathological samples with hemoglobin variants S. C. D. E and Bart's) were analyzed with the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument and with a commercially available capillary electrophoresis procedure for hemoglobin analysis (reference).

The positive percent agreement (PPA). the negative percent agreement (NPA). and their confidence intervals (95 % CI by Wilson score method) of the CAPI 3 NEONAT Hb procedure compared to the reference procedure have been calculated. The results are listed below:

Positive Percent Agreement (%): 100% (94.6 %;100.0 %).
Negative Percent Agreement (%): 100.0% (94.9 %;100.0 %).

Hb fractions	Number of samples
FA	71
FAS	25
FS	7
FCS	1
FAC	7
FAD	2
FAE	8
FA + Hb Bart's	10
FAS + Hb Bart’s	6
AFSC	1
Total	138

Qualitative method comparison – External study No. 1

The concordance study of the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP12-A2 guideline "User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition". sections 9. Comparison of Methods and 10. Data Analysis.

NOTE: The samples were analyzed in a laboratory based in the United States of America. All the samples followed the same guidelines in regard to sample integrity and were prepared according to the instructions for use of each technique.

Four hundred and eleven (411) different new-born whole blood samples (210 normal samples and 201 pathological samples with hemoglobin variants S. C. D. E and Bart’s) were analyzed with the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument and with a commercially available capillary electrophoresis procedure for hemoglobin analysis (reference).

The positive percent agreement (PPA). the negative percent agreement (NPA). and their confidence intervals (95 % CI by Wilson score method) of the CAPI 3 NEONAT Hb procedure compared to the reference procedure have been calculated. The results are listed below:

Positive Percent Agreement (%): 100.0 % (98.1 %;100.0 %).
Negative Percent Agreement (%): 100.0 % (98.2 %;100.0 %).

Hb fractions	Number of samples
FA	210
FAS	63
FAC	40
FA + Hb Bart's	35
FAD	15
FAS + Hb Bart's	12
FAE	9
FS	7
FSA	7
FAX	6
FCS	2
AFS	1
FSE	1
FCX	1
FE	1
FAC + Hb Bart's	1
Total	411

Qualitative method comparison – External study No. 2

The concordance study of the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP12-A2 guideline "User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition". sections 9. Comparison of Methods and 10. Data Analysis.

NOTE: The samples were analyzed in a laboratory based in Spain. All the samples followed the same guidelines in regard to sample integrity and were prepared according to the instructions for use of each technique.

Two hundred and forty (240) different new-born whole blood samples (120 normal samples and 120 pathological samples with hemoglobin variants S. C. D. E and Bart's) were analyzed with the CAPI 3 NEONAT Hb procedure performed with the CAPILLARYS 3 DBS instrument and with a commercially available capillary electrophoresis procedure for hemoglobin analysis (reference).

The positive percent agreement (PPA). the negative percent agreement (NPA). and their confidence intervals (95 % CI by Wilson score method) of the CAPI 3 NEONAT Hb procedure compared to the reference procedure have been calculated. The results are listed below:

Positive Percent Agreement (%): 100.0 % (96.9 %;100.0 %).
Negative Percent Agreement (%): 100.0 % (96.9 %;100.0 %).

Hb fractions	Number of samples
FA	120
FAS	53
FS	6
FSC	1
FAC	29
FAD	5
FAE	5
FAX	5
FA + Hb Bart's	13
FAS + Hb Bart’s	2
FAC + Hb Bart's	1
Total	240

7. CONCLUSION

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