ANIARA
Manufactured By: HYPHEN BioMed

LIAPHEN Fibrinogen ON BCS

Latex Immunoassay for the quantitative determination of Fibrinogen on BCS

1. LIAPHEN Fibrinogen (# A120102) reagents

	NAME	Reconstitution	Stability*	T° Stabilization
R1	**Latex reagent**	Ready to use	Refer insert	** 30 mn on board before any use

(*)Provided any contamination or evaporation is avoided. Stability can be adjusted according to the exact use conditions.

Stabilization of reagents: (**) It is necessary to let the reagent temperature to stabilize for at least 30 minutes on the automate board before any use.
Storage of reagents: Take care of putting up the specific caps back on the bottles before storing them at 2°-8° C, and of strictly respecting the temperature stabilization time of 30 minutes before using the reagents on the automate.
If the reagents are kept on the automate board, take care and use chimneys to limit as much as possible any evaporation of the reagents.

Homogenize the reagents before each use.

Any reagent of biological origin must be handled with all the required cautions, as being potentially infectious.

Do not interchange the reagents from different lots.

Reagents required but not provided:

- Plasma Calibrator titrated for Fibrinogen (eg: Biophen Plasma Calibrator #A222101)
- Normal and Abnormal quality control plasmas titrated for Fibrinogen (ex: BIOPHEN Normal Control Plasma -#A223201 and BIOPHEN Abnormal Control Plasma #A223301).
- Tris-NaCl-BSA pH 7.50 Buffer (eg: TBSA #AAR005A)

2. Preparation of the calibration curve and controls/samples.

- **Calibration curve:**

-Calibration is performed with a commercially available plasma calibrator, with a known Fibrinogen Concentration **"C" in g/L** (**eg Biophen Plasma Calibrator #A222101**). The calibrator must be loaded **1:10 manually prediluted in TBSA**. The test program for the calibration integrates dilutions of the calibrator (**managed by the BCS**) at various concentrations (to be defined by the user), **that correspond approximately to: "C", 2.5, 2.0, 1.5, 1.0, 0.5, 0.3 g/L Fibrinogen**.

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- **Tested plasma and controls:**

For normal plasmas and controls, plasmas should be loaded **prediluted manually 1:10 in TBSA** and then assayed at the **1:20** dilution **managed by the BCS (**ie the test dilution is **1:200 final).**

The control is performed with commercially available control plasmas, titrated for Fibrinogen. Various control plasmas are available: **Biophen Normal Control Plasma (#A223201), and Biophen Abnormal Control Plasma (#A223301) or Abnormal Fibrinogen Control Low (#ASC070K).**

Nota: For lyophilized calibrators and controls, following reconstitution with distilled water, let the reagent to stabilize 30 minutes at room temperature. It is recommended to run the calibration curve with a freshly reconstituted calibrator. It is necessary to let the reagent temperature to stabilize for at least 30 minutes onto the automate before any use. Take care avoiding any contamination or evaporation of the reagents. Stability can be adjusted according to the exact use conditions.
Homogenize before each use.
Do not freeze calibrators and quality control plasmas.

Quality controls must be run regularly, and for each new batch of reagents, after an important maintenance of the instrument, or if measured values are not in compliance with the one expected for the method.

3. Results:

- The calibration curve (working range) is of the **Akima lin-lin type.**
- The values obtained for patients and controls are directly calculated from the calibration curve.
- The results are expressed as **g/l** of fibrinogen.

The calibration curve is validated when reactivity, as well as measured control values, are in compliance.

A new calibration curve must be carried out for each new batch of reagents, after each important maintenance of the instrument, or when measured values for controls are out of the acceptance range for the method (after checking all other parameters for the system).

Performances may present variations according to the instrument used. Validate the expected values in the laboratory working conditions. Performances, as well as values for each new lot of quality controls used, must then be confirmed (and adjusted if necessary) in the laboratory working conditions.

NOTE:

- **The Calibrator, controls and samples are loaded, already manually prediluted 1:10 in TBSA, then a 1:20 (or adequate for calibrator) dilution is performed on BCS-XP.**

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PROGRAMMATION OF THE ANALYZER:

Creation of reagents files and diluent:

Definition of test. Reagents without lot data. Create the reagent files (and diluent)

Name:	**R1 LX FNG**
Abbreviation:	R1 LX FNG
clean when the reagent is modified	Intensive
☒ New calibration with any new lot of reagents	
Authorized lines from	1 to 14
Stability (*) < 15C	* > = 15C
Mix by jet Intensity	1
Frequency	No agitation
Reference numbers	Number
	add / remove / replace

Name:	**TBSA buffer**
Abbreviation:	TBSA
clean when the reagent is modified	Normal/Low
☒ New calibration with any new lot of reagents	
Authorized lines from	1 to 14
Stability (*) < 15C	* > = 15C
Mix by jet Intensity	1
Frequency	No agitation
Reference numbers	Number
	add / remove / replace

*To be defined by the user, according to the insert instructions and the exact use conditions.

Creation of calibration and controls files

Name:	**Cal**
Abbreviation:	Cal
clean when the reagent is modified	Low
☒ New calibration with any new lot of reagents	
Authorized lines from	1 to 14
Stability (*) < 15C	* > = 15C
Mix by jet Intensity	1
Frequency	No agitation
Reference numbers	Number
	add / remove / replace

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Name:	NormalCont
Abbreviation:	NormalCont
clean when the reagent is modified	Low
☒ New calibration with any new lot of reagents	
Authorized lines from 1 to 14	
Stability (*) < 15C * > = 15C	
Mix by jet Intensity 1 Frequency No agitation	
Reference numbers Number	
add / remove / replace	

Name:	LowCont
Abbreviation:	LowCont
clean when the reagent is modified	Low
☒ New calibration with any new lot of reagents	
Authorized lines from 1 to 14	
Stability (*) < 15C * > = 15C	
Mix by jet Intensity 1 Frequency No agitation	
Reference numbers Number	
add / remove / replace	

(*) To be filled by the user according to the insert instructions and the exact working conditions. Homogenize before each use.

Creation of the procedure

Once the various reagents, calibration and controls files are created, the procedure file must be created. Go to the “Definition tests, procedure” and enter the following parameters.

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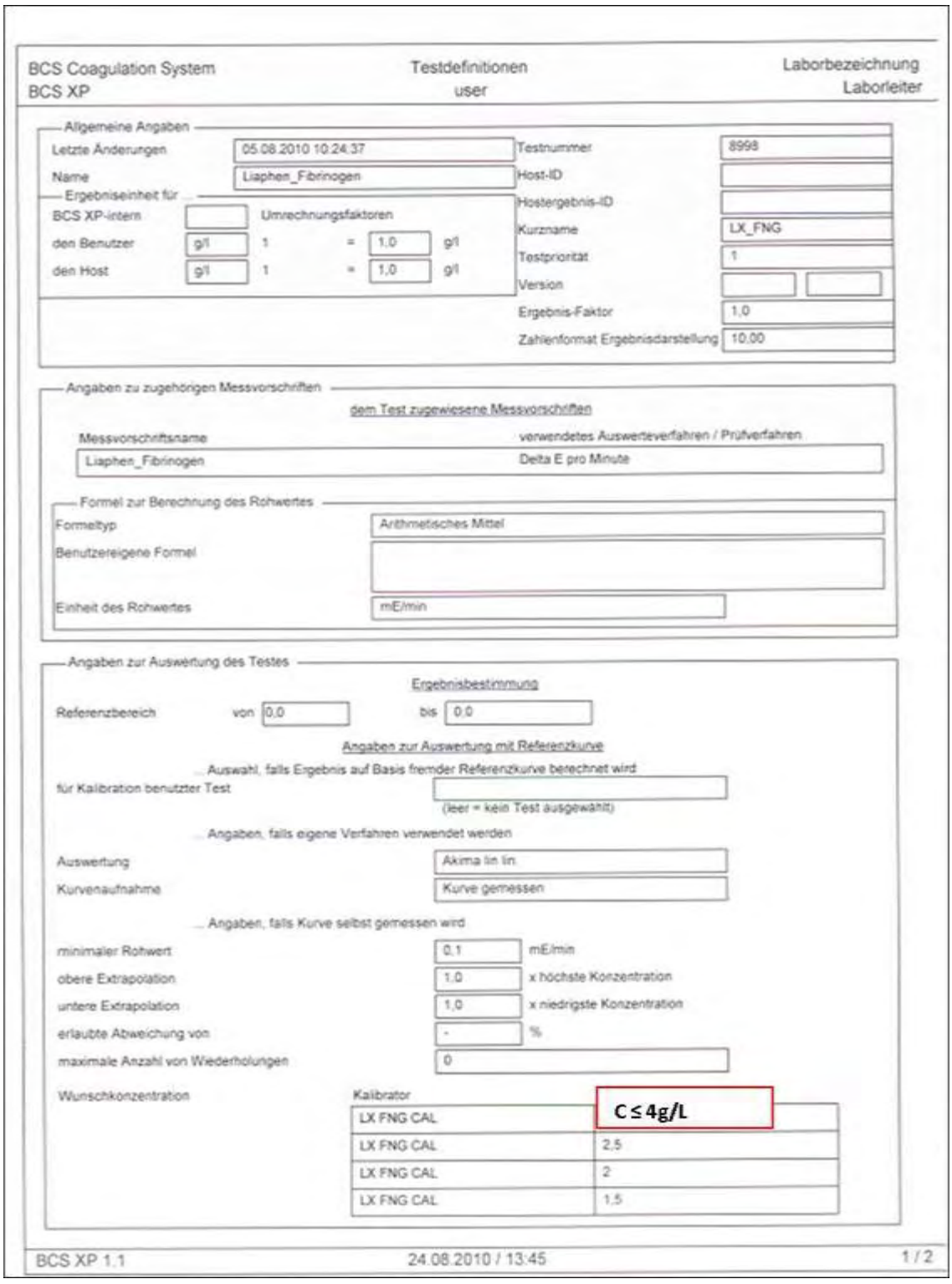

BCS Coagulation System
BCS XP

Testdefinitionen
user

Laborbezeichnung
Laborleiter

Allgemeine Angaben

Letzte Änderungen	05.08.2010 10:24:37	Testnummer	8998
Name	Liaphen_Fibrinogen	Host-ID	
		Hostergebnis-ID	
		Kurzname	LX_FNG
		Testpriorität	1
		Version	
		Ergebnis-Faktor	1,0
		Zahlenformat Ergebnisdarstellung	10,00

Ergebniseinheit für

BCS XP-intern		Umrechnungsfaktoren			
den Benutzer	g/l	1	=	1,0	g/l
den Host	g/l	1	=	1,0	g/l

Angaben zu zugehörigen Messvorschriften

dem Test zugewiesene Messvorschriften

Messvorschriftsname	verwendetes Auswerteverfahren / Prüfverfahren
Liaphen_Fibrinogen	Delta E pro Minute

Formel zur Berechnung des Rohwertes

Formeltyp	Arithmetisches Mittel
Benutzereigene Formel	
Einheit des Rohwertes	mE/min

Angaben zur Auswertung des Testes

Ergebnisbestimmung

Referenzbereich von 0,0 bis 0,0

Angaben zur Auswertung mit Referenzkurve

Auswahl, falls Ergebnis auf Basis fremder Referenzkurve berechnet wird

für Kalibration benutzter Test

(leer = kein Test ausgewählt)

Angaben, falls eigene Verfahren verwendet werden

Auswertung	Akima lin lin
Kurvenaufnahme	Kurve gemessen

Angaben, falls Kurve selbst gemessen wird

minimaler Rohwert	0,1	mE/min
obere Extrapolation	1,0	x höchste Konzentration
untere Extrapolation	1,0	x niedrigste Konzentration
erlaubte Abweichung von	-	%
maximale Anzahl von Wiederholungen	0	

Wunschkonzentration

Kalibrator	
LX FNG CAL	C ≤ 4g/L
LX FNG CAL	2,5
LX FNG CAL	2
LX FNG CAL	1,5

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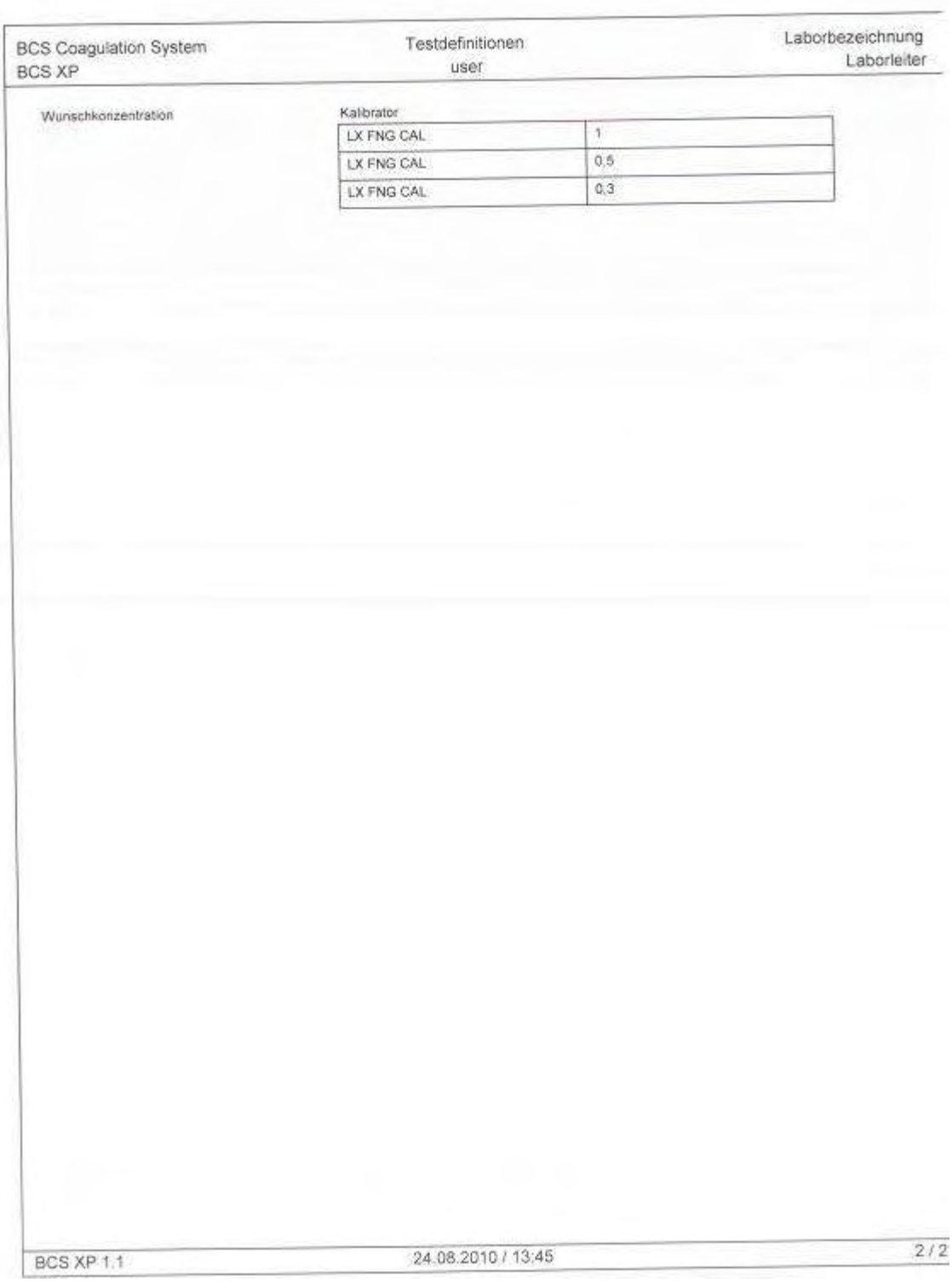

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Wunschkonzentration

Kalibrator

LX FNG CAL	1
LX FNG CAL	0,5
LX FNG CAL	0,3

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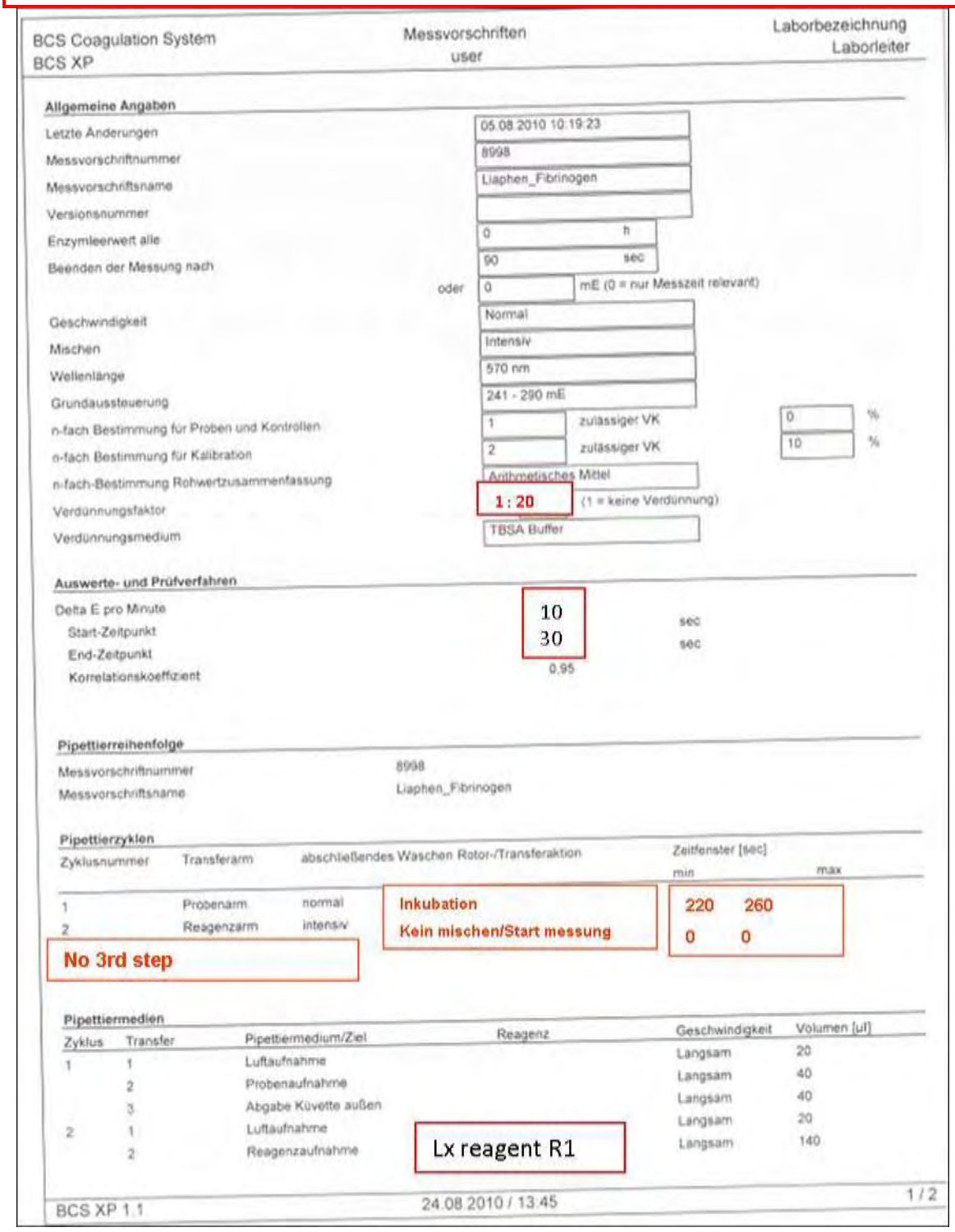

BCS Coagulation System
BCS XP

Messvorschriften
user

Laborbezeichnung
Laborleiter

Allgemeine Angaben

Letzte Änderungen	05.08.2010 10:19:23		
Messvorschriftnummer	8998		
Messvorschriftsname	Liaphen_Fibrinogen		
Versionsnummer			
Enzymleerwert alle	0 h		
Beenden der Messung nach	90 sec		
oder	0 mE (0 = nur Messzeit relevant)		
Geschwindigkeit	Normal		
Mischen	Intensiv		
Wellenlänge	570 nm		
Grundaussteuerung	241 - 290 mE		
n-fach Bestimmung für Proben und Kontrollen	1 zulässiger VK	0 %	
n-fach Bestimmung für Kalibration	2 zulässiger VK	10 %	
n-fach-Bestimmung Rohwertzusammenfassung	Arithmetisches Mittel		
Verdünnungsfaktor	1 : 20 (1 = keine Verdünnung)		
Verdünnungsmedium	TBSA Buffer		

Auswerte- und Prüfverfahren

Delta E pro Minute	10	sec
Start-Zeitpunkt	30	sec
End-Zeitpunkt		
Korrelationskoeffizient	0.95	

Pipettierreihenfolge

Messvorschriftnummer	8998
Messvorschriftsname	Liaphen_Fibrinogen

Pipettierzyklen

Zyklusnummer	Transferarm	abschließendes Waschen Rotor-/Transferaktion	Zeitfenster [sec] min	max
1	Probenarm	normal	Inkubation	220 260
2	Reagenzarm	intensiv	Kein mischen/Start messung	0 0

No 3rd step

Pipettiermedien

Zyklus	Transfer	Pipettiermedium/Ziel	Reagenz	Geschwindigkeit	Volumen [ul]
1	1	Luftaufnahme		Langsam	20
	2	Probenaufnahme		Langsam	40
	3	Abgabe Küvette außen		Langsam	40
2	1	Luftaufnahme		Langsam	20
	2	Reagenzaufnahme	Lx reagent R1	Langsam	140

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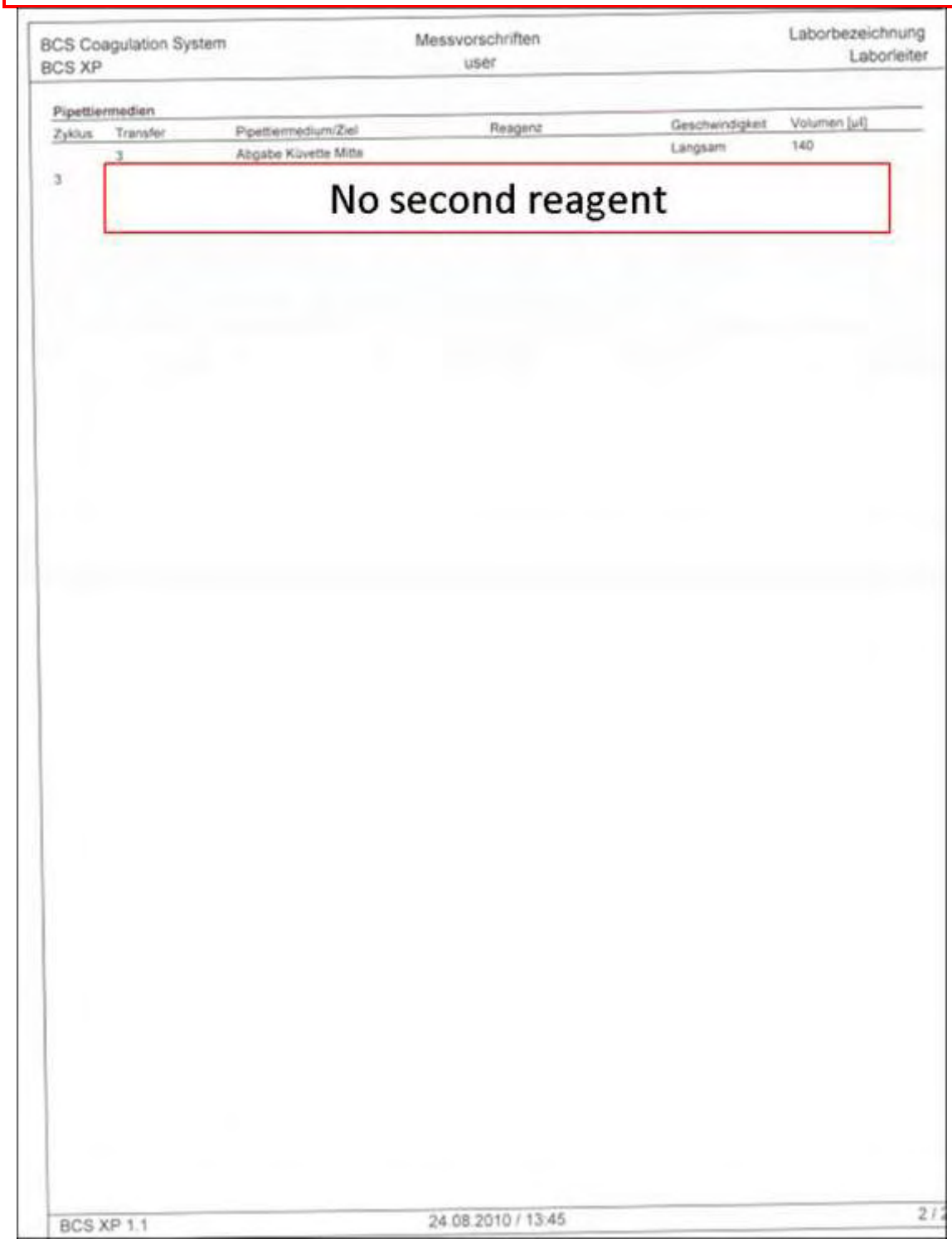

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Pipettiermedien

Zyklus	Transfer	Pipettiermedium/Ziel	Reagenz	Geschwindigkeit	Volumen [ul]
3	3	Abgabe Küvette Mitte		Langsam	140

No second reagent

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