



The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration: Calibrator lyophilized

Analyte: AMY

System: Buffer and stabilizer

Kind of quantity: Catalytic activity concentration

Calibration procedure: Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for AMY

Environmental condition: The catalytic concentration refers to a temperature of 37 °C

Investigated random sample: One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

Reference method value	5,722 µkat/L	(343,3 U/L)
Expanded uncertainty of measurement	0,161 µkat/L	(9,7 U/L)
Relative expanded uncertainty of measurement	2,8 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor *k* = 2,0. The expanded uncertainty was calculated according to the document DAkkS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
14.11.2013	343,14 U/L	12	
14.11.2013	340,33 U/L	Mean	343,3 U/L
14.11.2013	339,52 U/L	SD	3,1 U/L
15.11.2013	341,74 U/L	CV	0,9 %
15.11.2013	340,50 U/L		
15.11.2013	339,89 U/L		
18.11.2013	348,85 U/L		
18.11.2013	346,56 U/L		
18.11.2013	346,58 U/L		
19.11.2013	343,51 U/L		
19.11.2013	345,67 U/L		
19.11.2013	343,55 U/L		

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Deutsche Akkreditierungsstelle GmbH



als Kalibrierlaboratorium im / as calibration laboratory in the  
Deutschen Kalibrierdienst



**Kalibrierschein**  
*Calibration Certificate*

Kalibrierzeichen  
*Calibration mark*

1184
D-K-15117-02-00
2013-12

Gegenstand  
*Object*

Calibrator

Dieser Kalibrierschein dokumentiert die Rückführung auf nationale Normale zur Darstellung der Einheiten in Übereinstimmung mit dem Internationalen Einheitensystem (SI).

Hersteller  
*Manufacturer*

JCCLS

Die DAkkS ist Unterzeichner der multilateralen Übereinkommen der European co-operation for Accreditation (EA) und der International Laboratory Accreditation Cooperation (ILAC) zur gegenseitigen Anerkennung der Kalibrierscheine. Für die Einhaltung einer angemessenen Frist zur Wiederholung der Kalibrierung ist der Benutzer verantwortlich.

Identifikation  
*Identification*

CRM 001

Auftraggeber  
*Customer*

Asahi Kasei  
Tokyo, Japan

*This calibration certificate documents the traceability to national standards, which realize the units of measurement according to the International System of Units (SI).*

Auftragsnummer  
*Order No.*

ID-No. 896

*The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.*

Anzahl der Seiten des Kalibrierscheins 2  
*Number of pages of the certificate*

Datum der Kalibrierung Dec 18, 2013  
*Date of calibration*

*The user is obliged to have the object recalibrated at appropriate intervals.*

Dieser Kalibrierschein darf nur vollständig und unverändert weiterverbreitet werden. Auszüge oder Änderungen bedürfen der Genehmigung sowohl der Deutschen Akkreditierungsstelle GmbH als auch des ausstellenden Kalibrierlaboratoriums. Kalibrierscheine ohne Unterschrift haben keine Gültigkeit.

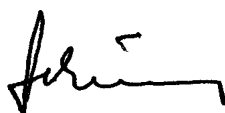
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Datum  
*Date*

Leiter des Kalibrierlaboratoriums  
*Head of the calibration laboratory*

Bearbeiter  
*Person in charge*

Dec 19, 2013



Prof. Dr. G. Schumann



R. Strache

The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration:	Calibrator lyophilized
Analyte:	ALP
System:	Buffer and stabilizer
Kind of quantity:	Catalytic activity concentration
Calibration procedure:	Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for ALP
Environmental condition:	The catalytic concentration refers to a temperature of 37 °C
Investigated random sample:	One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

Reference method value	2,475 µkat/L	(148,5 U/L)
Expanded uncertainty of measurement	0,063 µkat/L	(3,8 U/L)
Relative expanded uncertainty of measurement	2,5 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor  $k = 2,0$ . The expanded uncertainty was calculated according to the document DAkkS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
02.12.2013	147,03 U/L	Mean	148,5 U/L
02.12.2013	146,15 U/L	SD	1,7 U/L
02.12.2013	148,21 U/L	CV	1,1 %
05.12.2013	148,49 U/L		
05.12.2013	148,31 U/L		
05.12.2013	150,09 U/L		
09.12.2013	150,75 U/L		
09.12.2013	150,78 U/L		
09.12.2013	150,49 U/L		
10.12.2013	146,78 U/L		
10.12.2013	147,52 U/L		
10.12.2013	147,21 U/L		

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Deutsche Akkreditierungsstelle GmbH



als Kalibrierlaboratorium im / as calibration laboratory in the  
Deutschen Kalibrierdienst **DKD**

**Kalibrierschein**  
*Calibration Certificate*

Kalibrierzeichen  
*Calibration mark*

1185
D-K-15117-02-00
2013-12

Gegenstand  
*Object*

Calibrator

Dieser Kalibrierschein dokumentiert die Rückführung auf nationale Normale zur Darstellung der Einheiten in Übereinstimmung mit dem Internationalen Einheitensystem (SI).

Hersteller  
*Manufacturer*

JCCLS

Die DAkkS ist Unterzeichner der multilateralen Übereinkommen der European co-operation for Accreditation (EA) und der International Laboratory Accreditation Cooperation (ILAC) zur gegenseitigen Anerkennung der Kalibrierscheine. Für die Einhaltung einer angemessenen Frist zur Wiederholung der Kalibrierung ist der Benutzer verantwortlich.

Identifikation  
*Identification*

CRM 001

Auftraggeber  
*Customer*

Asahi Kasei  
Tokyo, Japan

*This calibration certificate documents the traceability to national standards, which realize the units of measurement according to the International System of Units (SI).*

Auftragsnummer  
*Order No.*

ID-No. 896

*The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.*

Anzahl der Seiten des Kalibrierscheins 2  
*Number of pages of the certificate*

Datum der Kalibrierung Dec 18, 2013  
*Date of calibration*

*The user is obliged to have the object recalibrated at appropriate intervals.*

Dieser Kalibrierschein darf nur vollständig und unverändert weiterverbreitet werden. Auszüge oder Änderungen bedürfen der Genehmigung sowohl der Deutschen Akkreditierungsstelle GmbH als auch des ausstellenden Kalibrierlaboratoriums. Kalibrierscheine ohne Unterschrift haben keine Gültigkeit.

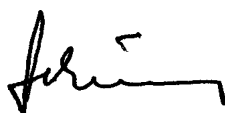
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Datum  
*Date*

Leiter des Kalibrierlaboratoriums  
*Head of the calibration laboratory*

Bearbeiter  
*Person in charge*

Dec 19, 2013



Prof. Dr. G. Schumann



R. Strache

The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration:	Calibrator lyophilized
Analyte:	ALT
System:	Buffer and stabilizer
Kind of quantity:	Catalytic activity concentration
Calibration procedure:	Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for ALT
Environmental condition:	The catalytic concentration refers to a temperature of 37 °C
Investigated random sample:	One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

Reference method value	2,716 µkat/L	(163,0 U/L)
Expanded uncertainty of measurement	0,060 µkat/L	(3,6 U/L)
Relative expanded uncertainty of measurement	2,2 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor  $k = 2,0$ . The expanded uncertainty was calculated according to the document DAkkS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
25.11.2013	162,87 U/L	Mean	163,0 U/L
25.11.2013	164,29 U/L	SD	1,0 U/L
25.11.2013	162,56 U/L	CV	0,6 %
26.11.2013	162,68 U/L		
26.11.2013	161,73 U/L		
26.11.2013	161,52 U/L		
27.11.2013	163,91 U/L		
27.11.2013	163,96 U/L		
27.11.2013	161,92 U/L		
28.11.2013	163,22 U/L		
28.11.2013	164,40 U/L		
28.11.2013	162,36 U/L		



The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration: Calibrator lyophilized

Analyte: AST

System: Buffer and stabilizer

Kind of quantity: Catalytic activity concentration

Calibration procedure: Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for AST

Environmental condition: The catalytic concentration refers to a temperature of 37 °C

Investigated random sample: One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

Reference method value	2,780 µkat/L	(166,8 U/L)
Expanded uncertainty of measurement	0,062 µkat/L	(3,7 U/L)
Relative expanded uncertainty of measurement	2,2 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor *k* = 2,0. The expanded uncertainty was calculated according to the document DAkkS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
25.11.2013	166,80 U/L	12	
25.11.2013	168,01 U/L	Mean	166,8 U/L
25.11.2013	165,90 U/L	SD	1,5 U/L
26.11.2013	165,95 U/L	CV	0,9 %
26.11.2013	166,51 U/L		
26.11.2013	164,99 U/L		
27.11.2013	166,97 U/L		
27.11.2013	167,96 U/L		
27.11.2013	163,60 U/L		
28.11.2013	167,89 U/L		
28.11.2013	169,21 U/L		
28.11.2013	167,82 U/L		





The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration:	Calibrator lyophilized
Analyte:	CK
System:	Buffer and stabilizer
Kind of quantity:	Catalytic activity concentration
Calibration procedure:	Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for CK
Environmental condition:	The catalytic concentration refers to a temperature of 37 °C
Investigated random sample:	One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

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Reference method value	7,274 µkat/L	(436,4 U/L)
Expanded uncertainty of measurement	0,175 µkat/L	(10,5 U/L)
Relative expanded uncertainty of measurement	2,4 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

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The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor *k* = 2,0. The expanded uncertainty was calculated according to the document DAkKS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkKS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
11.12.2013	435,12 U/L	12	
11.12.2013	433,21 U/L	Mean	436,4 U/L
11.12.2013	435,08 U/L	SD	3,0 U/L
12.12.2013	434,25 U/L	CV	0,7 %
12.12.2013	439,24 U/L		
12.12.2013	442,37 U/L		
16.12.2013	431,81 U/L		
16.12.2013	436,91 U/L		
16.12.2013	438,39 U/L		
17.12.2013	435,26 U/L		
17.12.2013	439,97 U/L		
17.12.2013	435,62 U/L		



The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration: Calibrator lyophilized

Analyte: GGT

System: Buffer and stabilizer

Kind of quantity: Catalytic activity concentration

Calibration procedure: Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for GGT

Environmental condition: The catalytic concentration refers to a temperature of 37 °C

Investigated random sample: One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

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Reference method value	2,501 µkat/L	(150,1 U/L)
Expanded uncertainty of measurement	0,062 µkat/L	(3,7 U/L)
Relative expanded uncertainty of measurement	2,5 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

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The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor *k* = 2,0. The expanded uncertainty was calculated according to the document DAkkS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
11.12.2013	149,49 U/L	Mean	150,1 U/L
11.12.2013	149,15 U/L	SD	0,8 U/L
11.12.2013	150,65 U/L	CV	0,5 %
12.12.2013	150,58 U/L		
12.12.2013	150,02 U/L		
12.12.2013	150,32 U/L		
16.12.2013	150,74 U/L		
16.12.2013	150,97 U/L		
16.12.2013	151,12 U/L		
17.12.2013	148,81 U/L		
17.12.2013	149,67 U/L		
17.12.2013	149,31 U/L		

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Deutsche Akkreditierungsstelle GmbH



als Kalibrierlaboratorium im / as calibration laboratory in the  
Deutschen Kalibrierdienst



**Kalibrierschein**  
*Calibration Certificate*

Kalibrierzeichen  
*Calibration mark*

1189
D-K-15117-02-00
2013-12

Gegenstand  
*Object*

Calibrator

Dieser Kalibrierschein dokumentiert die Rückführung auf nationale Normale zur Darstellung der Einheiten in Übereinstimmung mit dem Internationalen Einheitensystem (SI).

Hersteller  
*Manufacturer*

JCCLS

Die DAkkS ist Unterzeichner der multilateralen Übereinkommen der European co-operation for Accreditation (EA) und der International Laboratory Accreditation Cooperation (ILAC) zur gegenseitigen Anerkennung der Kalibrierscheine. Für die Einhaltung einer angemessenen Frist zur Wiederholung der Kalibrierung ist der Benutzer verantwortlich.

Identifikation  
*Identification*

CRM 001

Auftraggeber  
*Customer*

Asahi Kasei  
Tokyo, Japan

*This calibration certificate documents the traceability to national standards, which realize the units of measurement according to the International System of Units (SI). The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.*

Auftragsnummer  
*Order No.*

ID-No. 896

Anzahl der Seiten des Kalibrierscheins 2  
*Number of pages of the certificate*

Datum der Kalibrierung Dec 18, 2013  
*Date of calibration*

*The user is obliged to have the object recalibrated at appropriate intervals.*

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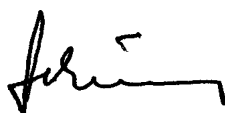
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Datum  
*Date*

Leiter des Kalibrierlaboratoriums  
*Head of the calibration laboratory*

Bearbeiter  
*Person in charge*

Dec 19, 2013



Prof. Dr. G. Schumann



R. Strache

The calibration is performed according to EN ISO 15195 and EN ISO 17025.

Object of calibration: Calibrator  
lyophilized

Analyte: LDH

System: Buffer and stabilizer

Kind of quantity: Catalytic activity concentration

Calibration procedure: Determination of the catalytic concentration of enzymes according to the primary IFCC reference procedure for LDH

Environmental condition: The catalytic concentration refers to a temperature of 37 °C

Investigated random sample: One filling of the material of investigation was analyzed on each measurement day. The number of measurement days and the number of measurements per measurement day can be seen in the list with the single values.

Measurement results:

Reference method value	7,130 µkat/L	(427,8 U/L)
Expanded uncertainty of measurement	0,161 µkat/L	(9,7 U/L)
Relative expanded uncertainty of measurement	2,3 %	
Coverage factor <i>k</i>	2,0	
Effective degrees of freedom	> 50	

The expanded uncertainty is declared and calculated by multiplying the standard uncertainty with the coverage factor *k* = 2,0. The expanded uncertainty was calculated according to the document DAkkS-DKD-3. The value of the measurable quantity lies within the attached range with a probability of 95 %.

The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. Further signatories within and outside Europe can be seen on the websites of EA ([www.european-accreditation.org](http://www.european-accreditation.org)) and ILAC ([www.ilac.org](http://www.ilac.org)).

Single values		Statistics of the single values	
Date	Value	Number	
02.12.2013	421,24 U/L	12	
02.12.2013	426,24 U/L	Mean	427,8 U/L
02.12.2013	425,57 U/L	SD	2,9 U/L
05.12.2013	428,11 U/L	CV	0,7 %
05.12.2013	427,32 U/L		
05.12.2013	431,90 U/L		
09.12.2013	428,73 U/L		
09.12.2013	429,24 U/L		
09.12.2013	425,84 U/L		
10.12.2013	429,14 U/L		
10.12.2013	432,01 U/L		
10.12.2013	428,41 U/L		

## Summary

Enzyme	Calibration certificate no.	Month	Year	Customer	City	Name of the specimen	Usage	Matrix	Condition	Manufacturer	Lot	Code	Beginning
AMY	1183	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013
ALP	1184	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013
ALT	1185	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013
AST	1186	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013
CK	1187	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013
GGT	1188	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013
LDH	1189	12	2013	Asahi Kasei	Tokyo, Japan	CRM 001	Calibrator	Buffer and stabilizer	lyophilized	JCCLS	1	896	28.10.2013

## Summary

Enzyme	Calibration certificate no.	End	Days	Values	RMV	SD	CV	$u$ (U/L)	$u$ (%)	k =	$U$ (U/L)	$U$ (%)
AMY	1183	18.12.2013	4	12	343,3	3,1	0,9	1,6	0,5	2,00 (veff>50)	9,7	2,8
ALP	1184	18.12.2013	4	12	148,5	1,7	1,1	0,8	0,6	2,00 (veff>50)	3,8	2,5
ALT	1185	18.12.2013	4	12	163,0	0,6	0,4	0,3	0,2	2,00 (veff>50)	3,6	2,2
AST	1186	18.12.2013	4	12	166,8	1,1	0,7	0,6	0,3	2,00 (veff>50)	3,7	2,2
CK	1187	18.12.2013	4	12	436,4	1,8	0,4	0,9	0,2	2,00 (veff>50)	10,5	2,4
GGT	1188	18.12.2013	4	12	150,1	0,7	0,5	0,4	0,2	2,00 (veff>50)	3,7	2,5
LDH	1189	18.12.2013	4	12	427,8	2,4	0,6	1,2	0,3	2,00 (veff>50)	9,7	2,3