



### **16.1.9.3 BIOANALYTICAL REPORTS**

Determination of Carboxyhemoglobin (COHb) in Human Plasma (Lithium Heparin) by Spectrophotometry

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## ANALYTICAL REPORT

STATUS: Final

VERSION: 1.0

DATE: 02APRIL 2015

*Study title:*

A randomized, controlled, open-label, 3-arm parallel group, single centre study to demonstrate reductions in exposure to selected smoke constituents in smoking, health subject switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement.

*Sponsor:* Philip Morris Products S.A.  
PMI Research and Development  
Quai Jeanrenaud 5, 2000 Neuchâtel, Switzerland

*Study number:* ZRHR-REXC-03-EU

*Principle Investigator:* Katarzyna Jarus-Dziedzic

*Clinical site:* BioVirtus Research Site Sp. z o.o.  
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*Analyte:* Carboxyhaemoglobin (COHb)

*Matrix:* Lithium heparin plasma

*Performed by:* Clinical Trial Laboratory Unit  
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*Beginning of the analysis:* 29.06.2013

*Termination of the analysis:* 19.09.2013

*Status of the report:* Final

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## Analytical Report Approval

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Abbreviations	4
1. Purpose of the study	5
2. Agreement criteria	5
3. Sample tracking	5
3.1. Sample collection	5
3.2. Sample receipt and maintenance	5
Table 1a: Tracking overview of COHb samples of the 1st cohort	6
Table 1b: Tracking overview of COHb samples of the 2 <sup>nd</sup> cohort	6
Table 1c: Tracking overview of COHb samples of the 3 <sup>rd</sup> cohort	7
Table 1d: Tracking overview of COHb samples of the 4 <sup>th</sup> cohort	7
Table 1e: Tracking overview of COHb samples of the 5 <sup>th</sup> cohort	7
3.3. Sample storage conditions	7
4. Analytical methods	7
4.1. CO-oximetry	7
4.1.1. Test principle	7
4.1.2. Calibration	8
4.1.3. Quality Control	8
Table 2. QC materials used in the study	8
Table 3a: QCs results of COHb 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> , 4 <sup>th</sup> & 5 <sup>th</sup> cohort samples	11
5. Summary of sample results	12
5.1.1. 1st cohort	12
Table 4. Performance of the COHb test per visit per cohort	12
Table 5a: The register of COHb results of the 1 <sup>st</sup> cohort	13
5.1.2. 2nd cohort	19
Table 5b: The register of COHb results of the 2 <sup>nd</sup> cohort	19
5.1.3. 3rd cohort	27
Table 5c: The register of COHb results of the 3 <sup>rd</sup> cohort	27
5.1.4. 4th cohort	35
Table 5d: The register of COHb results of the 4 <sup>th</sup> cohort	35
5.1.5. 5th cohort	42
Table 5e: The register of COHb result of the 5 <sup>th</sup> cohort	42
5.2. Description of the main problems and solutions	49
5.3. Deviations from analytical SOP	50
5.4. Analytical notes	50
6. Archiving of the data	50
7. References	50
Report Signatures	51

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<b>APM</b>	Analytical Project Manager
<b>BOE</b>	Biomarkers of Exposure
<b>COHb</b>	Carboxyhaemoglobin
<b>CTU</b>	Clinical Trial Unit
<b>CTL</b>	Control
<b>CV</b>	Coefficient of variation
<b>GCLP</b>	Good Clinical Laboratory Practice
<b>GCP</b>	Good Clinical Practice
<b>HCT</b>	Haematocrit
<b>LSI</b>	Laboratory Information System
<b>QA</b>	Quality Assurance
<b>QC</b>	Quality Control
<b>POCT</b>	Point of care testing
<b>%RE</b>	Relative Error (%), $\Delta\%$
<b>SCL</b>	Synevo Central Lab
<b>SD</b>	Standard Deviation
<b>SOP</b>	Standard Operating Procedure
<b>STD</b>	Standard
<b>tHb</b>	Total Haemoglobin concentration

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### 1. Purpose of the study

The Clinical Trials Laboratory Unit of Medical Laboratory Synevo Ursynów in Warsaw performed determinations of carboxyhaemoglobin (COHb) in clinical samples received from healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement.

The Analytical Report presents the summary of analysis of COHb results obtained from all participants enrolled to study from 5 cohorts (from 7 days per each cohort).

### 2. Agreement criteria

For the purpose of this study the requirements of GCLP were fulfilled in accordance with our SOP's and quality embracing the following [1,2,3]:

- a. GCLP compliant SOP's
  - Project management
  - Logistics
  - Study materials
- b. Laboratory SOP's
  - Equipment
  - Laboratory testing procedures
  - Method validation
- c. Study specific documents
  - Analytical Plan
  - Laboratory Manual

### 3. Samples tracking

#### 3.1. Sample collection

Blood samples for COHb determination were collected by conventional venipuncture using Monovette tubes for blood gas analysis Sarstedt (Cat. No. 05.1147.020). Blood was collected in BioVirtus facility (investigator) by professional nursing staff (phlebotomists) once a day at evening at visits from Day -1 to Day 4 and four times a day in Day 5.

Blood in amount of 2.0 ml was collected into barcode labelled syringe-tubes with 50 I.U. of calcium – balanced lithium heparin anticoagulant in liquid form to get the heparinized whole blood. Syringes were plugged with special stopper to avoid contact blood with atmosphere and packed together with laboratory request form into plastic zipped bags.

#### 3.2. Samples receipt and maintenance

Samples from each visit were shipped to the Synevo laboratory in 1 or 2 batches a day (from morning & evening collection) by Synevo's couriers after termination of venipuncture procedures. The total transport time from BioVirtus facility to Synevo Laboratory took usually about 30 minutes and did not exceed 1 hour.

Samples tubes in zipped bags were transported in specific plastic containers adapted to the shipment of the biological material and equipped with a temperature monitoring system. The cards of the samples transport with recorded an hour of sending, receiving samples in the laboratory and the temperature were included. The

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temperature of samples was stable and maintained within range of 2 – 8 ° C during transport. All the conditions of the receipt and storage of samples were in agreement with the known stability of COHb confirmed by method validation.

The number and date of samples receipt into the lab are summarized in [table 1a](#).

**Table 1a:** Tracking overview of COHb samples of the 1 – 5 cohorts

No	Date of collection	Visit No.	Date of delivery to the lab	Time of delivery HH:MM	Numbers of samples	Date of batch analysis
1	2013-07-11	Day -1	2013-07-12	10:30	28	2013-07-12
2	2013-07-12	Day 0	2013-07-13	09:50	28	2013-07-13
3	2013-07-13	Day 1	2013-07-14	09:20	28	2013-07-14
4	2013-07-14	Day 2	2013-07-15	09:27	28	2013-07-15
5	2013-07-15	Day 3	2013-07-16	10:00	28	2013-07-16
6	2013-07-16	Day 4	2013-07-17	09:25	28	2013-07-17
7	2013-07-17	Day 5	2013-07-17	14:25	56	2013-07-17
8	2013-07-17	Day 5	2013-07-18	10:25	56	2013-07-18
9	2013-07-25	Day -1	2013-07-26	09:20	35	2013-07-26
10	2013-07-26	Day 0	2013-07-27	09:19	35	2013-07-27
11	2013-07-28	Day 1	2013-07-28	09:00	35	2013-07-28
12	2013-07-28	Day 2	2013-07-29	09:40	35	2013-07-29
13	2013-07-29	Day 3	2013-07-30	10:15	34	2013-07-30
14	2013-07-30	Day 4	2013-07-31	10:00	34	2013-07-31
15	2013-07-31	Day 5	2013-07-31	14:20	68	2013-07-31
16	2013-07-31	Day 5	2013-08-01	11:00	68	2013-08-01
17	2013-08-08	Day -1	2013-08-09	NA	34	2013-08-09
18	2013-08-09	Day 0	2013-08-10	NA	34	2013-08-10
19	2013-08-10	Day 1	2013-08-11	NA	34	2013-08-11
20	2013-08-11	Day 2	2013-08-12	NA	34	2013-08-12
21	2013-08-12	Day 3	2013-08-13	09:04	34	2013-08-13
22	2013-08-13	Day 4	2013-08-14	09:44	34	2013-08-14
23	2013-08-14	Day 5	2013-08-14	14:37	68	2013-08-14
24	2013-08-14	Day 5	2013-08-15	10:30	68	2013-08-15
25	2013-08-21	Day -1	2013-08-22	10:30	35	2013-08-22
26	2013-08-22	Day 0	2013-08-23	09:10	33	2013-08-23
27	2013-08-23	Day 1	2013-08-24	08:50	31	2013-08-24
28	2013-08-24	Day 2	2013-08-25	08:42	31	2013-08-25
29	2013-08-25	Day 3	2013-08-26	09:07	31	2013-08-26
30	2013-08-26	Day 4	2013-08-27	09:02	31	2013-08-27
31	2013-08-27	Day 5	2013-08-27	14:50	62	2013-08-27
32	2013-08-27	Day 5	2013-08-28	10:20	62	2013-08-28
33	2013-09-12	Day -1	2013-09-13	10:04	37	2013-09-13
34	2013-09-13	Day 0	2013-09-14	10:05	32	2013-09-14
35	2013-09-14	Day 1	2013-09-15	08:35	32	2013-09-15
36	2013-09-15	Day 2	2013-09-16	09:45	32	2013-09-16
37	2013-09-16	Day 3	2013-09-17	10:00	32	2013-09-17
38	2013-09-17	Day 4	2013-09-18	10:10	32	2013-09-18
39	2013-09-18	Day 5	2013-09-18	15:15	64	2013-09-18
40	2013-09-18	Day 5	2013-09-19	10:25	64	2013-09-19

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### 3.3. Samples storage conditions

Samples from one visit were gathered in samples acquisition point at BioVirtus facility. Heparinized whole blood tubes and requests were checked and any discrepancies were noted. Samples were assigned unique accession number and put into the rack dedicated to the CO-oximetry. The COHb level in blood was determined usually immediately after sample receipt and registration.

After completion of analysis from one visit batch, all the tubes were stored in the refrigerator and then destroyed after 3 days storage.

During the storage of samples all technical problems with the temperature preservation were noted and all samples were at optimal required conditions until the date of destruction. The short – term & long – term stability of tested analyte (COHb) was widely known and described in the literature and also it was confirmed during the test validation procedure in the lab, therefore all the conditions of samples storage were in agreement with the confirmed COHb stability.

## 4. Analytical method

The analytical method used in the study for COHb testing and described below belongs to the routine POCT laboratory methods performed and validated according to internal laboratory SOP's. The equipment mentioned below and used for testing was located at Synevo Warszawa Ursynów Laboratory.

### 4.1 Co – oximetry

The determination of COHb in blood samples was performed once a day at visits: Day -1, Day 0, Day 1, Day 2, Day 3, Day 4 and four times a day at visit D-5.

The material for COHb testing was lithium heparinized whole blood.

The COHb testing was performed in CO-oximetry module of the Cobas b221 Roche system - an automatic POCT analyzer of the blood-gas critical parameters.

#### 4.1.1 Test principle

The COHb and other haemoglobin derivatives (deoxyhaemoglobin, oxyhaemoglobin, methhaemoglobin ) were measured by spectrophotometry as a percentage of the total haemoglobin (tHb) on the basis of the Lambert's-Beer's rule.

The CO-oximetry module consists of the ultrasound haemolyzer and the measuring chamber – the quartz cuvette of known dimensions.

Volume of blood sample is strictly determined by few factors:

- For module BG-ISE-tHb/SO<sub>2</sub> or COOX activated in analyzer the minimal required volume of blood is haematocrit (Hct) dependant: 112 µL for Hct ≤ 45% and 148 µL for Hct > 45% the minimum blood volume of the test tube.

- Volume of test tube. For 1 ml specimen is require 300 µL blood.

Blood was haemolyzed in ultrasound haematolyzer and passed to the measuring chamber where the spectrophotometric measurement was done. Reference values for COHb were: Smokers 8.0-9.0%, No Smokers 0.5-1.5%.



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#### 4.1.2 Calibration

The CO-oximetry module of Cobas b 221 analyzer required only occasional calibration of the total haemoglobin (tHb) level. It was done once before the study began, during installation of analyzer by Roche service engineers. The material used for calibration of COHb measurements was total Hb calibrator with known Hb level supplied by producer. System performs calibration several times within 24 hours: 2-points calibration every 12 h and 1-point calibration every 60 min.

#### 4.1.3. Quality Control

The precision and accuracy of the COHb measurement was monitored with QC samples at least once a day. Materials used for QC testing – COMBITROL PLUS B – is a multi-analyte controls material available at three levels. Controls was formulated using aqueous equilibrated solution with predetermined levels of oxygen, carbon dioxide and nitrogen with salt, organic and carbonate buffers and metabolites. There were four different Lots used during the study: one Lot No of Level 2 and Level 3 and two Lot No for Level 1.

The detailed characteristics of QC materials used for testing is presented in manufacturer insert. The table below presents main parameters related to COHb measurement:

**Table 2.** QC material used in the study

REF No.	COMBITROL PLUS B	LOT No.	Exp. Data	COHb Mean value	COHb $\pm 2$ SD range
03321193001	Level 1	21421024	31.08.2014	21,5%	19,0 - 24,0 %
03321193001	Level 1	21421025	31.10.2014	23,3%	20,8 - 25,8%
03321207001	Level 2	21421124	31.05.2014	10,9%	8,4 - 13,4%
03321215001	Level 3	21421220	30.06.2014	3,4%	0,9 - 5,9%

Controls were manufactured and distributed by Roche at three levels of measured COHb concentration [%] (low, normal and high) with acceptance limits established by manufacturer as a  $\pm 2$  limits of the nominal, mean value. If the COHb value of each QC sample was in the  $\pm 2$  limits, the analysis performed at the same day was valid, if the COHb of at least one of ten QCs was in the range of 2sd-3sd (between 2sd and the 3sd limits), the special warning was highlighted to enforce the appropriate response of the staff operating the device but under some special conditions, the QC measurements could be accepted and sample measurements could be continued.

Combitrol Plus B QC vials were stable 24 months when stored in the refrigerator.

24h before each QC testing, three vials of QCs were taken out from freezer and left at the room temperature until the testing.

All study results were obtained with QC results in the established acceptance limits.

The results of daily internal COHb QC samples performance are presented in [table 3a](#).

The copy example of COMBITROL PLUS B Level 1-3 original inserts are presented below.

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## COMBITROL PLUS B

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## LEVEL 1

REF 0 3321 193001 (BP9097)

LOT 21421025

2014/10

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11718724058066039063000000000000



121171252832079087143173049059



13069083423503208258106136163203051067



140470650711118824800000

pH	PCO <sub>2</sub> (kPa)	PO <sub>2</sub> (kPa)	Hb (g/dL)	SO <sub>2</sub> (%)	Na <sup>+</sup> (mmol/L)	K <sup>+</sup> (mmol/L)	Cl <sup>-</sup> (mmol/L)	Ca <sup>2+</sup> (mmol/L)
±0.03	±0.5 / ±4	±1.6 / ±12	±0.7 / ±0.4	±3.95	±4	±0.2	±4	±0.15
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
7.21 7.18-7.24	8.3 7.8-8.8	8.8 8.2-9.4	7.6 6.8-8.3	71.55 67.8-75.5	121 117-125	3.8 2.8-3.2	83 79-87	1.58 1.43-1.73
Hct (%)	O <sub>2</sub> Hb (%)	COHb (%)	Methb (%)	HbA <sub>1c</sub> (%)	BUN (mg/dL)	Glucose (mmol/L)	Lac (mmol/L)	Urea (mmol/L)
±5	±4.0	±2.5	±1.5	±2.0	±0.8 / ±14.0	±0.9 / ±16.0	±2.0	±3.0 / ±8.4
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
54 49-59	48.3 42.3-50.3	23.3 20.8-25.8	12.1 10.6-13.6	19.3 16.3-20.3	5.9 5.1-6.7	5.6 4.7-6.9	9.1 7.1-11.1	21.8 18.8-24.8

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## LEVEL 1

REF 0 3321 193001 (BP9097)

LOT 21421024

2014/08

Multi-Analyte Control for / Multianalyt-Kontrollmittel für / Contrôle multi-analyses pour / Control multiparamétrico para / Controllo multiparametrico per / Controllo multiparametrico para / Multianalyt-Kontrollmittel für / Multianalyse-kontrollmittel für / Multi-Parameter Control voor / Multiparametrisch-kontrollmiddel voor / Kontrolní materiál Multi-Analyte Control pro / Kontrola wieloparametrowa do / Multianalyt-kontrolli kätvõtteks / Tipunus Dälygus Multi-Analyte ysa / Multi-Analyt-Kontrolli / Multi-Analyte Control sa / 多項目測定用精度管理試料 / 多參數分析用試劑, 用于

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11716722059067041065000000000000



121161242731078086140170050060



13066080463543190240098128149189053069



1404806607311318824800000

pH	PCO <sub>2</sub> (kPa)	PO <sub>2</sub> (kPa)	Hb (g/dL)	SO <sub>2</sub> (%)	Na <sup>+</sup> (mmol/L)	K <sup>+</sup> (mmol/L)	Cl <sup>-</sup> (mmol/L)	Ca <sup>2+</sup> (mmol/L)
±0.03	±0.5 / ±4	±1.6 / ±12	±0.7 / ±0.4	±3.75	±4	±0.2	±4	±0.15
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
7.19 7.16-7.22	8.4 7.9-8.9	7.1 6.6-7.6	7.3 6.6-8.0	74.75 71.0-78.5	120 116-124	2.9 2.7-3.1	82 78-86	1.55 1.40-1.70
Hct (%)	O <sub>2</sub> Hb (%)	COHb (%)	Methb (%)	HbA <sub>1c</sub> (%)	BUN (mg/dL)	Glucose (mmol/L)	Lac (mmol/L)	Urea (mmol/L)
±5	±4.0	±2.5	±1.5	±2.0	±0.8 / ±14.0	±0.9 / ±16.0	±2.0	±3.0 / ±8.4
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
55 50-60	50.3 46.3-54.3	21.5 19.0-24.5	11.3 9.8-12.8	16.9 14.9-18.9	6.1 5.3-6.9	5.7 4.8-6.6	9.3 7.3-11.3	21.8 18.8-24.8

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## LEVEL 2

REF: 0321307001 (BP0606)

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2014/05

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Material Code  
101222142112405140BG Code  
11740746040046085109000000000000ISE Code  
121351434549096104107127035045COOX Code  
13115135708788084134044074084104116136MSS Code  
14018028023033058082000000

pH	PCO <sub>2</sub> (kPa) (mmHg)	PO <sub>2</sub> (kPa) (mmHg)	Hb (g/dL) (mmol/L)	SO <sub>2</sub> (%)	Na <sup>+</sup> (mmol/L)	K <sup>+</sup> (mmol/L)	Cl <sup>-</sup> (mmol/L)	Ca <sup>2+</sup> (mmol/L)
±0.03	±0.4 / ±3	±1.6 / ±12	±1.0 / ±0.8	±2.85	±4	±0.2	±4	±0.10
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
7.43 7.42-7.46	5.7 5.3-6.1	12.8 11.3-14.5	12.5 11.3-13.3	89.85 87.2-92.5	139 135-143	4.7 4.3-4.9	102 96-104	1.17 1.07-1.27
43 45-46	97 85-109	7.8 7.2-8.4						
Hct (%)	O <sub>2</sub> Hb (%)	COHb (%)	Methb (%)	Hlb (%)	Bil (mg/dL) (μmol/L)	Glu (mmol/L) (mg/dL)	Lac (mmol/L)	Urea (mmol/L) (mg/dL)
±5	±4.0	±2.5	±1.5	±2.0	±1.0 / ±17.0	±0.5 / ±9.0	±0.5	±1.2 / ±3.4
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
40 36-45	74.8 70.8-78.8	10.3 8.4-13.4	5.9 4.4-7.4	8.4 6.4-10.4	12.6 11.8-13.6	2.3 1.8-2.8	2.8 2.3-3.3	7.0 5.8-8.2
					215 196-232	41.4 32.4-50.4		18.8 16.2-23.0

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## COMBITROL PLUS B cobas®

## LEVEL 3

REF: 0321315001 (BP0606)

LOT: 21421220

2014/06

Multi-Analyte Control for Multianalyt-Kontrollmaterial für Kontrollen multi-analyses pour / Control multiparamétrico para / Control multiparametro per / Control multiparametrico para / Multianalytekontrol für / Multianalysekontrol für / Multi-Parameter Control voor / Multiparametrická kontrola pro / Kontrolní materiál Multi-Analyte Control pro / Kontrolis wieloparametrowa do / Multianalyt kontrolis kizozlalkijaz / Тестовый материал Много-Аналита про / Multi-Analit Kontrolis / Multi-Analyte Control sa / 多項目測定用精度管理試料 / 多参数分析用标准品, 用于

cobas b 221, Roche OMNI S

Bar coded value assignment - Target values / Barcodewerte-Zuordnung - Zielwerte / Attribution des valeurs de code-barres - Valeurs cibles / Asignación de valores de código de barras - Valores diana / Assegnazione dei valori del codice a barre - Valori teorici / Atribuição dos valores dos códigos de barras - Valores teóricos / Tildeling af barcodeværdier - Konfidensinterval / Tildeling av strekkodeværdier - Förelägnade värden / Strekkodeværdier - Målværdier / Tildeling waarden streepjescodes - Doelwaarden / Pírlizeti hodnot / Cílového kódu - Cílové hodnoty / Pírlizeti hodnot / Cílového kódu - Cílové hodnoty / Przykazna do wartosci zakodowanych w kodzie kreskowym - Wartości docelowe / Varsidulotit etnik-hozizondelate - Cilvēkvalis / Означения значений промаркированного материала - Аналоговые, теоретические / Баркодиза дегер беллиме - Hedef değeri / Приписывание на стойности с баркод - Приписани стойности / 予定値 - 標準値 / 表示目標値 - 目標値

Material Code  
101232142122006140BG Code  
11753759021027135159000000000000ISE Code  
121541626773116124048068023033COOX Code  
13193221881961098058004034005045205229MSS Code  
14181241010018015029000000

pH	PCO <sub>2</sub> (kPa) (mmHg)	PO <sub>2</sub> (kPa) (mmHg)	Hb (g/dL) (mmol/L)	SO <sub>2</sub> (%)	Na <sup>+</sup> (mmol/L)	K <sup>+</sup> (mmol/L)	Cl <sup>-</sup> (mmol/L)	Ca <sup>2+</sup> (mmol/L)
±0.03	±0.4 / ±3	±1.6 / ±12	±1.4 / ±0.9	±2.20	±4	±0.2	±4	±0.10
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
7.38 7.33-7.39	3.2 2.8-3.8	15.6 13.5-17.8	20.7 18.3-22.1	87.3 85.1-89.5	138 134-142	7.0 6.7-7.3	120 118-124	6.58 6.48-6.68
36 35-37	147 135-159	12.8 11.3-14.3						
Hct (%)	O <sub>2</sub> Hb (%)	COHb (%)	Methb (%)	Hlb (%)	Bil (mg/dL) (μmol/L)	Glu (mmol/L) (mg/dL)	Lac (mmol/L)	Urea (mmol/L) (mg/dL)
±5	±4.0	±2.5	±1.5	±2.0	±1.2 / ±21.0	±0.0 / ±54.1	±0.4	±0.7 / ±2.0
Mean(1) Range(2)	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range	Mean Range
38 33-43	82.1 68.1-96.1	3.4 1.8-5.8	1.8 0.4-3.4	2.5 0.8-4.5	21.7 20.5-22.9	21.1 18.1-24.1	1.8 1.0-1.8	2.2 1.5-2.9
					371 350-390	380.2 338.1-424.3		6.2 4.2-8.2

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QCs name		Combitrol PLUS B			Combitrol PLUS B			Combitrol PLUS B		
Level		Level 1			Level 2			Level 3		
LOT No.:		21421024			21421124			21421220		
Exp. Data:		31-08-2014			31.05.2014			30.06.2014		
Parameter:		COHb [%]			COHb [%]			COHb [%]		
Date	time	21.5 (mean)	Δ%	time	10.9 (mean)	Δ%	Time	3.4 (mean)	Δ%	
±2sd Range:		19.0-24.0			8.4-13.4			0.9-5.9		
2013-07-12	05:19	21.50	0.00				05:24	3.50	-2.94	
2013-07-13	02:22	21.50	0.00	02:16	11.00	-0.92				
2013-07-14	00:35	21.50	0.00	13:42	10.90	0.00	00:30	3.50	-2.94	
2013-07-15	05:29	21.50	0.00	05:53	11.00	-0.92	06:06	3.80	-11.76	
2013-07-16	01:02	21.60	-0.47	01:08	11.10	-1.83	01:21	3.60	-5.88	
2013-07-17	05:52	21.50	0.00	05:40	11.00	-0.92	05:33	3.50	-2.94	
2013-07-18	05:31	21.50	0.00	05:37	10.90	0.00	05:43	3.40	0.00	
2013-07-26	05:17	21.60	-0.47	05:22	11.00	-0.92				
2013-07-27	05:15	21.60	-0.47	05:10	11.00	-0.92	05:01	3.50	-2.94	
2013-07-28	05:22	21.50	0.00	05:12	11.00	-0.92	05:18	3.50	-2.94	
2013-07-29	05:58	21.50	0.00	06:03	10.90	0.00	06:49	3.50	-2.94	
2013-07-30	05:47	21.40	0.47	05:36	10.80	0.92	05:27	3.50	-2.94	
2013-07-31	06:06	21.40	0.47	05:57	10.90	0.00	05:52	3.50	-2.94	
2013-08-01	05:36	21.50	0.00	05:10	11.00	-0.92	05:32	3.50	-2.94	
2013-08-13	00:42	21.60	-0.47	00:47	11.00	-0.92	00:51	3.50	-2.94	
2013-08-14	06:04	21.60	-0.47	06:11	11.00	-0.92	06:15	3.50	-2.94	
2013-08-15	08:02	21.60	-0.47	08:16	11.00	-0.92	08:22	3.50	-2.94	
n		18.00								
average		21.5			-0.11					
SD		0.1								
CV%		0.31								
Average nominal										
%Δ										
New series of control Level 1										
Lot No.:		21421025			23.3 (mean)					
±2sd Range:		20.8-25.8								
2013-08-22	00:35	23.40	-0.43	00:43	10.90	0.00				
2013-08-23	05:47	23.30	0.00	05:52	10.90	0.00	05:57	3.50	-2.94	
2013-08-24	05:05	23.30	0.00	05:10	11.00	-0.92	05:19	3.50	-2.94	
2013-08-25	06:23	23.40	-0.43	06:28	11.00	-0.92	06:38	3.50	-2.94	
2013-08-26	00:50	23.40	-0.43	01:02	10.90	0.00	01:06	3.50	-2.94	
2013-08-27	06:24	23.30	0.00	06:19	10.90	0.00	06:28	3.50	-2.94	
2013-08-28	05:21	23.30	0.00	05:28	11.00	-0.92	05:35	3.50	-2.94	
2013-09-13	05:42	23.40	-0.43	05:50	11.00	-0.92	05:53	3.50	-2.94	
2013-09-14	05:40	23.40	-0.43	05:46	11.00	-0.92	05:52	3.50	-2.94	
2013-09-15	05:20	23.20	0.43	05:13	10.90	0.00	05:24	3.40	0.00	
2013-09-16	05:13	23.30	0.00	05:22	10.90	0.00	05:17	3.50	-2.94	
2013-09-17	05:54	23.40	-0.43	06:06	10.90	0.00	06:10	3.50	-2.94	
2013-09-18	05:14	23.40	-0.43	05:19	11.00	-0.92	05:25	3.50	-2.94	
2013-09-19	06:33	23.30	0.00	06:25	10.90	0.00	06:22	3.50	-2.94	
n		14.00			30.00			28.00		
average		23.34			-0.18			3.51		
SD		0.06			0.05			0.04		
CV%		0.28			0.47			1.10		
Δ average nominal										
%Δ										

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## 5. Summary of the Results

No. of expected samples	No. of received samples	No. of analysed samples	No. of discontinued subjects (samples not collected)
1690	1605	1604	85

5.1.1. 1<sup>st</sup> cohort

There were 280 of heparinized blood samples tested for COHb during the 1<sup>st</sup> cohort study. They were from a group of 28 subjects. 28 subjects finished the study with complete set of COHb results. There were no problems noted during the test performance.

The example copy of the result printout from the device is presented below.

Raport pomiarowy			
27.7.2013 09:51			
Numer serijny : 7263			
ID analizatora : cobas b221 ~S4~ (1)			
ID operatora : SYNEVO IHIT WARSZAWA			
Pract. Pat. ID			
ID pac. 0730163340			
Nazwisko			
Imię			
Oddział			
Typ próbki			
Typ krwi			
Wiek (A/F)			
Baro 1002.92 mbar			
pH	7.299 (-)	[ 7.350 - 7.450 ]	
PCO <sub>2</sub>	54.5 mmHg (+)	[ 35.0 - 45.0 ]	
PO <sub>2</sub>	59.9 mmHg (-)	[ 80.0 - 100.0 ]	
sHCO <sub>3</sub> <sup>-</sup>	26.1 mmol/L		
BE	-1.2 mmol/L		
SO <sub>2</sub> (o)	88.4 %		
COHb	4.4 % (+)	[ 0.5 - 2.5 ]	
Methb	0.7 %	[ 0.4 - 1.5 ]	
O.Hb	81.9 % (-)	[ 95.0 - 99.0 ]	
Ca <sup>2+</sup>	1.267 mmol/L	[ 1.120 - 1.320 ]	

Performance of the COHb testing in 1<sup>st</sup> cohort per visit presents [table 4](#) & [5a](#).

**Table 4.** Performance of the COHb test per visit per cohort.

Visit	1 st	2 nd	3 rd	4 th	5 th	Total
Day -1	28	35	34	35	37	169
Day 0	28	35	34	33	32	162
Day 1	28	35	34	31	32 *	160
Day 2	28	35	34	31	32	160
Day 3	28	34	34	31	32	159
Day 4	28	34	34	31	32	159
Day 5	112	136	136	124	128	636
<b>Total</b>	<b>280</b>	<b>344</b>	<b>340</b>	<b>316</b>	<b>325</b>	<b>1605</b>

\* one of the samples was invalid therefore the analyse was performed but no result was obtained.

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ConfidentialTable 5a: The register of the COHb result of the 1<sup>st</sup> cohort.

No.	Lab. No.	Subject	DBN	Visit No.	Collection data	Time	Result [%]
1	9730160510	0017	DB0817	DAY -1	2013 07 11	20:03	4.0
2	9730160520	0028	DB0482	DAY -1	2013 07 11	20:14	3.7
3	9730160530	0008	DB0307	DAY -1	2013 07 11	20:08	6.9
4	9730160540	0020	DB0446	DAY -1	2013 07 11	20:13	5.7
5	9730160550	0016	DB0772	DAY -1	2013 07 11	20:02	4.7
6	9730160790	0011	DB0487	DAY -1	2013 07 11	20:55	4.9
7	9730160800	0022	DB0698	DAY -1	2013 07 11	20:51	7.3
8	9730160810	0014	DB0391	DAY -1	2013 07 11	20:55	4.1
9	9730161670	0062	DB0789	DAY -1	2013 07 11	20:59	2.9
10	9730161700	0023	DB0456	DAY -1	2013 07 11	20:57	5.6
11	9730161710	0034	DB0511	DAY -1	2013 07 11	20:27	5.0
12	9730161720	0039	DB0763	DAY -1	2013 07 11	20:31	4.0
13	9730161740	0025	DB0239	DAY -1	2013 07 11	20:23	3.6
14	9730161790	0049	DB0808	DAY -1	2013 07 11	20:17	6.3
15	9730161810	0030	DB0860	DAY -1	2013 07 11	20:59	2.6
16	9730161870	0010	DB0436	DAY -1	2013 07 11	20:15	4.6
17	9730161890	0031	DB0149	DAY -1	2013 07 11	20:32	6.7
18	9730161900	0053	DB0826	DAY -1	2013 07 11	20:42	4.7
19	9730161910	0044	DB0254	DAY -1	2013 07 11	20:45	3.1
20	9730161920	0035	DB0510	DAY -1	2013 07 11	20:35	5.1
21	9730161940	0064	DB0678	DAY -1	2013 07 11	20:49	2.7
22	9730161970	0055	DB0815	DAY -1	2013 07 11	20:39	3.7
23	9730161980	0029	DB0443	DAY -1	2013 07 11	20:23	5.5
24	9730161990	0060	DB0849	DAY -1	2013 07 11	20:46	4.0
25	9730162000	0052	DB0810	DAY -1	2013 07 11	20:43	3.9
26	9730162020	0057	DB0803	DAY -1	2013 07 11	20:37	4.2
27	9730162100	0038	DB0837	DAY -1	2013 07 11	20:39	7.8
28	9730162110	0015	DB0485	DAY -1	2013 07 11	20:51	5.6
1	9730161470	0052	DB0810	DAY0	2013 07 12	20:35	5.5
2	9730161500	0055	DB0815	DAY0	2013 07 12	20:35	4.8
3	9730161510	0034	DB0511	DAY0	2013 07 12	20:21	4.9
4	9730161520	0030	DB0860	DAY0	2013 07 12	20:57	3.6
5	9730161540	0044	DB0254	DAY0	2013 07 12	20:38	3.6
6	9730161560	0053	DB0826	DAY0	2013 07 12	20:39	4.8
7	9730161570	0049	DB0808	DAY0	2013 07 12	20:16	8.5
8	9730161580	0022	DB0698	DAY0	2013 07 12	20:46	8.5
9	9730161640	0028	DB0482	DAY0	2013 07 12	20:08	4.4
10	9730161650	0023	DB0456	DAY0	2013 07 12	20:52	5.9
11	9730161660	0062	DB0789	DAY0	2013 07 12	20:54	3.5
12	9730161800	0025	DB0239	DAY0	2013 07 12	20:19	4.2
13	9730161840	0016	DB0772	DAY0	2013 07 12	20:02	5.8

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14	9730161860	0011	DB0487	DAY0	2013 07 12	20:50	3.6
15	9730161880	0015	DB0485	DAY0	2013 07 12	20:42	5.9
16	9730162030	0035	DB0510	DAY0	2013 07 12	20:31	4.7
17	9730162060	0020	DB0446	DAY0	2013 07 12	20:13	6.8
18	9730162080	0017	DB0817	DAY0	2013 07 12	20:05	6.2
19	9730162090	0038	DB0837	DAY0	2013 07 12	20:32	7.8
20	9730162120	0031	DB0149	DAY0	2013 07 12	20:26	9.3
21	9730162150	0010	DB0436	DAY0	2013 07 12	20:11	5.2
22	9730162170	0029	DB0443	DAY0	2013 07 12	20:17	7.4
23	9730162230	0039	DB0763	DAY0	2013 07 12	20:25	4.7
24	9730162250	0060	DB0849	DAY0	2013 07 12	20:40	4.6
25	9730162260	0014	DB0391	DAY0	2013 07 12	20:48	4.0
26	9730162270	0008	DB0307	DAY0	2013 07 12	20:08	7.4
27	9730162280	0064	DB0678	DAY0	2013 07 12	20:44	3.3
28	9730164440	0057	DB0803	DAY0	2013 07 12	20:27	4.7
1	9730160770	0017	DB0817	DAY1	2013 07 13	20:04	1.0
2	9730161380	0064	DB0678	DAY1	2013 07 13	20:42	2.7
3	9730161390	0044	DB0254	DAY1	2013 07 13	20:40	1.0
4	9730161400	0034	DB0511	DAY1	2013 07 13	20:20	1.1
5	9730161450	0015	DB0485	DAY1	2013 07 13	20:44	1.4
6	9730161460	0025	DB0239	DAY1	2013 07 13	20:18	4.8
7	9730161480	0028	DB0482	DAY1	2013 07 13	20:08	1.4
8	9730161490	0008	DB0307	DAY1	2013 07 13	20:06	1.5
9	9730161530	0020	DB0446	DAY1	2013 07 13	20:10	1.4
10	9730161600	0029	DB0443	DAY1	2013 07 13	20:14	5.2
11	9730161610	0014	DB0391	DAY1	2013 07 13	20:48	1.3
12	9730161620	0011	DB0487	DAY1	2013 07 13	20:51	1.1
13	9730161630	0049	DB0808	DAY1	2013 07 13	20:16	1.4
14	9730161690	0010	DB0436	DAY1	2013 07 13	20:12	1.4
15	9730161730	0016	DB0772	DAY1	2013 07 13	20:02	1.3
16	9730161750	0060	DB0849	DAY1	2013 07 13	20:40	1.2
17	9730161760	0052	DB0810	DAY1	2013 07 13	20:34	1.6
18	9730161770	0055	DB0815	DAY1	2013 07 13	20:32	3.8
19	9730161780	0030	DB0860	DAY1	2013 07 13	20:56	1.0
20	9730161820	0022	DB0698	DAY1	2013 07 13	20:46	1.4
21	9730161830	0053	DB0826	DAY1	2013 07 13	20:36	4.5
22	9730161850	0023	DB0456	DAY1	2013 07 13	20:52	1.2
23	9730161950	0031	DB0149	DAY1	2013 07 13	20:26	1.5
24	9730161960	0057	DB0803	DAY1	2013 07 13	20:24	1.2
25	9730162010	0038	DB0837	DAY1	2013 07 13	20:30	1.5
26	9730162040	0039	DB0763	DAY1	2013 07 13	20:22	1.1
27	9730162050	0035	DB0510	DAY1	2013 07 13	20:26	5.5
28	9730162190	0062	DB0789	DAY1	2013 07 13	20:54	1.0
1	9730160620	0030	DB0860	DAY2	2013 07 14	20:56	1.1
2	9730160780	0034	DB0511	DAY2	2013 07 14	20:20	1.1



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3	9730161010	0022	DB0698	DAY2	2013 07 14	20:46	1.1
4	9730161150	0016	DB0772	DAY2	2013 07 14	20:02	1.1
5	9730161160	0014	DB0391	DAY2	2013 07 14	20:48	1.2
6	9730161190	0011	DB0487	DAY2	2013 07 14	20:50	1.0
7	9730161220	0060	DB0849	DAY2	2013 07 14	20:40	1.1
8	9730161240	0044	DB0254	DAY2	2013 07 14	20:38	1.1
9	9730161260	0062	DB0789	DAY2	2013 07 14	20:54	1.0
10	9730161280	0023	DB0456	DAY2	2013 07 14	20:52	1.1
11	9730161300	0020	DB0446	DAY2	2013 07 14	20:10	1.2
12	9730161310	0064	DB0678	DAY2	2013 07 14	20:42	2.3
13	9730161320	0010	DB0436	DAY2	2013 07 14	20:12	1.0
14	9730161330	0015	DB0485	DAY2	2013 07 14	20:44	1.1
15	9730161340	0029	DB0443	DAY2	2013 07 14	20:14	5.4
16	9730161350	0049	DB0808	DAY2	2013 07 14	20:16	1.1
17	9730161360	0025	DB0239	DAY2	2013 07 14	20:18	4.8
18	9730161370	0055	DB0815	DAY2	2013 07 14	20:32	3.8
19	9730161430	0038	DB0837	DAY2	2013 07 14	20:30	1.2
20	9730161440	0052	DB0810	DAY2	2013 07 14	20:34	1.2
21	9730161550	0053	DB0826	DAY2	2013 07 14	20:36	4.5
22	9730161680	0031	DB0149	DAY2	2013 07 14	20:26	1.2
23	9730162130	0035	DB0510	DAY2	2013 07 14	20:28	4.4
24	9730162140	0039	DB0763	DAY2	2013 07 14	20:22	1.1
25	9730162160	0057	DB0803	DAY2	2013 07 14	20:24	1.1
26	9730162200	0008	DB0307	DAY2	2013 07 14	20:06	1.2
27	9730162210	0028	DB0482	DAY2	2013 07 14	20:08	1.0
28	9730162220	0017	DB0817	DAY2	2013 07 14	20:04	0.9
1	9730160950	0030	DB0860	DAY3	2013 07 15	20:56	1.0
2	9730160960	0023	DB0456	DAY3	2013 07 15	20:52	1.0
3	9730160970	0062	DB0789	DAY3	2013 07 15	20:54	1.0
4	9730160990	0011	DB0487	DAY3	2013 07 15	20:50	1.0
5	9730161020	0014	DB0391	DAY3	2013 07 15	20:48	1.2
6	9730161030	0055	DB0815	DAY3	2013 07 15	20:32	4.5
7	9730161040	0038	DB0837	DAY3	2013 07 15	20:30	1.2
8	9730161060	0044	DB0254	DAY3	2013 07 15	20:38	1.1
9	9730161080	0052	DB0810	DAY3	2013 07 15	20:34	1.1
10	9730161090	0022	DB0698	DAY3	2013 07 15	20:46	1.3
11	9730161100	0010	DB0436	DAY3	2013 07 15	20:12	1.0
12	9730161110	0029	DB0443	DAY3	2013 07 15	20:15	4.3
13	9730161130	0020	DB0446	DAY3	2013 07 15	20:10	1.2
14	9730161140	0053	DB0826	DAY3	2013 07 15	20:36	4.9
15	9730161170	0028	DB0482	DAY3	2013 07 15	20:08	1.0
16	9730161180	0025	DB0239	DAY3	2013 07 15	20:18	4.6
17	9730161200	0057	DB0803	DAY3	2013 07 15	20:24	1.1
18	9730161210	0049	DB0808	DAY3	2013 07 15	20:16	1.0
19	9730161230	0015	DB0485	DAY3	2013 07 15	20:40	1.1



Synevo Central Lab  
Confidential

20	9730161250	0039	DB0763	DAY3	2013 07 15	20:23	1.0
21	9730161270	0031	DB0149	DAY3	2013 07 15	20:26	1.1
22	9730161290	0034	DB0511	DAY3	2013 07 15	20:20	1.1
23	9730161410	0064	DB0678	DAY3	2013 07 15	20:42	2.6
24	9730161420	0060	DB0849	DAY3	2013 07 15	20:40	1.1
25	9730162180	0035	DB0510	DAY3	2013 07 15	20:28	4.6
26	9730162310	0008	DB0307	DAY3	2013 07 15	20:06	1.2
27	9730162330	0017	DB0817	DAY3	2013 07 15	20:04	0.9
28	9730162340	0016	DB0772	DAY3	2013 07 15	20:02	1.2
1	9730160650	0016	DB0772	DAY4	2013 07 16	20:02	1.1
2	9730160710	0039	DB0763	DAY4	2013 07 16	20:22	1.1
3	9730160720	0014	DB0391	DAY4	2013 07 16	20:48	1.1
4	9730160730	0044	DB0254	DAY4	2013 07 16	20:38	1.1
5	9730160740	0025	DB0239	DAY4	2013 07 16	20:18	4.8
6	9730160750	0060	DB0849	DAY4	2013 07 16	20:40	1.1
7	9730160760	0015	DB0485	DAY4	2013 07 16	20:44	1.0
8	9730160820	0064	DB0678	DAY4	2013 07 16	20:42	2.8
9	9730160830	0034	DB0511	DAY4	2013 07 16	20:20	1.1
10	9730160840	0022	DB0698	DAY4	2013 07 16	20:44	1.2
11	9730160850	0038	DB0837	DAY4	2013 07 16	20:30	1.1
12	9730160860	0035	DB0510	DAY4	2013 07 16	20:28	4.7
13	9730160870	0031	DB0149	DAY4	2013 07 16	20:26	1.1
14	9730160880	0052	DB0810	DAY4	2013 07 16	20:34	1.1
15	9730160890	0011	DB0487	DAY4	2013 07 16	20:50	1.0
16	9730160900	0023	DB0456	DAY4	2013 07 16	20:52	1.2
17	9730160910	0030	DB0860	DAY4	2013 07 16	20:56	1.0
18	9730160920	0055	DB0815	DAY4	2013 07 16	20:32	4.2
19	9730160930	0010	DB0436	DAY4	2013 07 16	20:12	1.0
20	9730160940	0053	DB0826	DAY4	2013 07 16	20:36	4.8
21	9730160980	0057	DB0803	DAY4	2013 07 16	20:24	1.0
22	9730161000	0029	DB0443	DAY4	2013 07 16	20:11	4.6
23	9730161050	0020	DB0446	DAY4	2013 07 16	20:09	1.2
24	9730161070	0062	DB0789	DAY4	2013 07 16	20:52	1.1
25	9730161120	0049	DB0808	DAY4	2013 07 16	20:16	1.0
26	9730162320	0017	DB0817	DAY4	2013 07 16	20:04	1.0
27	9730162370	0028	DB0482	DAY4	2013 07 16	20:10	1.0
28	9730162380	0008	DB0307	DAY4	2013 07 16	20:06	1.2
1	9730155160	0030	DB0860	DAY5	2013 07 17	06:49	1.0
2	9730155160	0030	DB0860	DAY5	2013 07 17	12:56	1.0
3	9730155160	0030	DB0860	DAY5	2013 07 17	16:51	1.0
4	9730155160	0030	DB0860	DAY5	2013 07 17	21:15	1.0
5	9730155200	0062	DB0789	DAY5	2013 07 17	08:18	1.2
6	9730155200	0062	DB0789	DAY5	2013 07 17	12:54	1.1
7	9730155200	0062	DB0789	DAY5	2013 07 17	16:50	1.0
8	9730155200	0062	DB0789	DAY5	2013 07 17	21:12	1.0

Synevo Central Lab  
Confidential

9	9730155240	0060	DB0849	DAY5	2013 07 17	06:33	1.2
10	9730155240	0060	DB0849	DAY5	2013 07 17	12:42	1.1
11	9730155240	0060	DB0849	DAY5	2013 07 17	16:35	1.2
12	9730155240	0060	DB0849	DAY5	2013 07 17	20:52	1.0
13	9730155280	0055	DB0815	DAY5	2013 07 17	06:24	2.7
14	9730155280	0055	DB0815	DAY5	2013 07 17	12:32	4.6
15	9730155280	0055	DB0815	DAY5	2013 07 17	16:27	4.5
16	9730155280	0055	DB0815	DAY5	2013 07 17	20:36	4.2
17	9730155320	0052	DB0810	DAY5	2013 07 17	08:16	1.1
18	9730155320	0052	DB0810	DAY5	2013 07 17	12:34	1.1
19	9730155320	0052	DB0810	DAY5	2013 07 17	16:29	1.1
20	9730155320	0052	DB0810	DAY5	2013 07 17	20:40	0.9
21	9730155360	0044	DB0254	DAY5	2013 07 17	06:30	1.1
22	9730155360	0044	DB0254	DAY5	2013 07 17	12:38	1.1
23	9730155360	0044	DB0254	DAY5	2013 07 17	16:33	1.0
24	9730155360	0044	DB0254	DAY5	2013 07 17	20:48	1.1
25	9730155400	0053	DB0826	DAY5	2013 07 17	06:29	2.6
26	9730155400	0053	DB0826	DAY5	2013 07 17	12:36	4.8
27	9730155400	0053	DB0826	DAY5	2013 07 17	16:31	3.9
28	9730155400	0053	DB0826	DAY5	2013 07 17	20:44	3.2
29	9730155440	0031	DB0149	DAY5	2013 07 17	06:46	1.0
30	9730155440	0031	DB0149	DAY5	2013 07 17	12:54	1.0
31	9730155440	0031	DB0149	DAY5	2013 07 17	16:49	1.0
32	9730155440	0031	DB0149	DAY5	2013 07 17	21:08	0.9
33	9730155480	0008	DB0307	DAY5	2013 07 17	06:26	1.2
34	9730155480	0008	DB0307	DAY5	2013 07 17	12:34	1.1
35	9730155480	0008	DB0307	DAY5	2013 07 17	16:30	1.2
36	9730155480	0008	DB0307	DAY5	2013 07 17	20:34	1.1
37	9730155520	0049	DB0808	DAY5	2013 07 17	08:15	1.0
38	9730155520	0049	DB0808	DAY5	2013 07 17	12:44	1.0
39	9730155520	0049	DB0808	DAY5	2013 07 17	16:42	1.1
40	9730155520	0049	DB0808	DAY5	2013 07 17	20:58	1.0
41	9730155560	0057	DB0803	DAY5	2013 07 17	06:44	0.9
42	9730155560	0057	DB0803	DAY5	2013 07 17	12:52	1.0
43	9730155560	0057	DB0803	DAY5	2013 07 17	16:47	0.9
44	9730155560	0057	DB0803	DAY5	2013 07 17	21:06	1.0
45	9730155600	0017	DB0817	DAY5	2013 07 17	08:12	1.0
46	9730155600	0017	DB0817	DAY5	2013 07 17	12:32	1.0
47	9730155600	0017	DB0817	DAY5	2013 07 17	16:27	1.0
48	9730155600	0017	DB0817	DAY5	2013 07 17	20:32	1.0
49	9730155640	0016	DB0772	DAY5	2013 07 17	06:22	1.2
50	9730155640	0016	DB0772	DAY5	2013 07 17	12:30	1.2
51	9730155640	0016	DB0772	DAY5	2013 07 17	16:25	1.2
52	9730155640	0016	DB0772	DAY5	2013 07 17	20:30	1.2
53	9730155680	0034	DB0511	DAY5	2013 07 17	06:40	0.9

Synevo Central Lab  
Confidential

54	9730155680	0034	DB0511	DAY5	2013 07 17	12:48	0.9
55	9730155680	0034	DB0511	DAY5	2013 07 17	16:50	0.9
56	9730155680	0034	DB0511	DAY5	2013 07 17	20:48	1.0
57	9730155720	0038	DB0837	DAY5	2013 07 17	06:22	1.2
58	9730155720	0038	DB0837	DAY5	2013 07 17	12:30	1.2
59	9730155720	0038	DB0837	DAY5	2013 07 17	16:25	1.1
60	9730155720	0038	DB0837	DAY5	2013 07 17	20:34	1.1
61	9730155760	0035	DB0510	DAY5	2013 07 17	06:48	3.4
62	9730155760	0035	DB0510	DAY5	2013 07 17	12:56	5.0
63	9730155760	0035	DB0510	DAY5	2013 07 17	16:57	4.7
64	9730155760	0035	DB0510	DAY5	2013 07 17	21:13	4.1
65	9730155800	0025	DB0239	DAY5	2013 07 17	06:38	2.5
66	9730155800	0025	DB0239	DAY5	2013 07 17	12:46	6.4
67	9730155800	0025	DB0239	DAY5	2013 07 17	16:42	5.8
68	9730155800	0025	DB0239	DAY5	2013 07 17	21:03	5.8
69	9730155840	0010	DB0436	DAY5	2013 07 17	08:16	1.1
70	9730155840	0010	DB0436	DAY5	2013 07 17	12:40	1.0
71	9730155840	0010	DB0436	DAY5	2013 07 17	16:37	1.1
72	9730155840	0010	DB0436	DAY5	2013 07 17	20:51	1.0
73	9730155880	0029	DB0443	DAY5	2013 07 17	06:37	2.7
74	9730155880	0029	DB0443	DAY5	2013 07 17	12:42	5.3
75	9730155880	0029	DB0443	DAY5	2013 07 17	16:40	5.0
76	9730155880	0029	DB0443	DAY5	2013 07 17	20:56	5.2
77	9730155920	0028	DB0482	DAY5	2013 07 17	08:13	1.1
78	9730155920	0028	DB0482	DAY5	2013 07 17	12:36	1.0
79	9730155920	0028	DB0482	DAY5	2013 07 17	16:31	1.2
80	9730155920	0028	DB0482	DAY5	2013 07 17	20:41	1.1
81	9730155960	0023	DB0456	DAY5	2013 07 17	06:45	1.2
82	9730155960	0023	DB0456	DAY5	2013 07 17	12:53	1.2
83	9730155960	0023	DB0456	DAY5	2013 07 17	16:47	1.1
84	9730155960	0023	DB0456	DAY5	2013 07 17	21:11	1.0
85	9730156000	0039	DB0763	DAY5	2013 07 17	06:42	0.9
86	9730156000	0039	DB0763	DAY5	2013 07 17	12:50	0.9
87	9730156000	0039	DB0763	DAY5	2013 07 17	16:46	1.0
88	9730156000	0039	DB0763	DAY5	2013 07 17	21:00	1.0
89	9730156040	0014	DB0391	DAY5	2013 07 17	06:40	1.1
90	9730156040	0014	DB0391	DAY5	2013 07 17	12:48	1.1
91	9730156040	0014	DB0391	DAY5	2013 07 17	16:44	1.1
92	9730156040	0014	DB0391	DAY5	2013 07 17	21:06	1.1
93	9730156080	0020	DB0446	DAY5	2013 07 17	06:33	1.2
94	9730156080	0020	DB0446	DAY5	2013 07 17	12:38	1.1
95	9730156080	0020	DB0446	DAY5	2013 07 17	16:43	1.2
96	9730156080	0020	DB0446	DAY5	2013 07 17	20:46	1.1
97	9730156120	0015	DB0485	DAY5	2013 07 17	08:17	1.2
98	9730156120	0015	DB0485	DAY5	2013 07 17	12:46	1.0

Synevo Central Lab  
Confidential

99	9730156120	0015	DB0485	DAY5	2013 07 17	16:39	1.0
100	9730156120	0015	DB0485	DAY5	2013 07 17	21:00	1.1
101	9730156160	0011	DB0487	DAY5	2013 07 17	06:43	1.1
102	9730156160	0011	DB0487	DAY5	2013 07 17	12:50	1.0
103	9730156160	0011	DB0487	DAY5	2013 07 17	16:45	1.0
104	9730156160	0011	DB0487	DAY5	2013 07 17	21:09	1.1
105	9730156200	0022	DB0698	DAY5	2013 07 17	06:39	1.3
106	9730156200	0022	DB0698	DAY5	2013 07 17	12:46	1.1
107	9730156200	0022	DB0698	DAY5	2013 07 17	16:41	1.1
108	9730156200	0022	DB0698	DAY5	2013 07 17	21:05	1.2
109	9730156240	0064	DB0678	DAY5	2013 07 17	06:34	1.9
110	9730156240	0064	DB0678	DAY5	2013 07 17	12:42	2.8
111	9730156240	0064	DB0678	DAY5	2013 07 17	16:37	2.7
112	9730156240	0064	DB0678	DAY5	2013 07 17	20:56	2.8

### 5.1.2. 2<sup>nd</sup> cohort

During the 2<sup>nd</sup> cohort study 344 of blood samples were tested totally for COHb. 34 subjects participated to the 2<sup>nd</sup> cohort.

34 subjects terminated the study with full set of the COHb determinations and 1 subject - 0085 was rejected from the study because of personal reason.

There were no problems noted during the test performance.

COHb test performance per visit presents [table 5b](#) of the report.

**Table 5b:** The register of the COHb result of the 2<sup>nd</sup> cohort.

No.	Lab. No.	Subject	DBN	Visit No.	Collection data	Time	Result [%]
1	9730162770	0066	DB0596	DAY -1	2013 07 25	20:40	4.0
2	9730163170	0080	DB0139	DAY -1	2013 07 25	21:04	4.6
3	9730163500	0086	DB0867	DAY -1	2013 07 25	20:28	4.8
4	9730163560	0037	DB0774	DAY -1	2013 07 25	20:26	5.2
5	9730163570	0117	DB0675	DAY -1	2013 07 25	20:05	3.9
6	9730163630	0122	DB0539	DAY -1	2013 07 25	21:08	4.5
7	9730163640	0093	DB0804	DAY -1	2013 07 25	20:22	4.3
8	9730163670	0001	DB0560	DAY -1	2013 07 25	21:10	4.3
9	9730163710	0090	DB0134	DAY -1	2013 07 25	20:24	3.4
10	9730163750	0104	DB0799	DAY -1	2013 07 25	20:03	2.6
11	9730163800	0112	DB0897	DAY -1	2013 07 25	21:06	3.8
12	9730163810	0042	DB0781	DAY -1	2013 07 25	20:50	4.4
13	9730163870	0021	DB0567	DAY -1	2013 07 25	20:58	3.1
14	9730164140	0063	DB0304	DAY -1	2013 07 25	20:42	6.0
15	9730164260	0106	DB0845	DAY -1	2013 07 25	20:34	3.3

Synevo Central Lab  
Confidential

16	9730164270	0051	DB0812	DAY -1	2013 07 25	20:30	3.3
17	9730164310	0121	DB0488	DAY -1	2013 07 25	20:32	3.5
18	9730164330	0013	DB0088	DAY -1	2013 07 25	20:56	5.2
19	9730164340	0067	DB0644	DAY -1	2013 07 25	20:38	3.9
20	9730164360	0114	DB0934	DAY -1	2013 07 25	20:54	3.9
21	9730164370	0071	DB0650	DAY -1	2013 07 25	20:48	6.0
22	9730164380	0072	DB0313	DAY -1	2013 07 25	20:18	4.5
23	9730164390	0123	DB0489	DAY -1	2013 07 25	20:36	2.6
24	9730164400	0085	DB0762	DAY -1	2013 07 25	20:44	2.2
25	9730164410	0069	DB0044	DAY -1	2013 07 25	20:52	4.9
26	9730164420	0088	DB0831	DAY -1	2013 07 25	20:46	3.5
27	9730164430	0087	DB0479	DAY -1	2013 07 25	20:14	3.2
28	9730164450	0074	DB0312	DAY -1	2013 07 25	20:20	4.7
29	9730164460	0110	DB0538	DAY -1	2013 07 25	20:04	4.6
30	9730164470	0118	DB0637	DAY -1	2013 07 25	21:00	4.4
31	9730164480	0107	DB0569	DAY -1	2013 07 25	21:02	5.1
32	9730164490	0083	DB0839	DAY -1	2013 07 25	20:08	4.9
33	9730164500	0105	DB0168	DAY -1	2013 07 25	20:16	4.3
34	9730164510	0076	DB0110	DAY -1	2013 07 25	20:10	3.4
35	9730164520	0004	DB0480	DAY -1	2013 07 25	20:12	3.0
1	9730162690	0122	DB0539	DAY0	2013 07 26	21:08	5.1
2	9730162890	0069	DB0044	DAY0	2013 07 26	20:52	5.9
3	9730163200	0118	DB0637	DAY0	2013 07 26	21:00	6.7
4	9730163260	0067	DB0644	DAY0	2013 07 26	20:38	4.9
5	9730163280	0121	DB0488	DAY0	2013 07 26	20:32	3.8
6	9730163340	0106	DB0845	DAY0	2013 07 26	20:34	4.4
7	9730163350	0051	DB0812	DAY0	2013 07 26	20:30	3.9
8	9730163380	0086	DB0867	DAY0	2013 07 26	20:28	5.0
9	9730163410	0066	DB0596	DAY0	2013 07 26	20:40	6.3
10	9730163430	0063	DB0304	DAY0	2013 07 26	20:42	5.2
11	9730163490	0104	DB0799	DAY0	2013 07 26	20:04	3.5
12	9730163530	0110	DB0538	DAY0	2013 07 26	20:04	6.7
13	9730163550	0117	DB0675	DAY0	2013 07 26	20:06	3.5
14	9730163590	0114	DB0934	DAY0	2013 07 26	20:54	5.1
15	9730163760	0107	DB0569	DAY0	2013 07 26	21:02	6.4
16	9730163820	0001	DB0560	DAY0	2013 07 26	21:10	4.4
17	9730163950	0076	DB0110	DAY0	2013 07 26	20:10	4.7
18	9730163990	0072	DB0313	DAY0	2013 07 26	20:18	6.2
19	9730164010	0090	DB0134	DAY0	2013 07 26	20:24	3.9
20	9730164020	0112	DB0897	DAY0	2013 07 26	21:06	5.2
21	9730164030	0037	DB0774	DAY0	2013 07 26	20:26	7.5
22	9730164040	0093	DB0804	DAY0	2013 07 26	20:24	5.7
23	9730164090	0087	DB0479	DAY0	2013 07 26	20:14	4.8
24	9730164110	0123	DB0489	DAY0	2013 07 26	20:36	4.7
25	9730164130	0004	DB0480	DAY0	2013 07 26	20:12	4.5

Synevo Central Lab  
Confidential

26	9730164150	0021	DB0567	DAY0	2013 07 26	20:58	4.1
27	9730164160	0074	DB0312	DAY0	2013 07 26	20:20	6.2
28	9730164170	0083	DB0839	DAY0	2013 07 26	20:08	4.1
29	9730164180	0088	DB0831	DAY0	2013 07 26	20:46	3.1
30	9730164190	0105	DB0168	DAY0	2013 07 26	20:16	5.4
31	9730164200	0080	DB0139	DAY0	2013 07 26	21:04	6.8
32	9730164220	0071	DB0650	DAY0	2013 07 26	20:48	6.8
33	9730164230	0085	DB0762	DAY0	2013 07 26	20:44	2.4
34	9730164280	0042	DB0781	DAY0	2013 07 26	20:50	4.2
35	9730164300	0013	DB0088	DAY0	2013 07 26	20:56	7.4
1	9730162660	0069	DB0044	DAY1	2013 07 27	20:52	1.2
2	9730162870	0104	DB0799	DAY1	2013 07 27	20:03	1.2
3	9730163160	0105	DB0168	DAY1	2013 07 27	20:16	4.6
4	9730163210	0071	DB0650	DAY1	2013 07 27	20:48	1.2
5	9730163240	0112	DB0897	DAY1	2013 07 27	21:06	1.2
6	9730163290	0107	DB0569	DAY1	2013 07 27	21:02	1.2
7	9730163460	0090	DB0134	DAY1	2013 07 27	20:24	1.2
8	9730163470	0088	DB0831	DAY1	2013 07 27	20:46	1.0
9	9730163480	0074	DB0312	DAY1	2013 07 27	20:20	1.4
10	9730163510	0004	DB0480	DAY1	2013 07 27	20:12	1.2
11	9730163600	0083	DB0839	DAY1	2013 07 27	20:08	1.3
12	9730163680	0110	DB0538	DAY1	2013 07 27	20:04	1.0
13	9730163720	0086	DB0867	DAY1	2013 07 27	20:28	1.2
14	9730163860	0080	DB0139	DAY1	2013 07 27	21:05	5.6
15	9730163880	0067	DB0644	DAY1	2013 07 27	20:38	2.7
16	9730163890	0093	DB0804	DAY1	2013 07 27	20:22	1.2
17	9730163900	0087	DB0479	DAY1	2013 07 27	20:14	4.0
18	9730163910	0072	DB0313	DAY1	2013 07 27	20:18	5.6
19	9730163920	0085	DB0762	DAY1	2013 07 27	20:44	1.1
20	9730163930	0037	DB0774	DAY1	2013 07 27	20:26	6.9
21	9730163940	0114	DB0934	DAY1	2013 07 27	20:54	1.5
22	9730163960	0001	DB0560	DAY1	2013 07 27	21:11	1.2
23	9730163970	0123	DB0489	DAY1	2013 07 27	20:36	1.1
24	9730163980	0066	DB0596	DAY1	2013 07 27	20:40	1.3
25	9730164000	0121	DB0488	DAY1	2013 07 27	20:33	2.9
26	9730164050	0021	DB0567	DAY1	2013 07 27	20:58	1.4
27	9730164060	0051	DB0812	DAY1	2013 07 27	20:35	1.1
28	9730164070	0042	DB0781	DAY1	2013 07 27	20:50	3.3
29	9730164080	0076	DB0110	DAY1	2013 07 27	20:10	1.5
30	9730164100	0117	DB0675	DAY1	2013 07 27	20:06	4.7
31	9730164120	0013	DB0088	DAY1	2013 07 27	20:56	1.2
32	9730164210	0106	DB0845	DAY1	2013 07 27	20:36	1.0
33	9730164240	0063	DB0304	DAY1	2013 07 27	20:42	1.2
34	9730164250	0122	DB0539	DAY1	2013 07 27	21:09	1.3
35	9730164290	0118	DB0637	DAY1	2013 07 27	21:00	5.1

Synevo Central Lab  
Confidential

1	9730162500	0107	DB0569	DAY2	2013 07 28	21:02	1.1
2	9730162520	0121	DB0488	DAY2	2013 07 28	20:32	3.7
3	9730162720	0069	DB0044	DAY2	2013 07 28	20:52	1.0
4	9730162740	0083	DB0839	DAY2	2013 07 28	20:08	1.2
5	9730162880	0013	DB0088	DAY2	2013 07 28	20:56	1.0
6	9730162950	0001	DB0560	DAY2	2013 07 28	21:10	1.1
7	9730163060	0086	DB0867	DAY2	2013 07 28	20:28	1.1
8	9730163090	0088	DB0831	DAY2	2013 07 28	20:46	1.0
9	9730163100	0071	DB0650	DAY2	2013 07 28	20:48	1.1
10	9730163120	0118	DB0637	DAY2	2013 07 28	21:00	4.4
11	9730163140	0090	DB0134	DAY2	2013 07 28	20:24	1.1
12	9730163150	0072	DB0313	DAY2	2013 07 28	20:18	5.7
13	9730163180	0112	DB0897	DAY2	2013 07 28	21:06	1.1
14	9730163300	0114	DB0934	DAY2	2013 07 28	20:54	1.0
15	9730163320	0004	DB0480	DAY2	2013 07 28	20:12	1.1
16	9730163390	0037	DB0774	DAY2	2013 07 28	20:27	6.1
17	9730163400	0051	DB0812	DAY2	2013 07 28	20:30	0.9
18	9730163420	0021	DB0567	DAY2	2013 07 28	20:58	1.2
19	9730163440	0063	DB0304	DAY2	2013 07 28	20:42	1.0
20	9730163450	0104	DB0799	DAY2	2013 07 28	20:02	1.0
21	9730163520	0093	DB0804	DAY2	2013 07 28	20:23	1.1
22	9730163540	0105	DB0168	DAY2	2013 07 28	20:16	5.0
23	9730163610	0042	DB0781	DAY2	2013 07 28	20:50	4.3
24	9730163620	0110	DB0538	DAY2	2013 07 28	20:04	0.8
25	9730163650	0122	DB0539	DAY2	2013 07 28	21:08	1.1
26	9730163660	0123	DB0489	DAY2	2013 07 28	20:36	1.0
27	9730163690	0074	DB0312	DAY2	2013 07 28	20:20	1.2
28	9730163700	0085	DB0762	DAY2	2013 07 28	20:44	1.1
29	9730163730	0117	DB0675	DAY2	2013 07 28	20:06	4.4
30	9730163740	0080	DB0139	DAY2	2013 07 28	21:04	7.7
31	9730163770	0106	DB0845	DAY2	2013 07 28	20:34	1.0
32	9730163780	0087	DB0479	DAY2	2013 07 28	20:14	4.1
33	9730163790	0067	DB0644	DAY2	2013 07 28	20:38	3.1
34	9730163830	0066	DB0596	DAY2	2013 07 28	20:40	1.0
35	9730163840	0076	DB0110	DAY2	2013 07 28	20:10	1.2
1	9730162300	0051	DB0812	DAY3	2013 07 29	20:30	1.0
2	9730162350	0106	DB0845	DAY3	2013 07 29	20:34	0.9
3	9730162430	0123	DB0489	DAY3	2013 07 29	20:36	1.0
4	9730162460	0122	DB0539	DAY3	2013 07 29	21:08	1.2
5	9730162480	0121	DB0488	DAY3	2013 07 29	20:32	3.4
6	9730162570	0037	DB0774	DAY3	2013 07 29	20:26	6.6
7	9730162590	0088	DB0831	DAY3	2013 07 29	20:46	1.0
8	9730162620	0090	DB0134	DAY3	2013 07 29	20:24	1.1
9	9730162680	0104	DB0799	DAY3	2013 07 29	20:02	1.0
10	9730162700	0087	DB0479	DAY3	2013 07 29	20:14	4.0

Synevo Central Lab  
Confidential

11	9730162710	0086	DB0867	DAY3	2013 07 29	20:28	1.1
12	9730162730	0004	DB0480	DAY3	2013 07 29	20:12	1.2
13	9730162760	0114	DB0934	DAY3	2013 07 29	20:54	1.1
14	9730162840	0066	DB0596	DAY3	2013 07 29	20:40	1.1
15	9730162850	0080	DB0139	DAY3	2013 07 29	21:04	6.1
16	9730162910	0110	DB0538	DAY3	2013 07 29	20:04	0.8
17	9730162920	0001	DB0560	DAY3	2013 07 29	21:10	1.1
18	9730162930	0112	DB0897	DAY3	2013 07 29	21:06	1.0
19	9730162940	0105	DB0168	DAY3	2013 07 29	20:16	4.6
20	9730162990	0107	DB0569	DAY3	2013 07 29	21:02	1.0
21	9730163050	0117	DB0675	DAY3	2013 07 29	20:06	5.3
22	9730163070	0063	DB0304	DAY3	2013 07 29	20:42	1.0
23	9730163110	0083	DB0839	DAY3	2013 07 29	20:08	1.0
24	9730163130	0072	DB0313	DAY3	2013 07 29	20:18	5.6
25	9730163190	0093	DB0804	DAY3	2013 07 29	20:22	1.2
26	9730163220	0042	DB0781	DAY3	2013 07 29	20:50	4.5
27	9730163230	0069	DB0044	DAY3	2013 07 29	20:52	1.0
28	9730163250	0118	DB0637	DAY3	2013 07 29	21:00	4.9
29	9730163270	0013	DB0088	DAY3	2013 07 29	20:56	0.9
30	9730163310	0076	DB0110	DAY3	2013 07 29	20:10	1.2
31	9730163330	0021	DB0567	DAY3	2013 07 29	20:58	1.2
32	9730163360	0071	DB0650	DAY3	2013 07 29	20:48	1.0
33	9730163370	0074	DB0312	DAY3	2013 07 29	20:20	1.1
34	9730163850	0067	DB0644	DAY3	2013 07 29	20:38	3.0
1	9730162240	0104	DB0799	DAY4	2013 07 30	20:02	1.0
2	9730162420	0123	DB0489	DAY4	2013 07 30	20:36	1.0
3	9730162440	0117	DB0675	DAY4	2013 07 30	20:06	4.8
4	9730162450	0118	DB0637	DAY4	2013 07 30	21:00	5.4
5	9730162470	0112	DB0897	DAY4	2013 07 30	21:06	1.0
6	9730162490	0080	DB0139	DAY4	2013 07 30	21:04	6.2
7	9730162530	0107	DB0569	DAY4	2013 07 30	21:02	1.2
8	9730162540	0072	DB0313	DAY4	2013 07 30	20:18	6.1
9	9730162550	0114	DB0934	DAY4	2013 07 30	20:54	1.2
10	9730162560	0069	DB0044	DAY4	2013 07 30	20:52	1.0
11	9730162580	0066	DB0596	DAY4	2013 07 30	20:40	1.0
12	9730162600	0088	DB0831	DAY4	2013 07 30	20:46	1.1
13	9730162610	0051	DB0812	DAY4	2013 07 30	20:30	1.0
14	9730162630	0037	DB0774	DAY4	2013 07 30	20:26	6.9
15	9730162640	0063	DB0304	DAY4	2013 07 30	20:42	1.0
16	9730162650	0122	DB0539	DAY4	2013 07 30	21:08	1.2
17	9730162670	0013	DB0088	DAY4	2013 07 30	20:56	0.9
18	9730162750	0042	DB0781	DAY4	2013 07 30	20:50	4.8
19	9730162780	0083	DB0839	DAY4	2013 07 30	20:08	0.9
20	9730162790	0071	DB0650	DAY4	2013 07 30	20:48	1.2
21	9730162810	0086	DB0867	DAY4	2013 07 30	20:28	1.2



Synevo Central Lab  
Confidential

22	9730162820	0021	DB0567	DAY4	2013 07 30	20:58	1.1
23	9730162830	0074	DB0312	DAY4	2013 07 30	20:20	1.1
24	9730162860	0121	DB0488	DAY4	2013 07 30	20:32	3.3
25	9730162900	0105	DB0168	DAY4	2013 07 30	20:16	5.4
26	9730162960	0106	DB0845	DAY4	2013 07 30	20:34	0.9
27	9730162970	0087	DB0479	DAY4	2013 07 30	20:14	3.8
28	9730162980	0076	DB0110	DAY4	2013 07 30	20:10	1.1
29	9730163000	0001	DB0560	DAY4	2013 07 30	21:10	1.3
30	9730163010	0090	DB0134	DAY4	2013 07 30	20:24	1.1
31	9730163020	0093	DB0804	DAY4	2013 07 30	20:22	1.2
32	9730163030	0004	DB0480	DAY4	2013 07 30	20:12	1.1
33	9730163040	0067	DB0644	DAY4	2013 07 30	20:38	3.6
34	9730163080	0110	DB0538	DAY4	2013 07 30	20:04	1.0
1	9730156280	0074	DB0312	DAY5	2013 07 31	06:40	1.2
2	9730156280	0074	DB0312	DAY5	2013 07 31	12:48	1.2
3	9730156280	0074	DB0312	DAY5	2013 07 31	16:48	1.2
4	9730156280	0074	DB0312	DAY5	2013 07 31	20:48	1.1
5	9730156320	0087	DB0479	DAY5	2013 07 31	06:34	2.3
6	9730156320	0087	DB0479	DAY5	2013 07 31	12:42	3.9
7	9730156320	0087	DB0479	DAY5	2013 07 31	16:42	4.8
8	9730156320	0087	DB0479	DAY5	2013 07 31	20:42	4.8
9	9730156360	0076	DB0110	DAY5	2013 07 31	08:38	1.2
10	9730156360	0076	DB0110	DAY5	2013 07 31	12:38	1.3
11	9730156360	0076	DB0110	DAY5	2013 07 31	16:38	1.1
12	9730156360	0076	DB0110	DAY5	2013 07 31	20:38	1.2
13	9730156400	0004	DB0480	DAY5	2013 07 31	06:32	1.2
14	9730156400	0004	DB0480	DAY5	2013 07 31	12:40	1.2
15	9730156400	0004	DB0480	DAY5	2013 07 31	16:40	1.1
16	9730156400	0004	DB0480	DAY5	2013 07 31	20:40	1.1
17	9730156440	0083	DB0839	DAY5	2013 07 31	06:28	1.1
18	9730156440	0083	DB0839	DAY5	2013 07 31	12:36	1.1
19	9730156440	0083	DB0839	DAY5	2013 07 31	16:36	1.1
20	9730156440	0083	DB0839	DAY5	2013 07 31	20:36	1.1
21	9730156480	0117	DB0675	DAY5	2013 07 31	06:26	3.3
22	9730156480	0117	DB0675	DAY5	2013 07 31	12:34	4.4
23	9730156480	0117	DB0675	DAY5	2013 07 31	16:34	5.3
24	9730156480	0117	DB0675	DAY5	2013 07 31	20:34	5.7
25	9730156520	0090	DB0134	DAY5	2013 07 31	06:46	1.1
26	9730156520	0090	DB0134	DAY5	2013 07 31	12:52	1.1
27	9730156520	0090	DB0134	DAY5	2013 07 31	16:52	1.1
28	9730156520	0090	DB0134	DAY5	2013 07 31	20:52	1.1
29	9730156560	0051	DB0812	DAY5	2013 07 31	08:58	1.1
30	9730156560	0051	DB0812	DAY5	2013 07 31	12:58	1.0
31	9730156560	0051	DB0812	DAY5	2013 07 31	16:58	1.0
32	9730156560	0051	DB0812	DAY5	2013 07 31	20:58	0.9

Synevo Central Lab  
Confidential

33	9730156600	0093	DB0804	DAY5	2013 07 31	06:42	1.3
34	9730156600	0093	DB0804	DAY5	2013 07 31	12:50	1.2
35	9730156600	0093	DB0804	DAY5	2013 07 31	16:50	1.1
36	9730156600	0093	DB0804	DAY5	2013 07 31	20:50	1.2
37	9730156640	0072	DB0313	DAY5	2013 07 31	06:38	4.6
38	9730156640	0072	DB0313	DAY5	2013 07 31	12:46	6.7
39	9730156640	0072	DB0313	DAY5	2013 07 31	16:46	6.3
40	9730156640	0072	DB0313	DAY5	2013 07 31	20:46	6.1
41	9730156680	0105	DB0168	DAY5	2013 07 31	06:36	2.7
42	9730156680	0105	DB0168	DAY5	2013 07 31	12:44	5.8
43	9730156680	0105	DB0168	DAY5	2013 07 31	16:44	6.3
44	9730156680	0105	DB0168	DAY5	2013 07 31	20:44	6.7
45	9730156720	0104	DB0799	DAY5	2013 07 31	08:30	1.1
46	9730156720	0104	DB0799	DAY5	2013 07 31	12:30	1.0
47	9730156720	0104	DB0799	DAY5	2013 07 31	16:30	1.0
48	9730156720	0104	DB0799	DAY5	2013 07 31	20:30	1.0
49	9730156760	0110	DB0538	DAY5	2013 07 31	06:24	1.0
50	9730156760	0110	DB0538	DAY5	2013 07 31	12:32	1.0
51	9730156760	0110	DB0538	DAY5	2013 07 31	16:32	0.9
52	9730156760	0110	DB0538	DAY5	2013 07 31	20:38	0.9
53	9730156800	0123	DB0489	DAY5	2013 07 31	09:04	1.1
54	9730156800	0123	DB0489	DAY5	2013 07 31	13:04	1.1
55	9730156800	0123	DB0489	DAY5	2013 07 31	17:04	1.1
56	9730156800	0123	DB0489	DAY5	2013 07 31	21:04	1.1
57	9730156840	0114	DB0934	DAY5	2013 07 31	08:46	1.1
58	9730156840	0114	DB0934	DAY5	2013 07 31	12:46	1.1
59	9730156840	0114	DB0934	DAY5	2013 07 31	16:46	1.1
60	9730156840	0114	DB0934	DAY5	2013 07 31	20:46	1.1
61	9730156880	0042	DB0781	DAY5	2013 07 31	06:35	2.8
62	9730156880	0042	DB0781	DAY5	2013 07 31	12:42	4.8
63	9730156880	0042	DB0781	DAY5	2013 07 31	16:42	5.0
64	9730156880	0042	DB0781	DAY5	2013 07 31	20:42	5.1
65	9730156920	0121	DB0488	DAY5	2013 07 31	06:52	2.3
66	9730156920	0121	DB0488	DAY5	2013 07 31	13:00	3.2
67	9730156920	0121	DB0488	DAY5	2013 07 31	17:00	3.6
68	9730156920	0121	DB0488	DAY5	2013 07 31	21:00	2.8
69	9730156960	0066	DB0596	DAY5	2013 07 31	06:24	1.0
70	9730156960	0066	DB0596	DAY5	2013 07 31	12:32	1.1
71	9730156960	0066	DB0596	DAY5	2013 07 31	16:32	1.0
72	9730156960	0066	DB0596	DAY5	2013 07 31	20:32	1.0
73	9730157000	0088	DB0831	DAY5	2013 07 31	06:30	1.1
74	9730157000	0088	DB0831	DAY5	2013 07 31	12:38	1.1
75	9730157000	0088	DB0831	DAY5	2013 07 31	16:38	0.9
76	9730157000	0088	DB0831	DAY5	2013 07 31	20:38	1.0
77	9730157040	0067	DB0644	DAY5	2013 07 31	06:22	2.5

Synevo Central Lab  
Confidential

78	9730157040	0067	DB0644	DAY5	2013 07 31	12:32	3.3
79	9730157040	0067	DB0644	DAY5	2013 07 31	16:30	3.6
80	9730157040	0067	DB0644	DAY5	2013 07 31	20:30	2.8
81	9730157120	0063	DB0304	DAY5	2013 07 31	08:34	1.1
82	9730157120	0063	DB0304	DAY5	2013 07 31	12:34	1.2
83	9730157120	0063	DB0304	DAY5	2013 07 31	16:34	1.0
84	9730157120	0063	DB0304	DAY5	2013 07 31	20:34	1.1
85	9730157160	0071	DB0650	DAY5	2013 07 31	08:40	1.1
86	9730157160	0071	DB0650	DAY5	2013 07 31	12:40	1.1
87	9730157160	0071	DB0650	DAY5	2013 07 31	16:40	1.1
88	9730157160	0071	DB0650	DAY5	2013 07 31	20:40	1.1
89	9730157200	0086	DB0867	DAY5	2013 07 31	08:56	1.2
90	9730157200	0086	DB0867	DAY5	2013 07 31	12:56	1.1
91	9730157200	0086	DB0867	DAY5	2013 07 31	16:56	1.0
92	9730157200	0086	DB0867	DAY5	2013 07 31	20:56	1.1
93	9730157240	0118	DB0637	DAY5	2013 07 31	06:44	2.5
94	9730157240	0118	DB0637	DAY5	2013 07 31	12:52	5.2
95	9730157240	0118	DB0637	DAY5	2013 07 31	16:52	5.4
96	9730157240	0118	DB0637	DAY5	2013 07 31	20:52	5.3
97	9730157320	0013	DB0088	DAY5	2013 07 31	08:48	1.2
98	9730157320	0013	DB0088	DAY5	2013 07 31	12:48	1.0
99	9730157320	0013	DB0088	DAY5	2013 07 31	16:48	0.9
100	9730157320	0013	DB0088	DAY5	2013 07 31	20:48	0.9
101	9730157400	0106	DB0845	DAY5	2013 07 31	06:54	1.0
102	9730157400	0106	DB0845	DAY5	2013 07 31	13:02	1.1
103	9730157400	0106	DB0845	DAY5	2013 07 31	17:02	0.8
104	9730157400	0106	DB0845	DAY5	2013 07 31	21:02	1.0
105	9730157440	0069	DB0044	DAY5	2013 07 31	06:36	1.2
106	9730157440	0069	DB0044	DAY5	2013 07 31	12:44	1.1
107	9730157440	0069	DB0044	DAY5	2013 07 31	16:44	1.1
108	9730157440	0069	DB0044	DAY5	2013 07 31	20:44	1.0
109	9730157480	0021	DB0567	DAY5	2013 07 31	06:42	1.2
110	9730157480	0021	DB0567	DAY5	2013 07 31	12:50	1.2
111	9730157480	0021	DB0567	DAY5	2013 07 31	16:50	1.1
112	9730157480	0021	DB0567	DAY5	2013 07 31	20:50	1.0
113	9730157560	0107	DB0569	DAY5	2013 07 31	06:46	1.2
114	9730157560	0107	DB0569	DAY5	2013 07 31	12:54	1.1
115	9730157560	0107	DB0569	DAY5	2013 07 31	16:54	1.2
116	9730157560	0107	DB0569	DAY5	2013 07 31	20:54	1.1
117	9730157600	0112	DB0897	DAY5	2013 07 31	06:50	1.2
118	9730157600	0112	DB0897	DAY5	2013 07 31	12:58	1.1
119	9730157600	0112	DB0897	DAY5	2013 07 31	16:59	1.1
120	9730157600	0112	DB0897	DAY5	2013 07 31	20:59	1.0
121	9730157640	0122	DB0539	DAY5	2013 07 31	06:52	1.2
122	9730157640	0122	DB0539	DAY5	2013 07 31	13:00	1.2

Synevo Central Lab  
Confidential

123	9730157640	0122	DB0539	DAY5	2013 07 31	17:00	1.1
124	9730157640	0122	DB0539	DAY5	2013 07 31	21:00	1.1
125	9730157680	0080	DB0139	DAY5	2013 07 31	06:48	2.5
126	9730157680	0080	DB0139	DAY5	2013 07 31	12:56	6.0
127	9730157680	0080	DB0139	DAY5	2013 07 31	16:56	5.5
128	9730157680	0080	DB0139	DAY5	2013 07 31	20:57	7.2
129	9730157720	0001	DB0560	DAY5	2013 07 31	06:54	1.2
130	9730157720	0001	DB0560	DAY5	2013 07 31	13:02	1.2
131	9730157720	0001	DB0560	DAY5	2013 07 31	17:02	1.1
132	9730157720	0001	DB0560	DAY5	2013 07 31	21:02	1.1
133	9730157760	0037	DB0774	DAY5	2013 07 31	06:47	4.1
134	9730157760	0037	DB0774	DAY5	2013 07 31	12:54	7.5
135	9730157760	0037	DB0774	DAY5	2013 07 31	16:54	7.3
136	9730157760	0037	DB0774	DAY5	2013 07 31	20:54	7.8

**5.1.3 3<sup>rd</sup> cohort**

During the 3<sup>rd</sup> cohort study 340 blood samples were tested for COHb concentration. There were 34 subjects participated in that cohort and all of them terminated the study with all COHb results.

There were no problems noted during the test performance.

Results of COHb for 3<sup>rd</sup> cohort samples are presented in [table 5c](#) of the report.

**Table 5c:** The register of the COHb result of the 3<sup>rd</sup> cohort.

No.	Lab. No.	Subject	DBM	Visit No.	Collection data	Time	Result [%]
1	9730214900	0170	DB0923	DAY -1	2013 08 08	20:50	3.5
2	9730214910	0148	DB0930	DAY -1	2013 08 08	20:06	6.8
3	9730214920	0140	DB0116	DAY -1	2013 08 08	21:10	3.4
4	9730214930	0139	DB0095	DAY -1	2013 08 08	21:04	4.3
5	9730214950	0169	DB0819	DAY -1	2013 08 08	20:48	3.9
6	9730215100	0137	DB0499	DAY -1	2013 08 08	20:32	3.5
7	9730215110	0185	DB0231	DAY -1	2013 08 08	20:34	4.1
8	9730215130	0145	DB0938	DAY -1	2013 08 08	20:36	2.8
9	9730215140	0147	DB0979	DAY -1	2013 08 08	20:38	4.2
10	9730215150	0192	DB1201	DAY -1	2013 08 08	21:06	5.3
11	9730215160	0155	DB0983	DAY -1	2013 08 08	20:40	2.1
12	9730215170	0190	DB1202	DAY -1	2013 08 08	21:08	4.3
13	9730215180	0126	DB0681	DAY -1	2013 08 08	20:14	3.0
14	9730215190	0152	DB0625	DAY -1	2013 08 08	20:22	3.6
15	9730215200	0128	DB0331	DAY -1	2013 08 08	20:16	4.7
16	9730215210	0162	DB0988	DAY -1	2013 08 08	20:20	3.3
17	9730215220	0167	DB0846	DAY -1	2013 08 08	20:44	4.3
18	9730215230	0133	DB0099	DAY -1	2013 08 08	20:24	7.2
19	9730215240	0149	DB0945	DAY -1	2013 08 08	20:18	3.8

Synevo Central Lab  
Confidential

20	9730215250	0127	DB0069	DAY -1	2013 08 08	20:26	3.0
21	9730215260	0156	DB0982	DAY -1	2013 08 08	20:28	8.2
22	9730215270	0134	DB0132	DAY -1	2013 08 08	20:10	5.0
23	9730215280	0136	DB0500	DAY -1	2013 08 08	20:30	4.3
24	9730215290	0129	DB0530	DAY -1	2013 08 08	20:12	4.9
25	9730215300	0191	DB1191	DAY -1	2013 08 08	20:46	2.7
26	9730215310	0181	DB0842	DAY -1	2013 08 08	20:08	6.2
27	9730215320	0130	DB0423	DAY -1	2013 08 08	20:04	2.5
28	9730215330	0153	DB0967	DAY -1	2013 08 08	20:02	5.7
29	9730215340	0160	DB0955	DAY -1	2013 08 08	20:52	5.3
30	9730215350	0189	DB1163	DAY -1	2013 08 08	20:54	4.2
31	9730215360	0183	DB0970	DAY -1	2013 08 08	20:56	4.7
32	9730215370	0177	DB0978	DAY -1	2013 08 08	20:42	6.4
33	9730215380	0150	DB0928	DAY -1	2013 08 08	20:58	3.6
34	9730215390	0187	DB0181	DAY -1	2013 08 08	21:00	4.4
1	9730214700	0147	DB0979	DAY0	2013 08 09	20:38	6.0
2	9730214710	0145	DB0938	DAY0	2013 08 09	20:36	5.0
3	9730214720	0155	DB0983	DAY0	2013 08 09	20:40	2.7
4	9730214730	0185	DB0231	DAY0	2013 08 09	20:34	4.9
5	9730214740	0156	DB0982	DAY0	2013 08 09	20:28	11.2
6	9730214750	0137	DB0499	DAY0	2013 08 09	20:32	3.1
7	9730214760	0136	DB0500	DAY0	2013 08 09	20:30	3.9
8	9730214770	0127	DB0069	DAY0	2013 08 09	20:26	4.0
9	9730214780	0133	DB0099	DAY0	2013 08 09	20:24	8.8
10	9730214790	0149	DB0945	DAY0	2013 08 09	20:18	4.2
11	9730214800	0152	DB0625	DAY0	2013 08 09	20:22	3.3
12	9730214810	0190	DB1202	DAY0	2013 08 09	21:08	8.8
13	9730214820	0192	DB1201	DAY0	2013 08 09	21:06	6.2
14	9730214830	0128	DB0331	DAY0	2013 08 09	20:16	4.3
15	9730214840	0126	DB0681	DAY0	2013 08 09	20:14	3.1
16	9730214850	0140	DB0116	DAY0	2013 08 09	21:10	4.1
17	9730214870	0162	DB0988	DAY0	2013 08 09	20:20	3.9
18	9730214880	0139	DB0095	DAY0	2013 08 09	21:04	5.3
19	9730214890	0129	DB0530	DAY0	2013 08 09	20:12	3.6
20	9730214940	0134	DB0132	DAY0	2013 08 09	20:10	7.3
21	9730214960	0181	DB0842	DAY0	2013 08 09	20:08	4.9
22	9730214970	0130	DB0423	DAY0	2013 08 09	20:04	3.7
23	9730214980	0148	DB0930	DAY0	2013 08 09	20:06	7.8
24	9730214990	0153	DB0967	DAY0	2013 08 09	20:02	6.1
25	9730215000	0183	DB0970	DAY0	2013 08 09	20:56	4.2
26	9730215010	0189	DB1163	DAY0	2013 08 09	20:54	3.6
27	9730215020	0187	DB0181	DAY0	2013 08 09	21:00	4.8
28	9730215030	0160	DB0955	DAY0	2013 08 09	20:52	5.6
29	9730215040	0150	DB0928	DAY0	2013 08 09	20:58	2.5
30	9730215050	0170	DB0923	DAY0	2013 08 09	20:50	3.7

Synevo Central Lab  
Confidential

31	9730215060	0169	DB0819	DAY0	2013 08 09	20:48	3.0
32	9730215070	0191	DB1191	DAY0	2013 08 09	20:46	3.9
33	9730215080	0167	DB0846	DAY0	2013 08 09	20:44	4.4
34	9730215090	0177	DB0978	DAY0	2013 08 09	20:43	7.1
1	9730214400	0156	DB0982	DAY1	2013 08 10	20:28	10.8
2	9730214410	0136	DB0500	DAY1	2013 08 10	20:30	1.0
3	9730214420	0137	DB0499	DAY1	2013 08 10	20:32	0.9
4	9730214430	0185	DB0231	DAY1	2013 08 10	20:34	1.2
5	9730214440	0145	DB0938	DAY1	2013 08 10	20:36	1.2
6	9730214450	0190	DB1202	DAY1	2013 08 10	21:08	1.1
7	9730214460	0139	DB0095	DAY1	2013 08 10	21:04	4.1
8	9730214470	0192	DB1201	DAY1	2013 08 10	21:06	1.2
9	9730214480	0187	DB0181	DAY1	2013 08 10	21:00	3.8
10	9730214490	0150	DB0928	DAY1	2013 08 10	20:58	1.1
11	9730214500	0183	DB0970	DAY1	2013 08 10	20:56	1.2
12	9730214510	0133	DB0099	DAY1	2013 08 10	20:24	1.4
13	9730214520	0189	DB1163	DAY1	2013 08 10	20:54	1.0
14	9730214530	0127	DB0069	DAY1	2013 08 10	20:26	1.1
15	9730214540	0152	DB0625	DAY1	2013 08 10	20:22	3.8
16	9730214550	0140	DB0116	DAY1	2013 08 10	21:10	3.6
17	9730214560	0169	DB0819	DAY1	2013 08 10	20:48	1.2
18	9730214570	0191	DB1191	DAY1	2013 08 10	20:46	3.5
19	9730214580	0160	DB0955	DAY1	2013 08 10	20:52	6.2
20	9730214590	0170	DB0923	DAY1	2013 08 10	20:50	1.1
21	9730214600	0162	DB0988	DAY1	2013 08 10	20:20	1.1
22	9730214610	0126	DB0681	DAY1	2013 08 10	20:14	2.9
23	9730214620	0130	DB0423	DAY1	2013 08 10	20:04	0.9
24	9730214630	0134	DB0132	DAY1	2013 08 10	20:10	1.7
25	9730214640	0149	DB0945	DAY1	2013 08 10	20:18	1.2
26	9730214650	0128	DB0331	DAY1	2013 08 10	20:16	1.4
27	9730214660	0129	DB0530	DAY1	2013 08 10	20:12	1.1
28	9730214670	0181	DB0842	DAY1	2013 08 10	20:08	1.4
29	9730214680	0148	DB0930	DAY1	2013 08 10	20:06	7.2
30	9730214690	0153	DB0967	DAY1	2013 08 10	20:02	1.3
31	9730216550	0155	DB0983	DAY1	2013 08 10	20:40	1.0
32	9730216600	0177	DB0978	DAY1	2013 08 10	20:45	1.6
33	9730216610	0167	DB0846	DAY1	2013 08 10	20:44	1.2
34	9730216640	0147	DB0979	DAY1	2013 08 10	20:38	1.3
1	9730215850	0149	DB0945	DAY2	2013 08 11	20:18	1.1
2	9730215860	0167	DB0846	DAY2	2013 08 11	20:40	1.1
3	9730215930	0133	DB0099	DAY2	2013 08 11	20:24	0.9
4	9730215990	0128	DB0331	DAY2	2013 08 11	20:16	1.1
5	9730216120	0156	DB0982	DAY2	2013 08 11	20:28	7.7
6	9730216130	0162	DB0988	DAY2	2013 08 11	20:20	1.1
7	9730216260	0152	DB0625	DAY2	2013 08 11	20:22	3.7

Synevo Central Lab  
Confidential

8	9730216280	0127	DB0069	DAY2	2013 08 11	20:26	1.0
9	9730216390	0169	DB0819	DAY2	2013 08 11	20:48	1.1
10	9730216410	0181	DB0842	DAY2	2013 08 11	20:08	1.2
11	9730216430	0129	DB0530	DAY2	2013 08 11	20:12	1.0
12	9730216440	0134	DB0132	DAY2	2013 08 11	20:10	1.2
13	9730216460	0145	DB0938	DAY2	2013 08 11	20:36	1.0
14	9730216470	0153	DB0967	DAY2	2013 08 11	20:02	1.1
15	9730216480	0148	DB0930	DAY2	2013 08 11	20:06	6.5
16	9730216490	0137	DB0499	DAY2	2013 08 11	20:32	0.9
17	9730216500	0190	DB1202	DAY2	2013 08 11	21:08	1.0
18	9730216520	0126	DB0681	DAY2	2013 08 11	20:14	2.8
19	9730216530	0136	DB0500	DAY2	2013 08 11	20:30	1.0
20	9730216560	0155	DB0983	DAY2	2013 08 11	20:40	1.0
21	9730216570	0191	DB1191	DAY2	2013 08 11	20:46	2.3
22	9730216580	0177	DB0978	DAY2	2013 08 11	20:42	1.2
23	9730216590	0187	DB0181	DAY2	2013 08 11	21:00	4.6
24	9730216620	0189	DB1163	DAY2	2013 08 11	20:54	0.9
25	9730216630	0185	DB0231	DAY2	2013 08 11	20:34	1.1
26	9730216650	0150	DB0928	DAY2	2013 08 11	20:58	1.0
27	9730216660	0130	DB0423	DAY2	2013 08 11	20:04	0.9
28	9730216670	0160	DB0955	DAY2	2013 08 11	20:52	5.5
29	9730216680	0140	DB0116	DAY2	2013 08 11	21:10	3.1
30	9730216690	0147	DB0979	DAY2	2013 08 11	20:38	1.0
31	9730216700	0192	DB1201	DAY2	2013 08 11	21:06	1.1
32	9730216710	0183	DB0970	DAY2	2013 08 11	20:56	1.1
33	9730216720	0170	DB0923	DAY2	2013 08 11	20:50	1.1
34	9730216730	0139	DB0095	DAY2	2013 08 11	21:04	3.9
1	9730215830	0145	DB0938	DAY3	2013 08 12	20:36	1.0
2	9730215960	0187	DB0181	DAY3	2013 08 12	21:00	4.3
3	9730215970	0139	DB0095	DAY3	2013 08 12	21:04	4.5
4	9730216050	0134	DB0132	DAY3	2013 08 12	20:10	1.1
5	9730216060	0148	DB0930	DAY3	2013 08 12	20:06	6.8
6	9730216070	0181	DB0842	DAY3	2013 08 12	20:08	1.1
7	9730216090	0183	DB0970	DAY3	2013 08 12	20:56	1.0
8	9730216100	0162	DB0988	DAY3	2013 08 12	20:20	1.1
9	9730216110	0149	DB0945	DAY3	2013 08 12	20:18	1.2
10	9730216140	0130	DB0423	DAY3	2013 08 12	20:04	0.9
11	9730216150	0153	DB0967	DAY3	2013 08 12	20:02	1.1
12	9730216160	0167	DB0846	DAY3	2013 08 12	20:44	1.1
13	9730216170	0191	DB1191	DAY3	2013 08 12	20:46	3.0
14	9730216180	0169	DB0819	DAY3	2013 08 12	20:48	1.1
15	9730216190	0170	DB0923	DAY3	2013 08 12	20:50	1.0
16	9730216200	0152	DB0625	DAY3	2013 08 12	20:22	4.2
17	9730216210	0177	DB0978	DAY3	2013 08 12	20:42	1.2
18	9730216220	0126	DB0681	DAY3	2013 08 12	20:14	2.9

Synevo Central Lab  
Confidential

19	9730216230	0133	DB0099	DAY3	2013 08 12	20:24	0.9
20	9730216240	0127	DB0069	DAY3	2013 08 12	20:26	1.0
21	9730216250	0155	DB0983	DAY3	2013 08 12	20:40	1.1
22	9730216270	0156	DB0982	DAY3	2013 08 12	20:28	10.2
23	9730216290	0129	DB0530	DAY3	2013 08 12	20:12	1.0
24	9730216300	0189	DB1163	DAY3	2013 08 12	20:54	1.0
25	9730216310	0160	DB0955	DAY3	2013 08 12	20:52	5.2
26	9730216320	0128	DB0331	DAY3	2013 08 12	20:16	1.0
27	9730216330	0190	DB1202	DAY3	2013 08 12	21:08	1.1
28	9730216340	0147	DB0979	DAY3	2013 08 12	20:38	1.2
29	9730216350	0136	DB0500	DAY3	2013 08 12	20:30	0.9
30	9730216360	0137	DB0499	DAY3	2013 08 12	20:32	0.9
31	9730216370	0185	DB0231	DAY3	2013 08 12	20:34	1.0
32	9730216380	0150	DB0928	DAY3	2013 08 12	20:58	0.9
33	9730216400	0140	DB0116	DAY3	2013 08 12	21:10	3.6
34	9730216510	0192	DB1201	DAY3	2013 08 12	21:06	1.3
1	9730215640	0153	DB0967	DAY4	2013 08 13	20:02	1.2
2	9730215650	0149	DB0945	DAY4	2013 08 13	20:18	1.1
3	9730215660	0156	DB0982	DAY4	2013 08 13	20:28	8.1
4	9730215670	0129	DB0530	DAY4	2013 08 13	20:12	1.1
5	9730215680	0162	DB0988	DAY4	2013 08 13	20:20	1.0
6	9730215690	0139	DB0095	DAY4	2013 08 13	21:04	4.2
7	9730215700	0127	DB0069	DAY4	2013 08 13	20:26	1.0
8	9730215710	0152	DB0625	DAY4	2013 08 13	20:22	2.8
9	9730215720	0133	DB0099	DAY4	2013 08 13	20:24	1.0
10	9730215730	0136	DB0500	DAY4	2013 08 13	20:30	1.0
11	9730215740	0126	DB0681	DAY4	2013 08 13	20:14	3.3
12	9730215750	0128	DB0331	DAY4	2013 08 13	20:16	1.2
13	9730215760	0145	DB0938	DAY4	2013 08 13	20:36	1.0
14	9730215770	0147	DB0979	DAY4	2013 08 13	20:38	1.2
15	9730215780	0185	DB0231	DAY4	2013 08 13	20:34	1.0
16	9730215790	0137	DB0499	DAY4	2013 08 13	20:32	1.0
17	9730215800	0160	DB0955	DAY4	2013 08 13	20:52	4.6
18	9730215810	0192	DB1201	DAY4	2013 08 13	21:06	1.2
19	9730215820	0140	DB0116	DAY4	2013 08 13	21:10	3.0
20	9730215840	0130	DB0423	DAY4	2013 08 13	20:04	1.0
21	9730215870	0181	DB0842	DAY4	2013 08 13	20:08	1.2
22	9730215880	0148	DB0930	DAY4	2013 08 13	20:06	7.7
23	9730215890	0189	DB1163	DAY4	2013 08 13	20:54	1.0
24	9730215900	0170	DB0923	DAY4	2013 08 13	20:50	1.1
25	9730215910	0191	DB1191	DAY4	2013 08 13	20:46	2.9
26	9730215940	0167	DB0846	DAY4	2013 08 13	20:44	1.2
27	9730215950	0190	DB1202	DAY4	2013 08 13	21:08	1.0
28	9730215980	0155	DB0983	DAY4	2013 08 13	20:40	1.0
29	9730216000	0169	DB0819	DAY4	2013 08 13	20:48	1.0



Synevo Central Lab  
Confidential

30	9730216010	0187	DB0181	DAY4	2013 08 13	21:00	4.9
31	9730216020	0177	DB0978	DAY4	2013 08 13	20:42	1.3
32	9730216030	0150	DB0928	DAY4	2013 08 13	20:58	1.0
33	9730216040	0183	DB0970	DAY4	2013 08 13	20:56	1.0
34	9730216080	0134	DB0132	DAY4	2013 08 13	20:10	1.2
1	9730212770	0149	DB0945	DAY5	2013 08 14	06:38	1.1
2	9730212770	0149	DB0945	DAY5	2013 08 14	12:46	1.1
3	9730212770	0149	DB0945	DAY5	2013 08 14	16:46	1.1
4	9730212770	0149	DB0945	DAY5	2013 08 14	20:46	1.1
5	9730212970	0147	DB0979	DAY5	2013 08 14	06:22	1.2
6	9730212970	0147	DB0979	DAY5	2013 08 14	12:30	1.2
7	9730212970	0147	DB0979	DAY5	2013 08 14	16:30	1.1
8	9730212970	0147	DB0979	DAY5	2013 08 14	20:31	1.1
9	9730213010	0169	DB0819	DAY5	2013 08 14	08:40	1.1
10	9730213010	0169	DB0819	DAY5	2013 08 14	12:40	1.0
11	9730213010	0169	DB0819	DAY5	2013 08 14	16:40	1.0
12	9730213010	0169	DB0819	DAY5	2013 08 14	20:40	1.0
13	9730213050	0191	DB1191	DAY5	2013 08 14	06:30	2.0
14	9730213050	0191	DB1191	DAY5	2013 08 14	12:38	2.8
15	9730213050	0191	DB1191	DAY5	2013 08 14	16:38	3.5
16	9730213050	0191	DB1191	DAY5	2013 08 14	20:38	3.7
17	9730213090	0177	DB0978	DAY5	2013 08 14	06:26	1.2
18	9730213090	0177	DB0978	DAY5	2013 08 14	12:34	1.3
19	9730213090	0177	DB0978	DAY5	2013 08 14	16:34	1.2
20	9730213090	0177	DB0978	DAY5	2013 08 14	20:34	1.2
21	9730213130	0152	DB0625	DAY5	2013 08 14	06:42	1.8
22	9730213130	0152	DB0625	DAY5	2013 08 14	12:50	4.4
23	9730213130	0152	DB0625	DAY5	2013 08 14	16:50	4.8
24	9730213130	0152	DB0625	DAY5	2013 08 14	20:50	4.7
25	9730213170	0137	DB0499	DAY5	2013 08 14	09:00	1.1
26	9730213170	0137	DB0499	DAY5	2013 08 14	13:00	1.1
27	9730213170	0137	DB0499	DAY5	2013 08 14	17:00	0.9
28	9730213170	0137	DB0499	DAY5	2013 08 14	21:00	1.0
29	9730213210	0185	DB0231	DAY5	2013 08 14	09:02	1.1
30	9730213210	0185	DB0231	DAY5	2013 08 14	13:02	1.1
31	9730213210	0185	DB0231	DAY5	2013 08 14	17:02	1.0
32	9730213210	0185	DB0231	DAY5	2013 08 14	21:02	1.1
33	9730213250	0155	DB0983	DAY5	2013 08 14	06:24	1.1
34	9730213250	0155	DB0983	DAY5	2013 08 14	12:32	1.0
35	9730213250	0155	DB0983	DAY5	2013 08 14	16:32	1.0
36	9730213250	0155	DB0983	DAY5	2013 08 14	20:32	1.0
37	9730213290	0183	DB0970	DAY5	2013 08 14	06:40	1.0
38	9730213290	0183	DB0970	DAY5	2013 08 14	12:48	1.0
39	9730213290	0183	DB0970	DAY5	2013 08 14	16:48	0.9
40	9730213290	0183	DB0970	DAY5	2013 08 14	20:48	1.0

Synevo Central Lab  
Confidential

41	9730213330	0189	DB1163	DAY5	2013 08 14	06:38	1.0
42	9730213330	0189	DB1163	DAY5	2013 08 14	12:46	1.0
43	9730213330	0189	DB1163	DAY5	2013 08 14	16:46	1.0
44	9730213330	0189	DB1163	DAY5	2013 08 14	20:46	0.9
45	9730213370	0160	DB0955	DAY5	2013 08 14	06:36	3.7
46	9730213370	0160	DB0955	DAY5	2013 08 14	12:44	3.7
47	9730213370	0160	DB0955	DAY5	2013 08 14	16:44	5.1
48	9730213370	0160	DB0955	DAY5	2013 08 14	20:44	4.8
49	9730213410	0167	DB0846	DAY5	2013 08 14	06:28	1.1
50	9730213410	0167	DB0846	DAY5	2013 08 14	12:36	1.3
51	9730213410	0167	DB0846	DAY5	2013 08 14	16:36	1.1
52	9730213410	0167	DB0846	DAY5	2013 08 14	20:36	1.1
53	9730213450	0170	DB0923	DAY5	2013 08 14	06:34	1.2
54	9730213450	0170	DB0923	DAY5	2013 08 14	12:42	1.3
55	9730213450	0170	DB0923	DAY5	2013 08 14	16:42	1.1
56	9730213450	0170	DB0923	DAY5	2013 08 14	20:42	1.0
57	9730213530	0148	DB0930	DAY5	2013 08 14	06:26	4.9
58	9730213530	0148	DB0930	DAY5	2013 08 14	12:34	7.5
59	9730213530	0148	DB0930	DAY5	2013 08 14	16:34	7.0
60	9730213530	0148	DB0930	DAY5	2013 08 14	20:34	6.4
61	9730213570	0145	DB0938	DAY5	2013 08 14	09:04	1.2
62	9730213570	0145	DB0938	DAY5	2013 08 14	13:04	1.0
63	9730213570	0145	DB0938	DAY5	2013 08 14	17:04	1.0
64	9730213570	0145	DB0938	DAY5	2013 08 14	21:04	0.9
65	9730213610	0150	DB0928	DAY5	2013 08 14	08:50	0.9
66	9730213610	0150	DB0928	DAY5	2013 08 14	12:50	0.9
67	9730213610	0150	DB0928	DAY5	2013 08 14	16:50	0.9
68	9730213610	0150	DB0928	DAY5	2013 08 14	20:50	0.8
69	9730213650	0127	DB0069	DAY5	2013 08 14	08:54	1.1
70	9730213650	0127	DB0069	DAY5	2013 08 14	12:54	1.0
71	9730213650	0127	DB0069	DAY5	2013 08 14	16:54	1.1
72	9730213650	0127	DB0069	DAY5	2013 08 14	20:54	1.0
73	9730213690	0187	DB0181	DAY5	2013 08 14	06:44	2.3
74	9730213690	0187	DB0181	DAY5	2013 08 14	12:52	5.3
75	9730213690	0187	DB0181	DAY5	2013 08 14	16:52	4.7
76	9730213690	0187	DB0181	DAY5	2013 08 14	20:52	5.3
77	9730213730	0139	DB0095	DAY5	2013 08 14	06:48	2.8
78	9730213730	0139	DB0095	DAY5	2013 08 14	12:56	4.5
79	9730213730	0139	DB0095	DAY5	2013 08 14	16:56	4.8
80	9730213730	0139	DB0095	DAY5	2013 08 14	20:56	4.8
81	9730213770	0181	DB0842	DAY5	2013 08 14	06:28	1.3
82	9730213770	0181	DB0842	DAY5	2013 08 14	12:36	1.3
83	9730213770	0181	DB0842	DAY5	2013 08 14	16:36	1.2
84	9730213770	0181	DB0842	DAY5	2013 08 14	20:36	1.2
85	9730213810	0192	DB1201	DAY5	2013 08 14	06:50	1.3

Synevo Central Lab  
Confidential

86	9730213810	0192	DB1201	DAY5	2013 08 14	12:58	1.3
87	9730213810	0192	DB1201	DAY5	2013 08 14	16:58	1.2
88	9730213810	0192	DB1201	DAY5	2013 08 14	20:58	1.2
89	9730213850	0190	DB1202	DAY5	2013 08 14	06:52	1.0
90	9730213850	0190	DB1202	DAY5	2013 08 14	13:00	1.0
91	9730213850	0190	DB1202	DAY5	2013 08 14	17:00	1.0
92	9730213850	0190	DB1202	DAY5	2013 08 14	21:00	1.0
93	9730213890	0130	DB0423	DAY5	2013 08 14	06:24	1.0
94	9730213890	0130	DB0423	DAY5	2013 08 14	12:32	1.0
95	9730213890	0130	DB0423	DAY5	2013 08 14	16:32	1.0
96	9730213890	0130	DB0423	DAY5	2013 08 14	20:32	1.0
97	9730213930	0140	DB0116	DAY5	2013 08 14	06:54	2.2
98	9730213930	0140	DB0116	DAY5	2013 08 14	13:02	4.0
99	9730213930	0140	DB0116	DAY5	2013 08 14	17:02	4.1
100	9730213930	0140	DB0116	DAY5	2013 08 14	21:02	3.5
101	9730213970	0129	DB0530	DAY5	2013 08 14	06:32	1.0
102	9730213970	0129	DB0530	DAY5	2013 08 14	12:40	1.1
103	9730213970	0129	DB0530	DAY5	2013 08 14	16:40	1.0
104	9730213970	0129	DB0530	DAY5	2013 08 14	20:40	0.9
105	9730214010	0133	DB0099	DAY5	2013 08 14	08:52	1.0
106	9730214010	0133	DB0099	DAY5	2013 08 14	12:52	1.0
107	9730214010	0133	DB0099	DAY5	2013 08 14	16:52	1.0
108	9730214010	0133	DB0099	DAY5	2013 08 14	20:52	1.0
109	9730214050	0134	DB0132	DAY5	2013 08 14	06:30	1.3
110	9730214050	0134	DB0132	DAY5	2013 08 14	12:38	1.3
111	9730214050	0134	DB0132	DAY5	2013 08 14	16:38	1.2
112	9730214050	0134	DB0132	DAY5	2013 08 14	20:38	1.3
113	9730214090	0156	DB0982	DAY5	2013 08 14	06:48	5.8
114	9730214090	0156	DB0982	DAY5	2013 08 14	12:56	9.4
115	9730214090	0156	DB0982	DAY5	2013 08 14	16:56	8.9
116	9730214090	0156	DB0982	DAY5	2013 08 14	20:56	10.1
117	9730214130	0128	DB0331	DAY5	2013 08 14	08:44	1.2
118	9730214130	0128	DB0331	DAY5	2013 08 14	12:44	1.2
119	9730214130	0128	DB0331	DAY5	2013 08 14	16:44	1.1
120	9730214130	0128	DB0331	DAY5	2013 08 14	20:44	1.1
121	9730214170	0126	DB0681	DAY5	2013 08 14	06:34	2.2
122	9730214170	0126	DB0681	DAY5	2013 08 14	12:42	2.5
123	9730214170	0126	DB0681	DAY5	2013 08 14	16:42	2.9
124	9730214170	0126	DB0681	DAY5	2013 08 14	20:42	3.4
125	9730214210	0153	DB0967	DAY5	2013 08 14	06:22	1.0
126	9730214210	0153	DB0967	DAY5	2013 08 14	12:30	1.1
127	9730214210	0153	DB0967	DAY5	2013 08 14	16:30	1.0
128	9730214210	0153	DB0967	DAY5	2013 08 14	20:30	1.0
129	9730214250	0162	DB0988	DAY5	2013 08 14	06:41	1.1
130	9730214250	0162	DB0988	DAY5	2013 08 14	12:48	1.1

Synevo Central Lab  
Confidential

131	9730214250	0162	DB0988	DAY5	2013 08 14	16:49	1.1
132	9730214250	0162	DB0988	DAY5	2013 08 14	20:48	1.0
133	9730214290	0136	DB0500	DAY5	2013 08 14	06:50	1.0
134	9730214290	0136	DB0500	DAY5	2013 08 14	12:58	1.1
135	9730214290	0136	DB0500	DAY5	2013 08 14	16:58	1.0
136	9730214290	0136	DB0500	DAY5	2013 08 14	20:58	1.0

#### 5.1.4. 4<sup>th</sup> cohort

During the 4<sup>th</sup> cohort study, the 316 of the blood samples were tested for COHb concentration. There were 35 subjects participated in that cohort and 4 subjects who were discontinued from the study because of medical reasons. Two of them were excluded on Day 0 and two of them on Day 1. The group of COHb for 4<sup>th</sup> cohort samples are presented in [table 5d](#) of the report.

**Table 5d:** The register of the COHb result of the 4<sup>th</sup> cohort.

No.	Lab. No.	Subject	DBN	Visit No.	Collection data	Time	Result [%]
1	9730222910	0234	DB1208	DAY -1	2013 08 21	20:18	3.6
2	9730224610	0218	DB1077	DAY -1	2013 08 21	21:02	3.3
3	9730224620	0204	DB0457	DAY -1	2013 08 21	20:54	3.0
4	9730224630	0256	DB0498	DAY -1	2013 08 21	20:22	5.2
5	9730224640	0251	DB1054	DAY -1	2013 08 21	20:34	5.0
6	9730224650	0198	DB0994	DAY -1	2013 08 21	20:38	4.1
7	9730224660	0240	DB1236	DAY -1	2013 08 21	20:26	6.9
8	9730224670	0206	DB0993	DAY -1	2013 08 21	20:40	5.5
9	9730224680	0262	DB0786	DAY -1	2013 08 21	20:24	3.4
10	9730224690	0232	DB1149	DAY -1	2013 08 21	20:12	2.6
11	9730224700	0195	DB1181	DAY -1	2013 08 21	21:06	3.3
12	9730224710	0242	DB1268	DAY -1	2013 08 21	20:30	5.6
13	9730224720	0193	DB0722	DAY -1	2013 08 21	20:08	3.4
14	9730224730	0249	DB1017	DAY -1	2013 08 21	20:06	6.8
15	9730224740	0197	DB0172	DAY -1	2013 08 21	21:10	4.1
16	9730224750	0211	DB1012	DAY -1	2013 08 21	20:04	3.4
17	9730224760	0220	DB0939	DAY -1	2013 08 21	20:28	3.3
18	9730224770	0228	DB1053	DAY -1	2013 08 21	20:10	5.1
19	9730224780	0255	DB1129	DAY -1	2013 08 21	20:58	3.8
20	9730224790	0265	DB0588	DAY -1	2013 08 21	21:00	6.4
21	9730224800	0216	DB0256	DAY -1	2013 08 21	20:46	7.0
22	9730224810	0230	DB1207	DAY -1	2013 08 21	21:04	4.6
23	9730224820	0196	DB1206	DAY -1	2013 08 21	21:08	2.3
24	9730224830	0264	DB0595	DAY -1	2013 08 21	20:52	3.1
25	9730224840	0245	DB1122	DAY -1	2013 08 21	20:20	7.5
26	9730224850	0200	DB1145	DAY -1	2013 08 21	20:44	3.2
27	9730224860	0202	DB0651	DAY -1	2013 08 21	20:42	3.9

Synevo Central Lab  
Confidential

28	9730224870	0252	DB1133	DAY -1	2013 08 21	20:56	3.4
29	9730224880	0241	DB1266	DAY -1	2013 08 21	20:32	5.2
30	9730224890	0203	DB0143	DAY -1	2013 08 21	20:16	3.2
31	9730224900	0224	DB0345	DAY -1	2013 08 21	20:14	3.5
32	9730224910	0247	DB1081	DAY -1	2013 08 21	20:36	3.1
33	9730224920	0210	DB1003	DAY -1	2013 08 21	20:02	5.3
34	9730224930	0229	DB0531	DAY -1	2013 08 21	20:50	2.9
35	9730224940	0244	DB0814	DAY -1	2013 08 21	20:48	3.8
1	9730222720	0230	DB1207	DAY0	2013 08 22	21:04	4.7
2	9730222770	0197	DB0172	DAY0	2013 08 22	21:10	6.0
3	9730222840	0218	DB1077	DAY0	2013 08 22	21:02	4.9
4	9730222850	0206	DB0993	DAY0	2013 08 22	20:40	6.5
5	9730222930	0202	DB0651	DAY0	2013 08 22	20:42	4.1
6	9730223030	0195	DB1181	DAY0	2013 08 22	21:06	3.5
7	9730223080	0255	DB1129	DAY0	2013 08 22	20:58	4.5
8	9730223250	0232	DB1149	DAY0	2013 08 22	20:12	2.8
9	9730223280	0196	DB1206	DAY0	2013 08 22	21:08	2.4
10	9730223350	0242	DB1268	DAY0	2013 08 22	20:30	6.8
11	9730223360	0220	DB0939	DAY0	2013 08 22	20:28	2.9
12	9730223370	0249	DB1017	DAY0	2013 08 22	20:06	8.1
13	9730223380	0264	DB0595	DAY0	2013 08 22	20:52	2.8
14	9730223390	0252	DB1133	DAY0	2013 08 22	20:56	4.1
15	9730223410	0210	DB1003	DAY0	2013 08 22	20:02	5.0
16	9730223420	0240	DB1236	DAY0	2013 08 22	20:26	7.2
17	9730223430	0224	DB0345	DAY0	2013 08 22	20:15	3.1
18	9730223440	0193	DB0722	DAY0	2013 08 22	20:08	4.0
19	9730223450	0228	DB1053	DAY0	2013 08 22	20:10	5.9
20	9730223460	0262	DB0786	DAY0	2013 08 22	20:24	3.8
21	9730223470	0256	DB0498	DAY0	2013 08 22	20:22	4.9
22	9730223480	0245	DB1122	DAY0	2013 08 22	20:20	7.9
23	9730223490	0234	DB1208	DAY0	2013 08 22	20:18	3.7
24	9730223500	0203	DB0143	DAY0	2013 08 22	20:16	3.3
25	9730223510	0241	DB1266	DAY0	2013 08 22	20:32	6.4
26	9730223520	0251	DB1054	DAY0	2013 08 22	20:34	4.5
27	9730223530	0204	DB0457	DAY0	2013 08 22	20:54	4.0
28	9730223540	0200	DB1145	DAY0	2013 08 22	20:44	4.7
29	9730223560	0198	DB0994	DAY0	2013 08 22	20:38	5.2
30	9730223570	0229	DB0531	DAY0	2013 08 22	20:50	3.5
31	9730223580	0244	DB0814	DAY0	2013 08 22	20:48	4.1
32	9730223590	0216	DB0256	DAY0	2013 08 22	20:46	7.9
33	9730223600	0265	DB0588	DAY0	2013 08 22	21:00	6.3
1	9730222950	0216	DB0256	DAY1	2013 08 23	20:46	1.0
2	9730222970	0204	DB0457	DAY1	2013 08 23	20:54	2.7
3	9730222980	0244	DB0814	DAY1	2013 08 23	20:48	1.0
4	9730222990	0264	DB0595	DAY1	2013 08 23	20:52	1.0

Synevo Central Lab  
Confidential

5	9730223000	0206	DB0993	DAY1	2013 08 23	20:40	1.4
6	9730223010	0229	DB0531	DAY1	2013 08 23	20:50	2.8
7	9730223020	0202	DB0651	DAY1	2013 08 23	20:42	1.1
8	9730223040	0265	DB0588	DAY1	2013 08 23	21:01	1.1
9	9730223050	0251	DB1054	DAY1	2013 08 23	20:35	1.0
10	9730223060	0200	DB1145	DAY1	2013 08 23	20:44	3.2
11	9730223070	0218	DB1077	DAY1	2013 08 23	21:02	1.1
12	9730223090	0230	DB1207	DAY1	2013 08 23	21:04	3.5
13	9730223100	0255	DB1129	DAY1	2013 08 23	20:58	1.1
14	9730223110	0252	DB1133	DAY1	2013 08 23	20:56	1.2
15	9730223140	0195	DB1181	DAY1	2013 08 23	21:06	1.1
16	9730223150	0197	DB0172	DAY1	2013 08 23	21:10	1.4
17	9730223160	0196	DB1206	DAY1	2013 08 23	21:08	1.1
18	9730223170	0232	DB1149	DAY1	2013 08 23	20:12	1.1
19	9730223180	0193	DB0722	DAY1	2013 08 23	20:08	1.0
20	9730223190	0228	DB1053	DAY1	2013 08 23	20:11	1.3
21	9730223200	0210	DB1003	DAY1	2013 08 23	20:02	1.2
22	9730223210	0249	DB1017	DAY1	2013 08 23	20:06	1.6
23	9730223230	0256	DB0498	DAY1	2013 08 23	20:22	1.2
24	9730223240	0234	DB1208	DAY1	2013 08 23	20:18	1.1
25	9730223260	0203	DB0143	DAY1	2013 08 23	20:16	0.8
26	9730223270	0224	DB0345	DAY1	2013 08 23	20:14	2.9
27	9730223290	0262	DB0786	DAY1	2013 08 23	20:24	3.4
28	9730223300	0220	DB0939	DAY1	2013 08 23	20:28	1.0
29	9730223310	0241	DB1266	DAY1	2013 08 23	20:32	1.4
30	9730223330	0198	DB0994	DAY1	2013 08 23	20:38	5.9
31	9730223340	0240	DB1236	DAY1	2013 08 23	20:26	1.2
1	9730222620	0251	DB1054	DAY2	2013 08 24	20:34	0.9
2	9730222650	0241	DB1266	DAY2	2013 08 24	20:32	1.2
3	9730222660	0198	DB0994	DAY2	2013 08 24	20:38	5.1
4	9730222670	0200	DB1145	DAY2	2013 08 24	20:44	3.2
5	9730222680	0202	DB0651	DAY2	2013 08 24	20:42	1.0
6	9730222690	0206	DB0993	DAY2	2013 08 24	20:40	1.2
7	9730222700	0244	DB0814	DAY2	2013 08 24	20:48	1.0
8	9730222710	0232	DB1149	DAY2	2013 08 24	20:12	1.1
9	9730222730	0229	DB0531	DAY2	2013 08 24	20:50	2.9
10	9730222750	0204	DB0457	DAY2	2013 08 24	20:54	2.6
11	9730222760	0228	DB1053	DAY2	2013 08 24	20:10	1.0
12	9730222780	0264	DB0595	DAY2	2013 08 24	20:52	1.2
13	9730222790	0240	DB1236	DAY2	2013 08 24	20:26	1.1
14	9730222800	0197	DB0172	DAY2	2013 08 24	21:10	1.0
15	9730222810	0193	DB0722	DAY2	2013 08 24	20:08	1.0
16	9730222820	0249	DB1017	DAY2	2013 08 24	20:06	1.2
17	9730222830	0210	DB1003	DAY2	2013 08 24	20:02	1.1
18	9730222860	0256	DB0498	DAY2	2013 08 24	20:22	1.1

Synevo Central Lab  
Confidential

19	9730222870	0234	DB1208	DAY2	2013 08 24	20:18	0.9
20	9730222880	0262	DB0786	DAY2	2013 08 24	20:24	3.0
21	9730222890	0203	DB0143	DAY2	2013 08 24	20:16	0.7
22	9730222900	0224	DB0345	DAY2	2013 08 24	20:14	3.6
23	9730222920	0195	DB1181	DAY2	2013 08 24	21:06	1.1
24	9730222940	0196	DB1206	DAY2	2013 08 24	21:08	0.9
25	9730222960	0230	DB1207	DAY2	2013 08 24	21:04	3.8
26	9730223870	0265	DB0588	DAY2	2013 08 24	21:00	1.0
27	9730223920	0220	DB0939	DAY2	2013 08 24	20:28	1.0
28	9730223980	0252	DB1133	DAY2	2013 08 24	20:56	1.2
29	9730224070	0218	DB1077	DAY2	2013 08 24	21:02	1.0
30	9730224160	0255	DB1129	DAY2	2013 08 24	20:58	1.0
31	9730224560	0216	DB0256	DAY2	2013 08 24	20:46	0.9
1	9730223610	0195	DB1181	DAY3	2013 08 25	21:06	1.0
2	9730223710	0196	DB1206	DAY3	2013 08 25	21:10	1.1
3	9730223740	0197	DB0172	DAY3	2013 08 25	21:10	1.0
4	9730223770	0230	DB1207	DAY3	2013 08 25	21:04	3.3
5	9730223780	0218	DB1077	DAY3	2013 08 25	21:02	0.9
6	9730223790	0265	DB0588	DAY3	2013 08 25	21:00	1.0
7	9730223800	0252	DB1133	DAY3	2013 08 25	20:56	1.0
8	9730223810	0255	DB1129	DAY3	2013 08 25	20:58	1.1
9	9730223820	0264	DB0595	DAY3	2013 08 25	20:52	1.1
10	9730223830	0204	DB0457	DAY3	2013 08 25	20:54	4.3
11	9730223840	0244	DB0814	DAY3	2013 08 25	20:48	1.1
12	9730223850	0229	DB0531	DAY3	2013 08 25	20:50	2.9
13	9730223860	0200	DB1145	DAY3	2013 08 25	20:44	3.1
14	9730223880	0216	DB0256	DAY3	2013 08 25	20:46	0.9
15	9730223890	0206	DB0993	DAY3	2013 08 25	20:40	1.0
16	9730223900	0202	DB0651	DAY3	2013 08 25	20:42	1.0
17	9730223910	0228	DB1053	DAY3	2013 08 25	20:11	1.1
18	9730223930	0232	DB1149	DAY3	2013 08 25	20:12	1.1
19	9730223940	0249	DB1017	DAY3	2013 08 25	20:06	1.2
20	9730223960	0193	DB0722	DAY3	2013 08 25	20:08	1.0
21	9730223970	0198	DB0994	DAY3	2013 08 25	20:38	5.7
22	9730223990	0251	DB1054	DAY3	2013 08 25	20:34	1.0
23	9730224000	0210	DB1003	DAY3	2013 08 25	20:02	1.2
24	9730224010	0241	DB1266	DAY3	2013 08 25	20:32	1.2
25	9730224030	0220	DB0939	DAY3	2013 08 25	20:28	0.9
26	9730224060	0203	DB0143	DAY3	2013 08 25	20:16	0.7
27	9730224080	0240	DB1236	DAY3	2013 08 25	20:26	1.0
28	9730224100	0262	DB0786	DAY3	2013 08 25	20:24	3.9
29	9730224230	0224	DB0345	DAY3	2013 08 25	20:14	4.0
30	9730224360	0234	DB1208	DAY3	2013 08 25	20:18	0.9
31	9730224370	0256	DB0498	DAY3	2013 08 25	20:22	1.0
1	9730223950	0232	DB1149	DAY4	2013 08 26	20:12	1.1

Synevo Central Lab  
Confidential

2	9730224020	0197	DB0172	DAY4	2013 08 26	21:10	0.9
3	9730224120	0234	DB1208	DAY4	2013 08 26	20:18	1.0
4	9730224130	0265	DB0588	DAY4	2013 08 26	21:00	1.0
5	9730224180	0203	DB0143	DAY4	2013 08 26	20:16	0.8
6	9730224190	0210	DB1003	DAY4	2013 08 26	20:02	1.2
7	9730224200	0224	DB0345	DAY4	2013 08 26	20:14	3.5
8	9730224210	0256	DB0498	DAY4	2013 08 26	20:22	1.0
9	9730224260	0249	DB1017	DAY4	2013 08 26	20:06	1.2
10	9730224270	0262	DB0786	DAY4	2013 08 26	20:24	3.7
11	9730224290	0228	DB1053	DAY4	2013 08 26	20:11	1.1
12	9730224300	0193	DB0722	DAY4	2013 08 26	20:08	1.1
13	9730224390	0244	DB0814	DAY4	2013 08 26	20:48	1.0
14	9730224410	0206	DB0993	DAY4	2013 08 26	20:40	1.2
15	9730224420	0216	DB0256	DAY4	2013 08 26	20:46	1.0
16	9730224430	0200	DB1145	DAY4	2013 08 26	20:44	3.5
17	9730224440	0202	DB0651	DAY4	2013 08 26	20:42	1.1
18	9730224450	0204	DB0457	DAY4	2013 08 26	20:54	3.6
19	9730224460	0264	DB0595	DAY4	2013 08 26	20:52	1.0
20	9730224470	0252	DB1133	DAY4	2013 08 26	20:56	1.1
21	9730224480	0255	DB1129	DAY4	2013 08 26	20:59	1.1
22	9730224490	0229	DB0531	DAY4	2013 08 26	20:50	3.0
23	9730224500	0241	DB1266	DAY4	2013 08 26	20:32	1.1
24	9730224510	0251	DB1054	DAY4	2013 08 26	20:34	1.0
25	9730224520	0198	DB0994	DAY4	2013 08 26	20:38	5.9
26	9730224530	0196	DB1206	DAY4	2013 08 26	21:08	1.1
27	9730224540	0218	DB1077	DAY4	2013 08 26	21:02	1.0
28	9730224550	0230	DB1207	DAY4	2013 08 26	21:05	3.7
29	9730224570	0220	DB0939	DAY4	2013 08 26	20:28	1.0
30	9730224580	0240	DB1236	DAY4	2013 08 26	20:26	1.0
31	9730224600	0195	DB1181	DAY4	2013 08 26	21:06	1.1
1	9730224950	0210	DB1003	DAY5	2013 08 27	06:23	1.1
2	9730224950	0210	DB1003	DAY5	2013 08 27	12:30	1.1
3	9730224950	0210	DB1003	DAY5	2013 08 27	16:30	1.1
4	9730224950	0210	DB1003	DAY5	2013 08 27	20:30	1.1
5	9730225110	0262	DB0786	DAY5	2013 08 27	06:44	2.7
6	9730225110	0262	DB0786	DAY5	2013 08 27	12:52	2.8
7	9730225110	0262	DB0786	DAY5	2013 08 27	16:52	3.6
8	9730225110	0262	DB0786	DAY5	2013 08 27	20:53	3.3
9	9730225150	0204	DB0457	DAY5	2013 08 27	06:38	2.0
10	9730225150	0204	DB0457	DAY5	2013 08 27	12:46	2.4
11	9730225150	0204	DB0457	DAY5	2013 08 27	16:46	3.0
12	9730225150	0204	DB0457	DAY5	2013 08 27	20:46	3.1
13	9730225230	0202	DB0651	DAY5	2013 08 27	06:26	1.0
14	9730225230	0202	DB0651	DAY5	2013 08 27	12:34	1.0
15	9730225230	0202	DB0651	DAY5	2013 08 27	16:34	1.0



Synevo Central Lab  
Confidential

16	9730225230	0202	DB0651	DAY5	2013 08 27	20:34	1.0
17	9730225270	0255	DB1129	DAY5	2013 08 27	06:42	1.1
18	9730225270	0255	DB1129	DAY5	2013 08 27	12:50	1.1
19	9730225270	0255	DB1129	DAY5	2013 08 27	16:50	1.1
20	9730225270	0255	DB1129	DAY5	2013 08 27	20:50	1.0
21	9730225310	0200	DB1145	DAY5	2013 08 27	06:28	2.1
22	9730225310	0200	DB1145	DAY5	2013 08 27	12:36	3.2
23	9730225310	0200	DB1145	DAY5	2013 08 27	16:36	3.3
24	9730225310	0200	DB1145	DAY5	2013 08 27	20:36	3.7
25	9730225350	0232	DB1149	DAY5	2013 08 27	06:32	1.1
26	9730225350	0232	DB1149	DAY5	2013 08 27	12:40	1.0
27	9730225350	0232	DB1149	DAY5	2013 08 27	16:40	1.1
28	9730225350	0232	DB1149	DAY5	2013 08 27	20:40	1.0
29	9730225390	0203	DB0143	DAY5	2013 08 27	08:44	0.8
30	9730225390	0203	DB0143	DAY5	2013 08 27	12:44	0.8
31	9730225390	0203	DB0143	DAY5	2013 08 27	16:44	0.7
32	9730225390	0203	DB0143	DAY5	2013 08 27	20:44	0.7
33	9730225430	0193	DB0722	DAY5	2013 08 27	06:28	1.0
34	9730225430	0193	DB0722	DAY5	2013 08 27	12:36	1.0
35	9730225430	0193	DB0722	DAY5	2013 08 27	16:36	1.1
36	9730225430	0193	DB0722	DAY5	2013 08 27	20:36	1.1
37	9730225470	0224	DB0345	DAY5	2013 08 27	06:34	2.4
38	9730225470	0224	DB0345	DAY5	2013 08 27	12:42	3.0
39	9730225470	0224	DB0345	DAY5	2013 08 27	16:42	3.9
40	9730225470	0224	DB0345	DAY5	2013 08 27	20:42	3.9
41	9730225550	0230	DB1207	DAY5	2013 08 27	06:48	2.5
42	9730225550	0230	DB1207	DAY5	2013 08 27	12:56	4.4
43	9730225550	0230	DB1207	DAY5	2013 08 27	16:56	4.7
44	9730225550	0230	DB1207	DAY5	2013 08 27	20:56	5.0
45	9730225590	0197	DB0172	DAY5	2013 08 27	09:02	1.2
46	9730225590	0197	DB0172	DAY5	2013 08 27	13:02	1.0
47	9730225590	0197	DB0172	DAY5	2013 08 27	17:02	1.0
48	9730225590	0197	DB0172	DAY5	2013 08 27	21:02	1.0
49	9730225630	0264	DB0595	DAY5	2013 08 27	06:36	1.1
50	9730225630	0264	DB0595	DAY5	2013 08 27	12:44	0.9
51	9730225630	0264	DB0595	DAY5	2013 08 27	16:44	1.0
52	9730225630	0264	DB0595	DAY5	2013 08 27	20:44	1.0
53	9730225710	0240	DB1236	DAY5	2013 08 27	08:54	1.0
54	9730225710	0240	DB1236	DAY5	2013 08 27	12:54	0.9
55	9730225710	0240	DB1236	DAY5	2013 08 27	16:54	0.9
56	9730225710	0240	DB1236	DAY5	2013 08 27	20:54	0.9
57	9730225830	0234	DB1208	DAY5	2013 08 27	06:38	1.0
58	9730225830	0234	DB1208	DAY5	2013 08 27	12:46	1.0
59	9730225830	0234	DB1208	DAY5	2013 08 27	16:46	1.0
60	9730225830	0234	DB1208	DAY5	2013 08 27	20:46	0.9

Synevo Central Lab  
Confidential

61	9730225870	0251	DB1054	DAY5	2013 08 27	09:02	1.1
62	9730225870	0251	DB1054	DAY5	2013 08 27	13:02	0.9
63	9730225870	0251	DB1054	DAY5	2013 08 27	17:02	1.0
64	9730225870	0251	DB1054	DAY5	2013 08 27	21:02	0.9
65	9730225910	0244	DB0814	DAY5	2013 08 27	06:32	1.2
66	9730225910	0244	DB0814	DAY5	2013 08 27	12:40	1.0
67	9730225910	0244	DB0814	DAY5	2013 08 27	16:40	1.0
68	9730225910	0244	DB0814	DAY5	2013 08 27	20:40	1.1
69	9730225950	0228	DB1053	DAY5	2013 08 27	06:30	1.1
70	9730225950	0228	DB1053	DAY5	2013 08 27	12:38	1.1
71	9730225950	0228	DB1053	DAY5	2013 08 27	16:38	1.0
72	9730225950	0228	DB1053	DAY5	2013 08 27	20:38	1.0
73	9730225990	0265	DB0588	DAY5	2013 08 27	08:52	1.0
74	9730225990	0265	DB0588	DAY5	2013 08 27	12:52	1.1
75	9730225990	0265	DB0588	DAY5	2013 08 27	16:52	1.0
76	9730225990	0265	DB0588	DAY5	2013 08 27	20:52	1.0
77	9730226030	0198	DB0994	DAY5	2013 08 27	06:22	4.2
78	9730226030	0198	DB0994	DAY5	2013 08 27	12:30	6.5
79	9730226030	0198	DB0994	DAY5	2013 08 27	16:30	6.0
80	9730226030	0198	DB0994	DAY5	2013 08 27	20:30	6.5
81	9730226070	0229	DB0531	DAY5	2013 08 27	06:34	1.8
82	9730226070	0229	DB0531	DAY5	2013 08 27	12:42	2.8
83	9730226070	0229	DB0531	DAY5	2013 08 27	16:43	2.8
84	9730226070	0229	DB0531	DAY5	2013 08 27	20:42	2.7
85	9730226110	0252	DB1133	DAY5	2013 08 27	08:48	1.1
86	9730226110	0252	DB1133	DAY5	2013 08 27	12:48	1.1
87	9730226110	0252	DB1133	DAY5	2013 08 27	16:48	1.1
88	9730226110	0252	DB1133	DAY5	2013 08 27	20:48	1.0
89	9730226150	0220	DB0939	DAY5	2013 08 27	06:48	1.0
90	9730226150	0220	DB0939	DAY5	2013 08 27	12:56	0.9
91	9730226150	0220	DB0939	DAY5	2013 08 27	16:56	0.9
92	9730226150	0220	DB0939	DAY5	2013 08 27	20:56	0.9
93	9730226190	0216	DB0256	DAY5	2013 08 27	06:30	1.0
94	9730226190	0216	DB0256	DAY5	2013 08 27	12:38	1.1
95	9730226190	0216	DB0256	DAY5	2013 08 27	16:38	0.9
96	9730226190	0216	DB0256	DAY5	2013 08 27	20:38	1.0
97	9730226230	0195	DB1181	DAY5	2013 08 27	06:50	1.1
98	9730226230	0195	DB1181	DAY5	2013 08 27	12:58	1.2
99	9730226230	0195	DB1181	DAY5	2013 08 27	16:58	1.2
100	9730226230	0195	DB1181	DAY5	2013 08 27	20:58	1.1
101	9730226270	0256	DB0498	DAY5	2013 08 27	06:42	1.0
102	9730226270	0256	DB0498	DAY5	2013 08 27	12:50	1.1
103	9730226270	0256	DB0498	DAY5	2013 08 27	16:50	1.1
104	9730226270	0256	DB0498	DAY5	2013 08 27	20:50	1.0
105	9730226310	0218	DB1077	DAY5	2013 08 27	08:54	1.0

Synevo Central Lab  
Confidential

106	9730226310	0218	DB1077	DAY5	2013 08 27	12:54	0.9
107	9730226310	0218	DB1077	DAY5	2013 08 27	16:54	0.9
108	9730226310	0218	DB1077	DAY5	2013 08 27	20:54	0.9
109	9730226350	0249	DB1017	DAY5	2013 08 27	08:34	1.2
110	9730226350	0249	DB1017	DAY5	2013 08 27	12:34	1.3
111	9730226350	0249	DB1017	DAY5	2013 08 27	16:34	1.1
112	9730226350	0249	DB1017	DAY5	2013 08 27	20:32	1.1
113	9730226390	0196	DB1206	DAY5	2013 08 27	06:52	1.0
114	9730226390	0196	DB1206	DAY5	2013 08 27	13:00	1.1
115	9730226390	0196	DB1206	DAY5	2013 08 27	17:00	1.1
116	9730226390	0196	DB1206	DAY5	2013 08 27	21:00	1.0
117	9730226430	0206	DB0993	DAY5	2013 08 27	06:24	1.2
118	9730226430	0206	DB0993	DAY5	2013 08 27	12:32	1.2
119	9730226430	0206	DB0993	DAY5	2013 08 27	16:32	1.1
120	9730226430	0206	DB0993	DAY5	2013 08 27	20:32	1.1
121	9730226470	0241	DB1266	DAY5	2013 08 27	06:52	1.2
122	9730226470	0241	DB1266	DAY5	2013 08 27	13:00	1.2
123	9730226470	0241	DB1266	DAY5	2013 08 27	17:00	1.1
124	9730226470	0241	DB1266	DAY5	2013 08 27	21:00	1.1

### 5.1.5 5<sup>th</sup> cohort

During the 5<sup>th</sup> cohort study, the 325 of blood samples were tested for COHb concentration. There were 37 subjects participated in that cohort and 5 subjects who were discontinued from the study due to medical reasons. The group of 32 subjects terminated the study (one subject without complete set of results – one result missing - patient 0328 Day 1 - sample was rejected because of too small volume of the sample)

The group of COHb for 5<sup>th</sup> cohort samples are presented in [table 5e](#) of the report.

**Table 5e:** The register of the COHb result of the 5<sup>th</sup> cohort.

No.	Lab. No.	Subject	DBN	Visit No.	Collection data	Time	Result [%]
1	9730162410	0306	DB1371	DAY -1	2013 09 12	21:12	5.3
2	9730164350	0312	DB0688	DAY -1	2013 09 12	21:14	5.8
3	9730236060	0277	DB1002	DAY -1	2013 09 12	20:10	5.7
4	9730236160	0300	DB1257	DAY -1	2013 09 12	20:28	1.5
5	9730236170	0308	DB1375	DAY -1	2013 09 12	20:08	5.9
6	9730236200	0269	DB1097	DAY -1	2013 09 12	20:30	4.4
7	9730236230	0317	DB1397	DAY -1	2013 09 12	20:12	4.2
8	9730236240	0325	DB1121	DAY -1	2013 09 12	20:06	4.7
9	9730236250	0315	DB1055	DAY -1	2013 09 12	20:04	2.0
10	9730236260	0291	DB0879	DAY -1	2013 09 12	20:14	4.1
11	9730236270	0316	DB1056	DAY -1	2013 09 12	20:02	1.7
12	9730236280	0283	DB1059	DAY -1	2013 09 12	20:20	3.9

Synevo Central Lab  
Confidential

13	9730236290	0288	DB0672	DAY -1	2013 09 12	20:16	3.7
14	9730236300	0328	DB0383	DAY -1	2013 09 12	20:18	3.3
15	9730236310	0292	DB1176	DAY -1	2013 09 12	20:28	3.8
16	9730236320	0287	DB1130	DAY -1	2013 09 12	20:24	3.0
17	9730236330	0272	DB1315	DAY -1	2013 09 12	20:50	6.1
18	9730236340	0266	DB1220	DAY -1	2013 09 12	20:22	5.1
19	9730236350	0299	DB1125	DAY -1	2013 09 12	20:49	3.8
20	9730236360	0289	DB0913	DAY -1	2013 09 12	20:46	4.5
21	9730236370	0321	DB1166	DAY -1	2013 09 12	20:44	3.2
22	9730236380	0296	DB1373	DAY -1	2013 09 12	20:40	3.7
23	9730236390	0273	DB0174	DAY -1	2013 09 12	20:36	4.9
24	9730236400	0307	DB1234	DAY -1	2013 09 12	20:38	2.7
25	9730236410	0281	DB0894	DAY -1	2013 09 12	20:42	4.7
26	9730236420	0322	DB1039	DAY -1	2013 09 12	20:34	3.2
27	9730236430	0301	DB1094	DAY -1	2013 09 12	21:11	4.6
28	9730236440	0282	DB0056	DAY -1	2013 09 12	21:04	3.9
29	9730236450	0309	DB1272	DAY -1	2013 09 12	20:32	4.9
30	9730236460	0318	DB0857	DAY -1	2013 09 12	20:08	5.2
31	9730236470	0276	DB1150	DAY -1	2013 09 12	21:06	2.0
32	9730236480	0279	DB0077	DAY -1	2013 09 12	21:02	4.8
33	9730236490	0320	DB0629	DAY -1	2013 09 12	20:58	6.1
34	9730236500	0313	DB0827	DAY -1	2013 09 12	20:56	3.1
35	9730236510	0298	DB1196	DAY -1	2013 09 12	21:00	4.9
36	9730236520	0285	DB1066	DAY -1	2013 09 12	20:54	4.6
37	9730236530	0278	DB0445	DAY -1	2013 09 12	20:52	4.8
1	9730160570	0306	DB1371	DAY0	2013 09 13	21:12	6.8
2	9730160690	0301	DB1094	DAY0	2013 09 13	21:10	7.1
3	9730236540	0296	DB1373	DAY0	2013 09 13	20:40	3.8
4	9730236550	0281	DB0894	DAY0	2013 09 13	20:42	6.1
5	9730236560	0307	DB1234	DAY0	2013 09 13	20:38	4.2
6	9730236570	0266	DB1220	DAY0	2013 09 13	20:22	5.5
7	9730236580	0317	DB1397	DAY0	2013 09 13	20:12	4.3
8	9730236590	0321	DB1166	DAY0	2013 09 13	20:44	3.5
9	9730236600	0289	DB0913	DAY0	2013 09 13	20:46	4.3
10	9730236620	0316	DB1056	DAY0	2013 09 13	20:02	2.2
11	9730236630	0283	DB1059	DAY0	2013 09 13	20:20	3.8
12	9730236650	0315	DB1055	DAY0	2013 09 13	20:04	3.6
13	9730236660	0325	DB1121	DAY0	2013 09 13	20:06	5.6
14	9730236670	0308	DB1375	DAY0	2013 09 13	20:08	6.7
15	9730236680	0277	DB1002	DAY0	2013 09 13	20:10	7.9
16	9730236690	0287	DB1130	DAY0	2013 09 13	20:24	3.7
17	9730236700	0278	DB0445	DAY0	2013 09 13	20:52	4.1
18	9730236720	0291	DB0879	DAY0	2013 09 13	20:14	3.7
19	9730236730	0292	DB1176	DAY0	2013 09 13	20:26	4.2
20	9730236740	0300	DB1257	DAY0	2013 09 13	20:28	1.6

Synevo Central Lab  
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21	9730236750	0328	DB0383	DAY0	2013 09 13	20:18	3.2
22	9730236760	0298	DB1196	DAY0	2013 09 13	21:00	5.7
23	9730236770	0320	DB0629	DAY0	2013 09 13	20:58	6.6
24	9730236780	0313	DB0827	DAY0	2013 09 13	20:56	3.1
25	9730236790	0282	DB0056	DAY0	2013 09 13	21:04	6.1
26	9730236800	0285	DB1066	DAY0	2013 09 13	20:54	6.0
27	9730236810	0272	DB1315	DAY0	2013 09 13	20:50	5.9
28	9730236820	0318	DB0857	DAY0	2013 09 13	21:08	9.1
29	9730236830	0276	DB1150	DAY0	2013 09 13	21:06	2.1
30	9730236860	0279	DB0077	DAY0	2013 09 13	21:02	4.7
31	9730236870	0273	DB0174	DAY0	2013 09 13	20:36	5.4
32	9730236880	0322	DB1039	DAY0	2013 09 13	20:34	2.6
1	9730160610	0301	DB1094	DAY1	2013 09 14	21:10	1.4
2	9730235890	0287	DB1130	DAY1	2013 09 14	20:24	1.3
3	9730235900	0300	DB1257	DAY1	2013 09 14	20:28	1.0
4	9730235910	0292	DB1176	DAY1	2013 09 14	20:26	1.2
5	9730235930	0306	DB1371	DAY1	2013 09 14	21:12	1.2
6	9730235940	0322	DB1039	DAY1	2013 09 14	20:34	3.1
7	9730235950	0283	DB1059	DAY1	2013 09 14	20:20	3.8
8	9730235970	0328	DB0383	DAY1	2013 09 14	20:18	-
9	9730235980	0291	DB0879	DAY1	2013 09 14	20:14	1.3
10	9730235990	0317	DB1397	DAY1	2013 09 14	20:12	1.0
11	9730236000	0318	DB0857	DAY1	2013 09 14	21:08	8.4
12	9730236010	0321	DB1166	DAY1	2013 09 14	20:44	1.2
13	9730236020	0273	DB0174	DAY1	2013 09 14	20:36	1.4
14	9730236040	0307	DB1234	DAY1	2013 09 14	20:38	1.4
15	9730236050	0296	DB1373	DAY1	2013 09 14	20:40	1.2
16	9730236070	0276	DB1150	DAY1	2013 09 14	21:06	1.2
17	9730236080	0282	DB0056	DAY1	2013 09 14	21:04	1.3
18	9730236100	0279	DB0077	DAY1	2013 09 14	21:02	1.1
19	9730236110	0281	DB0894	DAY1	2013 09 14	20:42	1.5
20	9730236120	0298	DB1196	DAY1	2013 09 14	21:00	4.8
21	9730236130	0272	DB1315	DAY1	2013 09 14	20:50	1.2
22	9730236140	0289	DB0913	DAY1	2013 09 14	20:46	1.0
23	9730236150	0313	DB0827	DAY1	2013 09 14	20:56	3.1
24	9730236180	0278	DB0445	DAY1	2013 09 14	20:52	5.7
25	9730236190	0320	DB0629	DAY1	2013 09 14	20:58	1.2
26	9730236210	0266	DB1220	DAY1	2013 09 14	20:22	1.1
27	9730236220	0285	DB1066	DAY1	2013 09 14	20:54	5.5
28	9730236960	0277	DB1002	DAY1	2013 09 14	20:10	1.6
29	9730237040	0315	DB1055	DAY1	2013 09 14	20:04	2.9
30	9730237060	0308	DB1375	DAY1	2013 09 14	20:08	1.9
31	9730237080	0316	DB1056	DAY1	2013 09 14	20:02	1.0
32	9730237190	0325	DB1121	DAY1	2013 09 14	20:06	1.4
1	9730235070	0300	DB1257	DAY2	2013 09 15	20:28	1.0

Synevo Central Lab  
Confidential

2	9730235120	0283	DB1059	DAY2	2013 09 15	20:20	3.6
3	9730235200	0279	DB0077	DAY2	2013 09 15	21:02	1.1
4	9730235210	0292	DB1176	DAY2	2013 09 15	20:26	1.0
5	9730235430	0266	DB1220	DAY2	2013 09 15	20:22	1.0
6	9730235530	0313	DB0827	DAY2	2013 09 15	20:56	3.0
7	9730235860	0285	DB1066	DAY2	2013 09 15	20:54	5.1
8	9730235880	0307	DB1234	DAY2	2013 09 15	20:38	1.1
9	9730236900	0272	DB1315	DAY2	2013 09 15	20:50	1.2
10	9730236910	0276	DB1150	DAY2	2013 09 15	21:06	1.2
11	9730236920	0321	DB1166	DAY2	2013 09 15	20:44	1.1
12	9730236940	0317	DB1397	DAY2	2013 09 15	20:12	0.8
13	9730236950	0298	DB1196	DAY2	2013 09 15	21:00	4.3
14	9730236970	0318	DB0857	DAY2	2013 09 15	21:08	7.7
15	9730236980	0291	DB0879	DAY2	2013 09 15	20:14	1.2
16	9730236990	0301	DB1094	DAY2	2013 09 15	21:10	1.2
17	9730237000	0306	DB1371	DAY2	2013 09 15	21:12	1.0
18	9730237010	0328	DB0383	DAY2	2013 09 15	20:18	3.1
19	9730237020	0278	DB0445	DAY2	2013 09 15	20:52	4.5
20	9730237030	0322	DB1039	DAY2	2013 09 15	20:34	3.4
21	9730237070	0281	DB0894	DAY2	2013 09 15	20:42	1.2
22	9730237090	0320	DB0629	DAY2	2013 09 15	20:58	1.1
23	9730237100	0273	DB0174	DAY2	2013 09 15	20:36	1.2
24	9730237110	0316	DB1056	DAY2	2013 09 15	20:02	1.0
25	9730237120	0315	DB1055	DAY2	2013 09 15	20:04	2.9
26	9730237130	0287	DB1130	DAY2	2013 09 15	20:24	1.2
27	9730237140	0296	DB1373	DAY2	2013 09 15	20:40	1.0
28	9730237150	0308	DB1375	DAY2	2013 09 15	20:08	1.4
29	9730237160	0325	DB1121	DAY2	2013 09 15	20:06	1.0
30	9730237180	0277	DB1002	DAY2	2013 09 15	20:10	1.3
31	9730237200	0282	DB0056	DAY2	2013 09 15	21:04	1.2
32	9730237220	0289	DB0913	DAY2	2013 09 15	20:46	1.0
1	9730234900	0277	DB1002	DAY3	2013 09 16	20:10	1.3
2	9730234920	0313	DB0827	DAY3	2013 09 16	20:56	3.8
3	9730234980	0285	DB1066	DAY3	2013 09 16	20:54	4.5
4	9730235250	0289	DB0913	DAY3	2013 09 16	20:46	0.9
5	9730235290	0272	DB1315	DAY3	2013 09 16	20:50	1.1
6	9730235310	0321	DB1166	DAY3	2013 09 16	20:44	1.1
7	9730235350	0278	DB0445	DAY3	2013 09 16	20:52	4.9
8	9730235540	0325	DB1121	DAY3	2013 09 16	20:06	1.0
9	9730235550	0315	DB1055	DAY3	2013 09 16	20:04	3.0
10	9730235560	0301	DB1094	DAY3	2013 09 16	21:10	1.2
11	9730235610	0276	DB1150	DAY3	2013 09 16	21:06	1.2
12	9730235620	0316	DB1056	DAY3	2013 09 16	20:02	1.0
13	9730235640	0306	DB1371	DAY3	2013 09 16	21:12	0.9
14	9730235650	0282	DB0056	DAY3	2013 09 16	21:04	1.2

Synevo Central Lab  
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15	9730235680	0279	DB0077	DAY3	2013 09 16	21:02	1.0
16	9730235700	0308	DB1375	DAY3	2013 09 16	20:08	1.3
17	9730235720	0307	DB1234	DAY3	2013 09 16	20:38	1.1
18	9730235730	0322	DB1039	DAY3	2013 09 16	20:34	2.8
19	9730235740	0273	DB0174	DAY3	2013 09 16	20:36	1.0
20	9730235750	0281	DB0894	DAY3	2013 09 16	20:42	1.2
21	9730235760	0300	DB1257	DAY3	2013 09 16	20:28	0.9
22	9730235770	0292	DB1176	DAY3	2013 09 16	20:26	1.0
23	9730235780	0287	DB1130	DAY3	2013 09 16	20:24	1.1
24	9730235790	0296	DB1373	DAY3	2013 09 16	20:40	1.1
25	9730235800	0266	DB1220	DAY3	2013 09 16	20:22	1.0
26	9730235810	0283	DB1059	DAY3	2013 09 16	20:20	3.4
27	9730235820	0298	DB1196	DAY3	2013 09 16	21:00	5.1
28	9730235830	0291	DB0879	DAY3	2013 09 16	20:14	1.1
29	9730235840	0317	DB1397	DAY3	2013 09 16	20:12	0.9
30	9730235850	0328	DB0383	DAY3	2013 09 16	20:18	2.7
31	9730235870	0318	DB0857	DAY3	2013 09 16	21:08	8.6
32	9730237050	0320	DB0629	DAY3	2013 09 16	20:58	1.2
1	9730234930	0283	DB1059	DAY4	2013 09 17	20:20	4.1
2	9730235040	0300	DB1257	DAY4	2013 09 17	20:28	1.0
3	9730235050	0292	DB1176	DAY4	2013 09 17	20:26	1.1
4	9730235090	0266	DB1220	DAY4	2013 09 17	20:22	1.1
5	9730235220	0287	DB1130	DAY4	2013 09 17	20:24	1.2
6	9730235260	0273	DB0174	DAY4	2013 09 17	20:36	1.2
7	9730235270	0322	DB1039	DAY4	2013 09 17	20:34	3.0
8	9730235280	0316	DB1056	DAY4	2013 09 17	20:02	1.0
9	9730235300	0291	DB0879	DAY4	2013 09 17	20:14	1.2
10	9730235320	0328	DB0383	DAY4	2013 09 17	20:18	3.0
11	9730235330	0308	DB1375	DAY4	2013 09 17	20:08	1.3
12	9730235340	0325	DB1121	DAY4	2013 09 17	20:06	1.1
13	9730235360	0315	DB1055	DAY4	2013 09 17	20:04	2.7
14	9730235370	0277	DB1002	DAY4	2013 09 17	20:10	1.3
15	9730235380	0317	DB1397	DAY4	2013 09 17	20:12	0.9
16	9730235390	0279	DB0077	DAY4	2013 09 17	21:02	1.1
17	9730235400	0298	DB1196	DAY4	2013 09 17	21:00	5.9
18	9730235410	0313	DB0827	DAY4	2013 09 17	20:56	3.0
19	9730235420	0320	DB0629	DAY4	2013 09 17	20:58	1.1
20	9730235440	0285	DB1066	DAY4	2013 09 17	20:54	6.0
21	9730235450	0278	DB0445	DAY4	2013 09 17	20:52	4.4
22	9730235460	0272	DB1315	DAY4	2013 09 17	20:50	1.2
23	9730235470	0307	DB1234	DAY4	2013 09 17	20:38	1.1
24	9730235490	0296	DB1373	DAY4	2013 09 17	20:40	1.2
25	9730235500	0321	DB1166	DAY4	2013 09 17	20:44	1.2
26	9730235520	0306	DB1371	DAY4	2013 09 17	21:12	0.9
27	9730235570	0282	DB0056	DAY4	2013 09 17	21:04	1.1

Synevo Central Lab  
Confidential

28	9730235590	0281	DB0894	DAY4	2013 09 17	20:42	1.1
29	9730235600	0289	DB0913	DAY4	2013 09 17	20:46	1.0
30	9730235630	0301	DB1094	DAY4	2013 09 17	21:10	1.1
31	9730235660	0318	DB0857	DAY4	2013 09 17	21:08	7.7
32	9730235670	0276	DB1150	DAY4	2013 09 17	21:06	1.2
1	9730232610	0315	DB1055	DAY5	2013 09 18	06:24	2.0
2	9730232610	0315	DB1055	DAY5	2013 09 18	12:32	3.1
3	9730232610	0315	DB1055	DAY5	2013 09 18	16:32	3.4
4	9730232610	0315	DB1055	DAY5	2013 09 18	20:32	2.9
5	9730232650	0325	DB1121	DAY5	2013 09 18	08:34	1.0
6	9730232650	0325	DB1121	DAY5	2013 09 18	12:34	1.1
7	9730232650	0325	DB1121	DAY5	2013 09 18	16:34	1.1
8	9730232650	0325	DB1121	DAY5	2013 09 18	20:34	1.0
9	9730232690	0277	DB1002	DAY5	2013 09 18	06:30	1.4
10	9730232690	0277	DB1002	DAY5	2013 09 18	12:38	1.4
11	9730232690	0277	DB1002	DAY5	2013 09 18	16:38	1.4
12	9730232690	0277	DB1002	DAY5	2013 09 18	20:38	1.4
13	9730232730	0316	DB1056	DAY5	2013 09 18	06:22	1.0
14	9730232730	0316	DB1056	DAY5	2013 09 18	12:30	1.0
15	9730232730	0316	DB1056	DAY5	2013 09 18	16:30	1.0
16	9730232730	0316	DB1056	DAY5	2013 09 18	20:30	0.9
17	9730232770	0308	DB1375	DAY5	2013 09 18	06:28	1.4
18	9730232770	0308	DB1375	DAY5	2013 09 18	12:36	1.5
19	9730232770	0308	DB1375	DAY5	2013 09 18	16:36	1.4
20	9730232770	0308	DB1375	DAY5	2013 09 18	20:36	1.3
21	9730232810	0317	DB1397	DAY5	2013 09 18	08:40	0.9
22	9730232810	0317	DB1397	DAY5	2013 09 18	12:40	0.8
23	9730232810	0317	DB1397	DAY5	2013 09 18	16:40	0.9
24	9730232810	0317	DB1397	DAY5	2013 09 18	20:40	0.9
25	9730232850	0291	DB0879	DAY5	2013 09 18	06:34	1.3
26	9730232850	0291	DB0879	DAY5	2013 09 18	12:42	1.2
27	9730232850	0291	DB0879	DAY5	2013 09 18	16:42	1.3
28	9730232850	0291	DB0879	DAY5	2013 09 18	20:42	1.2
29	9730232890	0283	DB1059	DAY5	2013 09 18	06:40	2.1
30	9730232890	0283	DB1059	DAY5	2013 09 18	12:48	3.5
31	9730232890	0283	DB1059	DAY5	2013 09 18	16:48	4.0
32	9730232890	0283	DB1059	DAY5	2013 09 18	20:48	4.6
33	9730232930	0328	DB0383	DAY5	2013 09 18	06:38	1.9
34	9730232930	0328	DB0383	DAY5	2013 09 18	12:46	2.8
35	9730232930	0328	DB0383	DAY5	2013 09 18	16:46	3.4
36	9730232930	0328	DB0383	DAY5	2013 09 18	20:46	2.9
37	9730232970	0266	DB1220	DAY5	2013 09 18	08:50	1.0
38	9730232970	0266	DB1220	DAY5	2013 09 18	12:50	1.0
39	9730232970	0266	DB1220	DAY5	2013 09 18	16:50	1.0
40	9730232970	0266	DB1220	DAY5	2013 09 18	20:50	1.1



Synevo Central Lab  
Confidential

41	9730233010	0300	DB1257	DAY5	2013 09 18	06:48	0.9
42	9730233010	0300	DB1257	DAY5	2013 09 18	12:56	0.9
43	9730233010	0300	DB1257	DAY5	2013 09 18	16:56	0.9
44	9730233010	0300	DB1257	DAY5	2013 09 18	20:56	0.9
45	9730233050	0287	DB1130	DAY5	2013 09 18	06:44	1.1
46	9730233050	0287	DB1130	DAY5	2013 09 18	12:52	1.1
47	9730233050	0287	DB1130	DAY5	2013 09 18	16:52	1.2
48	9730233050	0287	DB1130	DAY5	2013 09 18	20:52	1.1
49	9730233090	0322	DB1039	DAY5	2013 09 18	06:54	2.2
50	9730233090	0322	DB1039	DAY5	2013 09 18	13:02	2.5
51	9730233090	0322	DB1039	DAY5	2013 09 18	17:02	3.2
52	9730233090	0322	DB1039	DAY5	2013 09 18	21:02	3.1
53	9730233130	0273	DB0174	DAY5	2013 09 18	09:04	1.2
54	9730233130	0273	DB0174	DAY5	2013 09 18	13:04	1.2
55	9730233130	0273	DB0174	DAY5	2013 09 18	17:04	1.1
56	9730233130	0273	DB0174	DAY5	2013 09 18	21:04	1.0
57	9730233170	0292	DB1176	DAY5	2013 09 18	08:54	1.1
58	9730233170	0292	DB1176	DAY5	2013 09 18	12:54	1.0
59	9730233170	0292	DB1176	DAY5	2013 09 18	16:54	1.1
60	9730233170	0292	DB1176	DAY5	2013 09 18	20:54	1.0
61	9730233210	0307	DB1234	DAY5	2013 09 18	06:22	1.1
62	9730233210	0307	DB1234	DAY5	2013 09 18	12:30	1.1
63	9730233210	0307	DB1234	DAY5	2013 09 18	16:30	1.1
64	9730233210	0307	DB1234	DAY5	2013 09 18	20:30	1.1
65	9730233250	0296	DB1373	DAY5	2013 09 18	06:24	1.1
66	9730233250	0296	DB1373	DAY5	2013 09 18	12:32	1.1
67	9730233250	0296	DB1373	DAY5	2013 09 18	16:32	1.0
68	9730233250	0296	DB1373	DAY5	2013 09 18	20:32	1.0
69	9730233290	0281	DB0894	DAY5	2013 09 18	06:26	1.1
70	9730233290	0281	DB0894	DAY5	2013 09 18	12:34	1.2
71	9730233290	0281	DB0894	DAY5	2013 09 18	16:34	1.1
72	9730233290	0281	DB0894	DAY5	2013 09 18	20:34	1.1
73	9730233330	0321	DB1166	DAY5	2013 09 18	06:28	1.1
74	9730233330	0321	DB1166	DAY5	2013 09 18	12:36	1.1
75	9730233330	0321	DB1166	DAY5	2013 09 18	16:36	1.1
76	9730233330	0321	DB1166	DAY5	2013 09 18	20:36	1.1
77	9730233370	0289	DB0913	DAY5	2013 09 18	08:38	1.1
78	9730233370	0289	DB0913	DAY5	2013 09 18	12:38	1.0
79	9730233370	0289	DB0913	DAY5	2013 09 18	16:38	1.1
80	9730233370	0289	DB0913	DAY5	2013 09 18	20:38	1.0
81	9730233410	0320	DB0629	DAY5	2013 09 18	06:42	1.2
82	9730233410	0320	DB0629	DAY5	2013 09 18	12:50	1.3
83	9730233410	0320	DB0629	DAY5	2013 09 18	16:50	1.2
84	9730233410	0320	DB0629	DAY5	2013 09 18	20:50	1.2
85	9730233450	0298	DB1196	DAY5	2013 09 18	06:44	2.4

Synevo Central Lab  
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86	9730233450	0298	DB1196	DAY5	2013 09 18	12:52	5.2
87	9730233450	0298	DB1196	DAY5	2013 09 18	16:52	6.2
88	9730233450	0298	DB1196	DAY5	2013 09 18	20:52	5.8
89	9730233490	0313	DB0827	DAY5	2013 09 18	06:40	1.8
90	9730233490	0313	DB0827	DAY5	2013 09 18	12:48	3.3
91	9730233490	0313	DB0827	DAY5	2013 09 18	16:48	3.9
92	9730233490	0313	DB0827	DAY5	2013 09 18	20:48	3.5
93	9730233530	0285	DB1066	DAY5	2013 09 18	06:38	3.5
94	9730233530	0285	DB1066	DAY5	2013 09 18	12:46	4.6
95	9730233530	0285	DB1066	DAY5	2013 09 18	16:46	5.0
96	9730233530	0285	DB1066	DAY5	2013 09 18	20:46	5.1
97	9730233650	0318	DB0857	DAY5	2013 09 18	06:52	4.4
98	9730233650	0318	DB0857	DAY5	2013 09 18	13:00	7.4
99	9730233650	0318	DB0857	DAY5	2013 09 18	17:00	8.3
100	9730233650	0318	DB0857	DAY5	2013 09 18	21:00	7.7
101	9730233690	0278	DB0445	DAY5	2013 09 18	06:36	2.6
102	9730233690	0278	DB0445	DAY5	2013 09 18	12:44	3.5
103	9730233690	0278	DB0445	DAY5	2013 09 18	16:44	4.3
104	9730233690	0278	DB0445	DAY5	2013 09 18	20:44	5.2
105	9730233730	0272	DB1315	DAY5	2013 09 18	06:34	1.1
106	9730233730	0272	DB1315	DAY5	2013 09 18	12:42	1.2
107	9730233730	0272	DB1315	DAY5	2013 09 18	16:42	1.3
108	9730233730	0272	DB1315	DAY5	2013 09 18	20:42	1.2
109	9730233770	0301	DB1094	DAY5	2013 09 18	06:54	1.3
110	9730233770	0301	DB1094	DAY5	2013 09 18	13:02	1.3
111	9730233770	0301	DB1094	DAY5	2013 09 18	17:02	1.1
112	9730233770	0301	DB1094	DAY5	2013 09 18	21:02	1.1
113	9730233810	0282	DB0056	DAY5	2013 09 18	06:48	1.1
114	9730233810	0282	DB0056	DAY5	2013 09 18	12:56	1.2
115	9730233810	0282	DB0056	DAY5	2013 09 18	16:56	1.1
116	9730233810	0282	DB0056	DAY5	2013 09 18	20:56	1.1
117	9730233850	0279	DB0077	DAY5	2013 09 18	06:46	0.9
118	9730233850	0279	DB0077	DAY5	2013 09 18	12:54	1.1
119	9730233850	0279	DB0077	DAY5	2013 09 18	16:54	1.0
120	9730233850	0279	DB0077	DAY5	2013 09 18	20:54	0.9
121	9730233890	0276	DB1150	DAY5	2013 09 18	06:50	1.3
122	9730233890	0276	DB1150	DAY5	2013 09 18	12:58	1.2
123	9730233890	0276	DB1150	DAY5	2013 09 18	16:58	1.1
124	9730233890	0276	DB1150	DAY5	2013 09 18	20:58	1.2
125	9730233970	0306	DB1371	DAY5	2013 09 18	09:04	0.9
126	9730233970	0306	DB1371	DAY5	2013 09 18	13:04	1.0
127	9730233970	0306	DB1371	DAY5	2013 09 18	17:04	1.0
128	9730233970	0306	DB1371	DAY5	2013 09 18	21:04	0.9

## 5.2 Description of the main problems and solutions relating to the assays.

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Long term stability of the COHb samples is known and described in the literature. Our internal test validation procedure confirmed the 24-hour stability of the COHb when stored in refrigerator.

The evening batches of COHb samples were delivered to the laboratory at morning hours (35 batches). The morning batches were delivered to the laboratory at afternoon hours (5 batches). The analysis was performed at the day of sample delivery (40 batches). This testing procedure and time between sampling and analysis was in agreement with COHb stability.

All samples were stored in the refrigerator until analysis. They were removed from the refrigerator immediately before testing and thoroughly mixed first in the haematologic stirrer and then manually by 8-10 up-down and axis rotations.

### 5.3 Deviations from analytical SOP

All analytical batches during COHb testing were performed according to the internal analytical SOP consistent with test procedure and the method developed during validation. Because of the excellent stability of the COHb in the blood, the time of analysis extended to about 3 days ranged in the period of known stability of the analyte and if time delay would occur during the analysis it wouldn't affect the result of the COHb determinations in the batches.

Results from that batches were accepted and validated – only one sample was invalid and the result from its analysis was rejected.

### 5.4 Analytical notes

There was one analytical problem noted with small blood amount collected from the subject of Day 1 evening collection of the 5<sup>th</sup> cohort batches (9730235790 from 2013-09-15). It was less than 1.0 mL of blood collected (instead of 2.0 mL). The COHb test wasn't performed in that sample because of too small blood volume.

The likely effect of the heparin anticoagulant in liquid formulation on the sample dilution was not evaluated because of the incidental frequency of that error.

It was stated that dilution of the sample caused by reduced volume of blood in relation to the heparin didn't affect directly the final COHb concentration in the sample because of very low volume of heparin used in the tube as an anticoagulant.

## 6 Archiving of the data

The analytical raw data are stored in the Synevo facilities under supervising of the responsible personnel of Synevo Central Lab with appropriate control and adequate protection from fire, flood and unauthorized access according to local and GLP regulations concerning archiving study documentation:

- Study documentation (hard copy) – 15 years
- Electronic data backups according to Synevo SOPs

**The overall performance of the Carboxyhaemoglobin assay method the acceptance criteria and result obtained were of the required integrity and quality.**

**These data can be used for further interpretation.**

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1. OECD Principles of Good Laboratory Practices Directive 87/18/EEC, Directive 88/320/EEC
2. Kit inserts for the analytes, Roche
3. SOPs of the COHb determination in whole heparinised blood.
4. Validation Report of the COHb determination in the whole blood
5. Results of Internal Quality Control for the COHb
6. Laboratory Samples Inventory List
7. Samples shipment Logs
8. COHb results printout.

**Report Signature**

The ZRHR-REXC-03-EU study was performed according to GLP rules.

The bioanalytical report accurately reflects the raw data.

This report has been prepared by Anna Faryj

2.04.2015 Anna Faryj (signature, data)

This report has been reviewed by Magdalena Szydłowska

3.04.2015 Magdalena Szydłowska (signature, data)