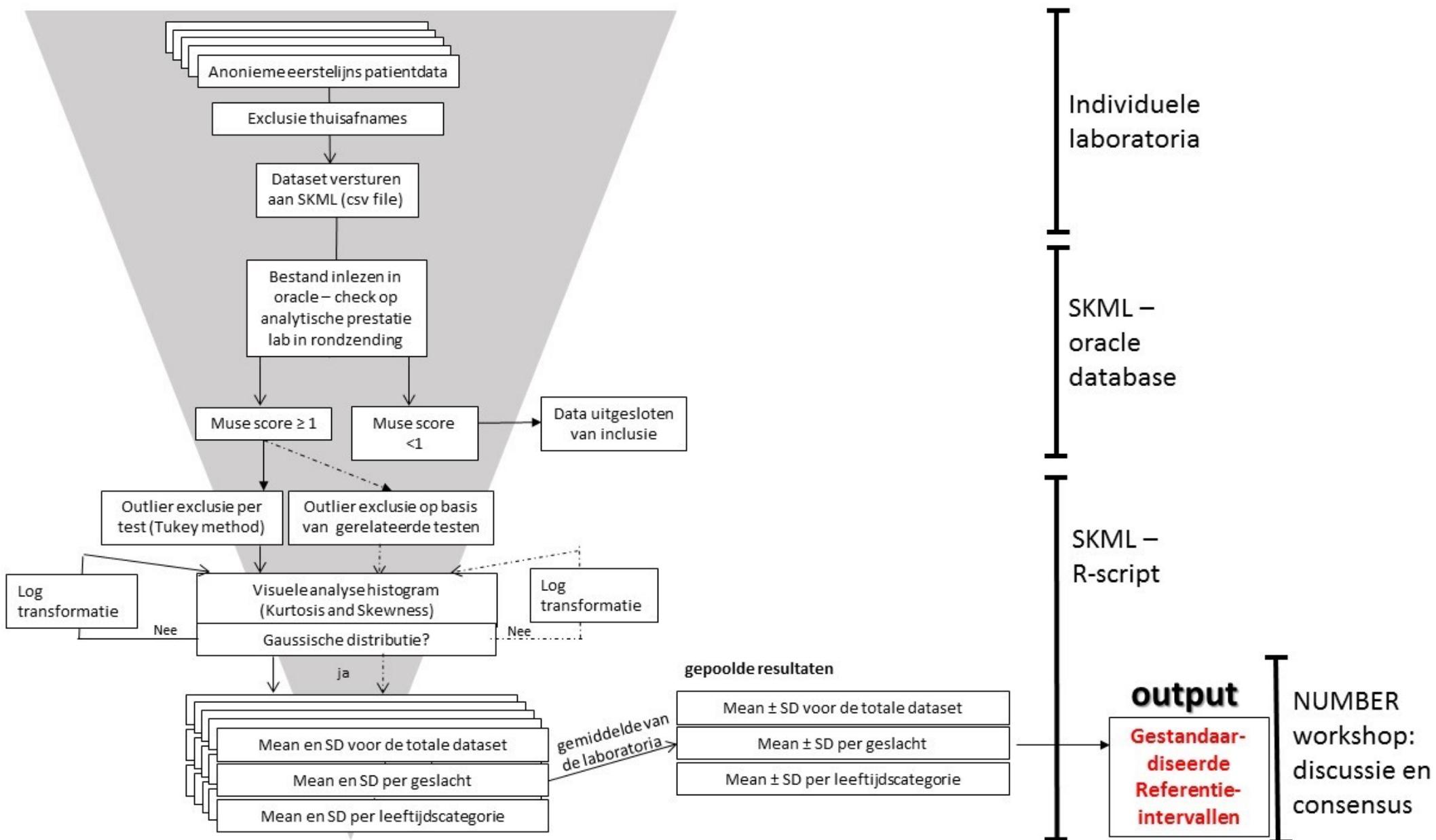


Bijlage 1



RESEARCH PROTOCOL version 1

**NUMBER: SKML structural
monitoring system for
reference intervals**

12-10-2020

PROTOCOL TITLE 'Nederlandse UniforMe BEslisgrenzen en Referentie-intervallen'

Short title	<i>NUMBER SKML structural monitoring system for reference intervals</i>
Version	1
Date	12-10-2020
Project leader	<i>Prof.dr. Marc Thelen,</i>
Principal investigator(s) (in Dutch: hoofdonderzoeker/ uitvoerder)	<i>Marith van Schrojenstein Lantman</i>
Sponsor (in Dutch: verrichter/opdrachtgever)	-
Subsidising party	<i>SKMS</i>
Statistical advisor	-
Advanced Data Management Advisor	-

PROTOCOL SIGNATURE SHEET

Name	Signature	Date
Head of Department & Project leader:		13-10-2020
Principal Investigator:		12-10-2020

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

CA	Competent Authority
CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
CV	Curriculum Vitae
EQA	External Quality Assessment
EU	European Union
GCP	Good Clinical Practice
IC	Informed Consent
JCTLM	Joint Committee for Traceability in Laboratory Medicine
METC	Medical research ethics committee (MREC); in Dutch: medisch ethische toetsing commissie (METC)
SI	Système International
SKML	Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek
Sponsor	The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.
Wbp	Personal Data Protection Act (in Dutch: Wet Bescherming Persoonsgevens)
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen)

SUMMARY

Rationale: Reference intervals are commonly used as a decision making tool. However, reference intervals differ greatly between laboratories in the Netherlands. In the NUMBER (Nederlandse UniforMe Beslisgrenzen En Referentie-intervallen) working group, we set up a ‘big-data’ approach to determine standardized traceable reference intervals for 16 general chemistry tests. A next important step is to set up a structural monitoring system in the Netherlands to calculate and verify reference intervals for laboratory tests regularly.

Objectives:

-Building an infrastructure to structurally verify reference intervals and decision limits using existing laboratory databases of primary care patients

Study design: Secondary data-analysis of existing anonymous medical laboratory databases.

Study population: Primary care

Main study deliverables:

Infrastructure to structurally verify reference intervals and decision limits

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: not applicable.

1. INTRODUCTION AND RATIONALE

Reference intervals are commonly used as a decision making tool.(1) The quality of the reference intervals plays an equally important role in result interpretation as the quality of the result itself.(2) Unfortunately, in the Netherlands, universal reference intervals and decision limits are still lacking for many of these tests. Current reference intervals differ according to manufacturer, method, and method generation and are often established in a clinical study setting, in which more strict pre-analytical conditions are applied than in daily clinical practice. This hinders universal use of clinical guidelines, prevents adequate interpretation of laboratory test results and leads to incorrect and unequal treatment of patients. We therefore initiated a national endeavour, called NUMBER (Nederlandse UniforMe Beslisgrenzen En Referentie-intervallen), in which we set up a 'big-data' approach to determine traceable reference intervals for 16 general chemistry tests.(3)

An important next step is to set up a national infrastructure and database to automatically calculate and verify reference intervals in the Netherlands, to monitor the accuracy of the national reference intervals using actual anonymous patient data. We will establish a representative database to determine uniform reference intervals and decision limits and a surveillance system to structurally monitor constancy or potential changes in reference intervals and decision limits with time. With this database we will also support clinical laboratories in their obligations to verify and monitor reference intervals for all tests, and to report the source for these reference intervals, as is stated in NEN-EN-ISO 15189:2012/C11:2015 (the guideline on requirements for quality and competence of medical laboratories).

2. OBJECTIVES

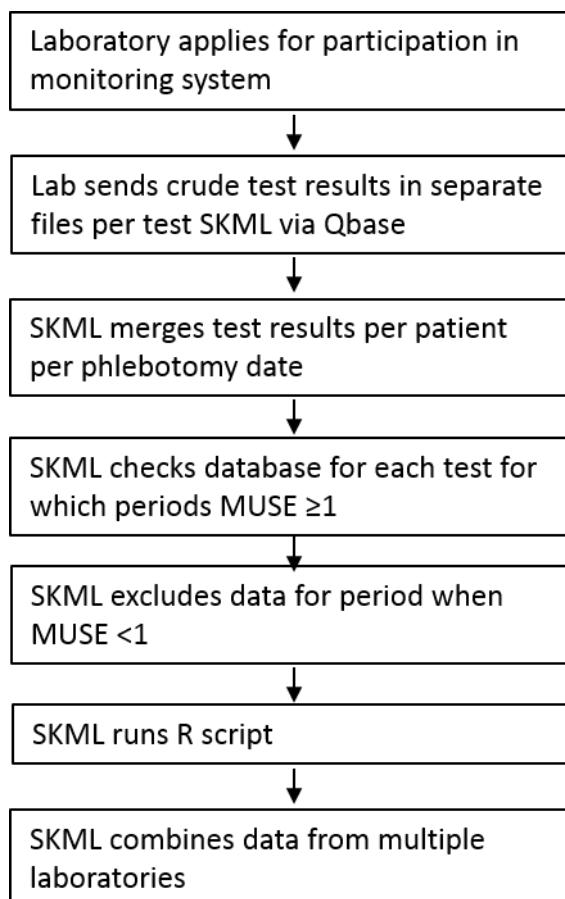
Building an infrastructure to structurally verify reference intervals and decision limits, using existing laboratory databases of primary care patients

3. STUDY DESIGN

We aim to deduce and verify standardized reference intervals from data that are readily available in clinical laboratory databases. For this purpose, clinical laboratories from across the Netherlands will provide anonymous laboratory results of primary care patients (data extraction of 12 months). We strive to cover all available manufacturers, to enhance generalizability of the results.

Initially, we focus on SI-standardized clinical tests from the Dutch EQA programmes ‘SKML Combi General Chemistry’ and ‘SKML Combi Lipids’ (www.skml.nl/rondzendingen) for which the reference systems are listed in the JCTLM database (www.jctlm.org), and programmes ‘SKML Hemocytometry’ and ‘SKML Coagulation’.

Data will be centrally collected at the SKML (Figure 1). Data will be uploaded via Qbase.



SKML will check for each laboratory for each laboratory test if quality criteria are met (4). Data from poor performers, defined as a ‘multi sample evaluation (MUSE)’ score of zero in EQA-reports (indicating a Total Allowable Error (Tea) sigma value below 2) will be excluded. Outliers will be excluded, as described previously, using the Tukey method.(3) Data will be transformed to a normal distribution (if necessary), and means and standard deviations (SDs) were calculated. Then, average means and SDs per test will be calculated to generate pooled (mean \pm 2SD) reference intervals.(3) Analyses will be performed using R for data science.

4. STUDY POPULATION

4.1 Population (base)

Existing laboratory databases on test results from primary care patients.

4.2 Inclusion criteria

Laboratories can participate in this project when the following conditions apply:

- Test results for primary care patients are available
- The laboratory participates in the Dutch EQA programmes 'SKML Combi General Chemistry' and 'SKML Combi Lipids', 'SKML Hemocytometry' and 'SKML Coagulation'.
- The laboratory is able to extract anonymous test results for a period of 12 months from their laboratory information system (Excel 2007 or above, .xlsx file)

4.3 Exclusion criteria

Test results from patients that were visited at home will be excluded from the analysis.

4.4 Sample size calculation

Laboratories will provide data for a period of 12 months, ensuring sufficient data to perform stratified analyses sex and different age groups (minimally 120 test results per subgroup(5).

5. TREATMENT OF SUBJECTS

This chapter is not applicable for this project.

6. INVESTIGATIONAL PRODUCT

This chapter is not applicable for this project.

7. NON-INVESTIGATIONAL PRODUCT

This chapter is not applicable for this project.

8. METHODS

8.1 Study parameters/endpoints

Deliverables of this project are:

- Infrastructure to structurally verify reference intervals and decision limits in time and space

8.2 Randomisation, blinding and treatment allocation

This section is not applicable for this project.

8.3 Study procedures

Figure 1 provides a general overview of the study procedures.

9. STATISTICAL ANALYSIS

Data analyses will be performed in two steps, using a standardized script in R.

Step 1: Calculating reference intervals per test per laboratory (3)

First, per laboratory, per test, we will label and discard outliers using the Tukey method as recommended (4): the lower and upper cutoffs for outliers will be defined as $Q1 - (1.5 \times IQR)$ and $Q3 + (1.5 \times IQR)$, respectively, where $Q1$ is the lower sample quartile, $Q3$ is the upper sample quartile and $IQR = Q3 - Q1$. When an outlier is detected, results from related tests will be discarded as well.

Histograms will be visually inspected and formal tests will be performed (Z score for Skewness and Kurtosis between -1.96 and 1.96 and P value Shapiro Wilk test >0.05) to determine the presence of a normal Gaussian distribution. If absent, the data will be transformed (log, Box-Cox, etc) to achieve an approximately Gaussian distribution.

Per laboratory, per test, the mean and standard deviation will be calculated, for the total dataset, and stratified in the following subgroups (if applicable):

- Sex: Male / Female
- Age:
 - Newborns / infants : <28 days of age (WHO definition), 28 days to <1 year
 - 1-5 yrs, 6-12 yrs, 12-18 yrs, 19-50 yrs, 51-65 yrs, 66-80 yrs, 80+ yrs.

Step 2: generating pooled reference intervals

A average means and SDs per test will be calculated to generate pooled ($\text{mean} \pm 2\text{SD}$) reference intervals .

10. ETHICAL CONSIDERATIONS

10.1 Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki (version 64, 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

11. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

11.1 Handling and storage of data and documents

Participating laboratories extract anonymous data from their laboratory information system to Excel 2007 or above (.xlsx) for the requested tests, for a period of 12 months.

Per test, the following variables will be included in the data file:

- Identifier (e.g. laboratory order number)
- Birth date
- Phlebotomy date and time
- Sex
- Test result
- Specialty (as a check, to exclude tests requested by other specialties than general practitioners)

To obtain accurate reference intervals for each age category, including newborns, infants and youngsters, it is of vital importance to obtain exact birth dates. Apart from birth date and sex, no additional identifying information (such as postal address, living situation, health status etc) will be provided to the SKML. Therefore, it will not be possible to trace the laboratory results to an individual subject in the Netherlands.

Laboratories are asked to provide a unique identification number for each patient in the dataset, allowing merging of the data files at the data center at the SKML. The key to the code will only be available at the local laboratories and will not be provided to the SKML. After merging of the individual files at the SKML, the identification number will be removed from all datasets.

Datasets will be sent uploaded securely via the QBase Portable from SKML.

11.2 Data will be handled confidentially. The handling of personal data will comply with the General Data Protection Regulation (GDPR (AVG)).Monitoring and Quality Assurance

11.3 Public disclosure and publication policy

Scientific publications will be targeted for high ranking peer-reviewed journals; publication will be open access manner where possible. Results will be presented at (inter)national meetings in the field of clinical chemistry.

12. REFERENCES

1. Koerbin G, Sikaris KA, Jones GR, Ryan J, Reed M, Tate J, et al. Evidence-based approach to harmonised reference intervals. *Clin Chim Acta*. 2014;432:99-107.
2. Klee GG, Ichihara K, Ozarda Y, Baumann NA, Straseski J, Bryant SC, et al. Reference Intervals: Comparison of Calculation Methods and Evaluation of Procedures for Merging Reference Measurements From Two US Medical Centers. *Am J Clin Pathol*. 2018;150(6):545-54.
3. den Elzen WPJ, Brouwer N, Thelen MH, Le Cessie S, Haagen IA, Cobbaert CM. NUMBER: standardized reference intervals in the Netherlands using a 'big data' approach. *Clin Chem Lab Med*. 2018;57(1):42-56.
4. Thelen MHM, Jansen RTP, Weykamp CW, Steigstra H, Meijer R, Cobbaert CM. Expressing analytical performance from multi-sample evaluation in laboratory EQA. *Clin Chem Lab Med*. 2017;55(10):1509-16.
5. Ozarda Y, Ichihara K, Barth JH, Klee G, Committee on Reference I, Decision Limits IFFCC, et al. Protocol and standard operating procedures for common use in a worldwide multicenter study on reference values. *Clin Chem Lab Med*. 2013;51(5):1027-40.

Bijlage 3

2020-7054 niet WMO-plichtig

Elst, Devin van <Devin.vanElst@radboudumc.nl>

namens

Postbus Commissie Mensgebonden Onderzoek <METCoost-en-CMO@radboudumc.nl>

Do 29-10-2020 14:47

Aan: Schrojenstein Lantman, Marith van <Marith.vanSchrojensteinLantman@radboudumc.nl>

CC: Postbus RTC Clinical Studies <rtcclinicalstudies@radboudumc.nl>

Titel van het onderzoeksprotocol: SKML structural monitoring system for reference intervals

CMO dossiernummer: 2020-7054

Naam hoofdonderzoeker: Marith van Schrojenstein Lantman

Naam onderzoekscentrum: Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek

Naam indiener: Marith van Schrojenstein Lantman

Datum indiening: 19 oktober 2020

Geachte mevrouw van Schrojenstein Lantman,

U heeft de commissie verzocht een uitspraak te doen over of bovengenoemd onderzoek onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt en op grond daarvan door een erkende medisch-ethische toetsingscommissie beoordeeld moet worden.

De onderzoeksdeelnemers worden niet aan WMO-plichtige handelingen onderworpen en aan hen worden geen WMO-plichtige gedragingen opgelegd.

Op grond hiervan verklaart de commissie dat het onderzoek niet onder de WMO valt. Voor de uitvoering ervan is derhalve geen positief oordeel vereist van de CMO regio Arnhem - Nijmegen of een andere erkende medisch-ethische toetsingscommissie.

Dit oordeel is tot stand gekomen na bestudering van de volgende documenten:

- Aanbiedingsbrief van Marith van Schrojenstein Lantman d.d. 23 oktober 2020
- Onderzoeksprotocol versie 1 d.d. 12 oktober 2020

De commissie heeft uw onderzoek alleen beoordeeld op WMO-plicht en niet aan een inhoudelijk oordeel onderworpen.

Voor zover u dit nog niet heeft gedaan raad ik u aan in de deelnemende centra na te gaan of voor de uitvoering van uw niet-WMO-onderzoek een beoordeling door de niet-WMO-toetsingscommissie ter plekke vereist is.

Graag attender ik u op de wet- en regelgeving m.b.t. niet-WMO-plichtig onderzoek en het beleid van het Radboudumc daaromtrent, te vinden in het [Integraal Kwaliteitssysteem wetenschappelijk onderzoek](#) (IKS). Hier vindt u onder het kopje Radboudumc SOPs o.a. het '[Normenkader statusonderzoek](#)'. Mocht u vragen hebben over informatie in het IKS dan kunt u [contact opnemen](#) met het RTC Clinical Studies.

Ik vertrouw erop u met dit bericht van dienst te zijn.

Met vriendelijke groet,

Prof. Dr. P.N.R. Dekhuijzen, voorzitter

-
Concernstaf Kwaliteit en Veiligheid
Commissie Mensgebonden Onderzoek
commissiemensgebondenonderzoek@radboudumc.nl
T (024) 3613154

Radboud universitair medisch centrum
Tandheelkunde gebouw
Philips van Leydenlaan 25 (route 348), Nijmegen
www.radboudumc.nl
www.cmoregio-a-n.nl

-
cc RTCCS

Title: SKML structural monitoring system for reference intervals

Filenumber: 2020-7054

Dear ms. Schrojenstein Lantman,

Please be informed that the abovementioned study will be carried out in accordance with the applicable legislation concerning review by an accredited research ethics committee.

Best regards,
Prof. dr. P.N.R. Dekhuijzen, chairman

Research Ethics Committee
Radboud University Medical Centre

Specificatie NUMBER-labdata

SKML, 23-8-2021

1. Bestandsnaam

Een lab levert één CSV-bestand per kalenderjaar aan met de volgende naam:

<SKML-deelnemernummer>_NUMBER_<jaar>.csv

Bijvoorbeeld 16_NUMBER_2020.csv

In het geval het niet mogelijk is om een CSV-bestand aan te leveren, dan mag als alternatief een Excel-bestand worden aangeleverd met dezelfde structuur en de volgende naam:

<SKML-deelnemernummer>_NUMBER_<jaar>.xlsx

Bijvoorbeeld 16_NUMBER_2020.xlsx

2. Bestandsopmaak

De eerste regel bevat kolomnamen. Die mogen afwijken van wat hieronder staat zolang de volgorde maar identiek is.

Het CSV-bestand bevat puntkomma's (;) als scheidingstekens. Dubbele aanhalingstekens ("") mogen een veld omsluiten. Dit is nodig als een veld zelf een puntkomma of dubbele aanhalingstekens bevat. In het laatste geval moet het dubbele aanhalingsteken zelf twee keer achter elkaar worden opgenomen.

Het bestand bevat de volgende verplicht gevulde kolommen en ook in die volgorde:

Kolomnaam	Type	Omschrijving
PTP_ID	geheel getal	SKML-deelnemernummer <i>zie SKML-rapport</i>
DATE_OF_BIRTH	dd-mm-jjjj	Geboortedatum
SEX	M/V/X	Geslacht
COLLECTION_DATE	dd-mm-jjjj hh:mm	Afnamedatum en -tijd <i>gescheiden door één spatie, zonder seconden</i>
ANALYTE	tekst	SKML-bepaling <i>letterlijk zoals in de tabellen hieronder</i>
RESULT	getal	Resultaat <i>decimaalteken: komma of punt</i>
UNIT	tekst	Eenheid in UCUM-notatie <i>letterlijk zoals in de tabellen hieronder</i>
MATRIX	tekst	Serum, LiHep-Plasma, NaF of EDTA <i>letterlijk</i>

De combinatie (PTP_ID, DATE_OF_BIRTH, SEX, COLLECTION_DATE, ANALYTE) dient uniek te zijn.

Voor een juiste berekening van de referentie-intervallen is het van belang dat alleen testresultaten worden ingestuurd die voldoen aan de volgende criteria:

- Aangevraagd door een huisarts
- Geen thuisafname

De volgende 23 bepalingen van de SKML-rondzending 'Klinische Chemie, bloed' worden momenteel ondersteund:

SKML-bepaling	Eenheden	Toelichting
ALAT	U/L	
Albumine	g/L	
Alk. Fosfatase	U/L	
Amylase	U/L	
Anorg. Fosfaat	mmol/L	
ASAT	U/L	
Bilirubine	umol/L	Dit betreft bilirubine totaal.
Calcium	mmol/L	
Chloride	mmol/L	
CK	U/L	Voor deze bepaling is nog geen NUMBER referentie-interval beschikbaar. Deze data worden gebruikt om eerder gevonden resultaten te valideren en consensus te bereiken voor een gestandaardiseerd referentie-interval.
Gamma-GT	U/L	
Glucose (N)	mmol/L	Dit betreft nuchtere glucose. Voor deze bepaling is nog geen NUMBER referentie-interval beschikbaar. Deze data worden gebruikt om eerder gevonden resultaten te valideren en consensus te bereiken voor een gestandaardiseerd referentie-interval.
Glucose (NN)	mmol/L	Dit betreft niet-nuchtere glucose. Voor deze bepaling is nog geen NUMBER referentie-interval beschikbaar. Deze data worden gebruikt om eerder gevonden resultaten te valideren en consensus te bereiken voor een gestandaardiseerd referentie-interval.
IJzer	umol/L	
Kalium	mmol/L	
Kreatinine	umol/L	
LD	U/L	Dit betreft LDH.
Lipase	U/L	Voor deze bepaling is nog geen NUMBER referentie-interval beschikbaar. Deze data worden gebruikt om eerder gevonden resultaten te valideren en consensus te bereiken voor een gestandaardiseerd referentie-interval.
Magnesium	mmol/L	
Natrium	mmol/L	
Totaal Eiwit	g/L	
Uraat	umol/L mmol/L	Voor deze bepaling is nog geen NUMBER referentie-interval beschikbaar. Deze data worden gebruikt om eerder gevonden resultaten te valideren en consensus te bereiken voor een gestandaardiseerd referentie-interval.
Ureum	mmol/L	

Om voor bovenstaande SKML-bepalingen de referentie-intervallen op een goede manier te kunnen berekenen, zijn ook gegevens nodig van 2 aanvullende bepalingen (voor details: Den Elzen, Brouwer et al. CCLM 2018):

SKML-bepaling	Eenheden	Toelichting
HbA1c	mmol/mol	Om het risico te verkleinen dat voor het berekenen van het referentie-interval voor glucose resultaten worden meegenomen van patiënten met diabetes, worden alleen die glucose resultaten in de analyses meegenomen wanneer geen HbA1c is aangevraagd op hetzelfde afnamemoment.
Hemoglobine	mmol/L	Voor het berekenen van referentie-intervallen voor ijzer worden resultaten geëxcludeerd als op hetzelfde afnamemoment voor een patiënt een verlaagd hemoglobine gemeten is.

Bij vragen over het bestand kunt u contact opnemen met SKML via NUMBER@skml.nl.

Bijlage 5

PTP_ID	DATE_OF_BIRTH	SEX	COLLECTION_DATE	ANALYTE	RESULT	UNIT
4	14-11-1982	V	13-9-2020 18:59	ALAT	50	U/L
4	14-11-1982	V	13-9-2020 18:59	Albumine	40	g/L
4	14-11-1982	V	13-9-2020 18:59	Alk. Fosfatase	150	U/L
4	14-11-1982	V	13-9-2020 18:59	Amylase	250	U/L
4	14-11-1982	V	13-9-2020 18:59	Anorg. Fosfaat	1	mmol/L
4	14-11-1982	V	13-9-2020 18:59	ASAT	50	U/L
4	14-11-1982	V	13-9-2020 18:59	Bilirubine	20	umol/L
4	14-11-1982	V	13-9-2020 18:59	Calcium	2,5	mmol/L
4	14-11-1982	V	13-9-2020 18:59	Chloride	100	mmol/L
4	14-11-1982	V	13-9-2020 18:59	CK	150	U/L
4	14-11-1982	V	13-9-2020 18:59	Gamma-GT	50	U/L
4	14-11-1982	V	13-9-2020 18:59	Glucose (N)	10	mmol/L
4	14-11-1982	V	13-9-2020 18:59	Glucose (NN)	10	mmol/L
4	14-11-1982	V	13-9-2020 18:59	IJzer	30	umol/L
4	14-11-1982	V	13-9-2020 18:59	Kalium	4	mmol/L
4	14-11-1982	V	13-9-2020 18:59	Kreatinine	100	umol/L
4	14-11-1982	V	13-9-2020 18:59	LD	500	U/L
4	14-11-1982	V	13-9-2020 18:59	Lipase	25	U/L
4	14-11-1982	V	13-9-2020 18:59	Magnesium	1	mmol/L
4	14-11-1982	V	13-9-2020 18:59	Natrium	140	mmol/L
4	14-11-1982	V	13-9-2020 18:59	Totaal Eiwit	70	g/L
4	14-11-1982	V	13-9-2020 18:59	Uraat	500	umol/L
4	14-11-1982	V	13-9-2020 18:59	Ureum	10	mmol/L
4	14-11-1982	V	13-9-2020 18:59	HbA1c	50	mmol/mol
4	14-11-1982	V	13-9-2020 18:59	Hemoglobine	7	mmol/L

MATRIX

LiHep-Plasma

NaF

NaF

LiHep-Plasma

EDTA

EDTA

Bijlage 6

Bestand Bewerken Beeld Geschiedenis Bladwijzers Extra Help

F FileCap x +

← → ⌂ ⌂ https://filetransfer.skml.nl/FileCap/sign-up ☆

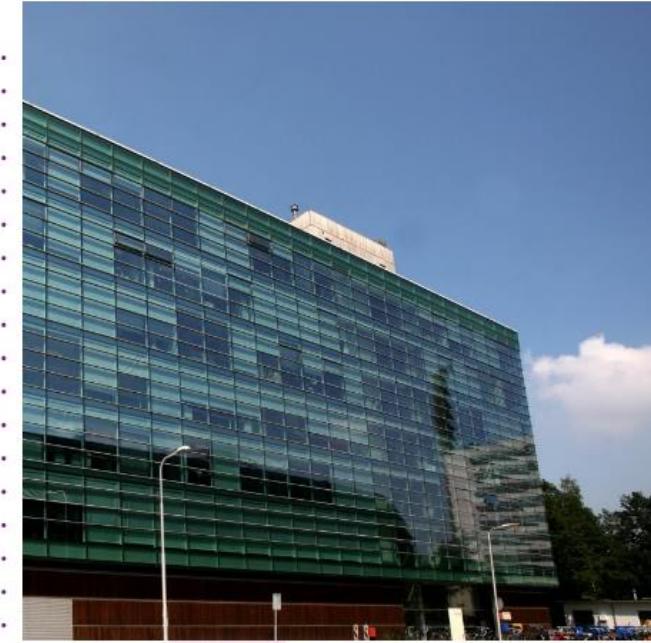
Meest bezocht Aan de slag Turn Admin Off! Andere bladwijzers

NL ▾

 Aanmelden

Om bestanden te kunnen versturen met FileCap, dient uw contactpersoon bij SKML u hiervoor te machtigen via een uitnodiging.

Neem contact op met uw contactpersoon om een uitnodiging te ontvangen.



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bijlage 7

Twee tabellen die zijn toegevoegd aan de SKML Oracle-database.
NUMBER_TEMP voor het laden van data van een enkel lab (een zogenaamde staging tabel) en
NUMBER_RESULT voor de data van alle labs:

```
create table SKZL.NUMBER_RESULT
(
    ptp_id          INTEGER not null,
    date_of_birth   DATE not null,
    sex              VARCHAR2(1) not null,
    collection_date DATE not null,
    analyte         VARCHAR2(50) not null,
    result           NUMBER not null,
    unit             VARCHAR2(20) not null,
    matrix           VARCHAR2(20) not null,
    recnum           INTEGER,
    colnum           INTEGER
)
;
alter table SKZL.NUMBER_RESULT
    add constraint PK_NUMBER_RESULT primary key (PTP_ID, DATE_OF_BIRTH, SEX,
COLLECTION_DATE, ANALYTE);
alter table SKZL.NUMBER_RESULT
    add constraint CH_NUMBER_RESULT_MATRIX
    check (matrix in ('Serum', 'LiHep-Plasma', 'NaF', 'EDTA'));
alter table SKZL.NUMBER_RESULT
    add constraint CH_NUMBER_RESULT_SEX
    check (sex in ('M', 'V', 'X'));

create table SKZL.NUMBER_TEMP
(
    ptp_id          INTEGER not null,
    date_of_birth   DATE not null,
    sex              VARCHAR2(1) not null,
    collection_date DATE not null,
    analyte         VARCHAR2(50) not null,
    result           NUMBER not null,
    unit             VARCHAR2(20) not null,
    matrix           VARCHAR2(20) not null,
    recnum           INTEGER,
    colnum           INTEGER
)
;
alter table SKZL.NUMBER_TEMP
    add constraint PK_NUMBER_TEMP primary key (PTP_ID, DATE_OF_BIRTH, SEX,
COLLECTION_DATE, ANALYTE);
alter table SKZL.NUMBER_TEMP
    add constraint CH_NUMBER_TEMP_MATRIX
    check (matrix in ('Serum', 'LiHep-Plasma', 'NaF', 'EDTA'));
alter table SKZL.NUMBER_TEMP
    add constraint CH_NUMBER_TEMP_SEX
    check (sex in ('M', 'V', 'X'));
```

Bijlage 8 rapportage exclusie malperformance laboratorium op een analyt

view uit SKML Oracle database – alle data input

The screenshot shows the PL/SQL Developer interface with a query window displaying the results of a SELECT * query from the NUMBER_TEMP table. The results are ordered by recnum. The table has columns: PTP_ID, DATE_OF_BIRTH, SEX, COLLECTION_DATE, ANALYTE, RESULT, UNIT, MATRIX, RECNUM, and COLNUM. The data includes various laboratory parameters like ALAT, Albumine, Alk. Fosfatase, Amylase, Anorg. Fosfaat, Bilirubine, Calcium, Chloride, CK, Creatinine, Gamma-GT, Glucose (N), Glucose (NN), Total Eiwit, Uraat, Ureum, HbA1c, and Hemoglobine, along with their respective values and units.

PTP_ID	DATE_OF_BIRTH	SEX	COLLECTION_DATE	ANALYTE	RESULT	UNIT	MATRIX	RECNUM	COLNUM
1	4-14-1982	V	13-9-2020 18:59:00	ALAT	50	U/L	LiHep-Plasma	2	
2	4-14-1982	V	13-9-2020 18:59:00	Albumine	40	g/L	LiHep-Plasma	3	
3	4-14-1982	V	13-9-2020 18:59:00	Alk. Fosfatase	150	U/L	LiHep-Plasma	4	
4	4-14-1982	V	13-9-2020 18:59:00	Amylase	250	U/L	LiHep-Plasma	5	
5	4-14-1982	V	13-9-2020 18:59:00	Anorg. Fosfaat	1	mmol/L	LiHep-Plasma	6	
6	4-14-1982	V	13-9-2020 18:59:00	ASAT	50	U/L	LiHep-Plasma	7	
7	4-14-1982	V	13-9-2020 18:59:00	Bilirubine	20	umol/L	LiHep-Plasma	8	
8	4-14-1982	V	13-9-2020 18:59:00	Calcium	2,5	mmol/L	LiHep-Plasma	9	
9	4-14-1982	V	13-9-2020 18:59:00	Chloride	100	mmol/L	LiHep-Plasma	10	
10	4-14-1982	V	13-9-2020 18:59:00	CK	150	U/L	LiHep-Plasma	11	
11	4-14-1982	V	13-9-2020 18:59:00	Gamma-GT	50	U/L	LiHep-Plasma	12	
12	4-14-1982	V	13-9-2020 18:59:00	Glucose (N)	10	mmol/L	NaF	13	
13	4-14-1982	V	13-9-2020 18:59:00	Glucose (NN)	10	mmol/L	NaF	14	
14	4-14-1982	V	13-9-2020 18:59:00	Izera	30	umol/L	LiHep-Plasma	15	
15	4-14-1982	V	13-9-2020 18:59:00	Kalium	4	mmol/L	LiHep-Plasma	16	
16	4-14-1982	V	13-9-2020 18:59:00	Kreatinine	100	umol/L	LiHep-Plasma	17	
17	4-14-1982	V	13-9-2020 18:59:00	Lipase	500	U/L	LiHep-Plasma	18	
18	4-14-1982	V	13-9-2020 18:59:00	Lipase	25	U/L	LiHep-Plasma	19	
19	4-14-1982	V	13-9-2020 18:59:00	Magnesium	1	mmol/L	LiHep-Plasma	20	
20	4-14-1982	V	13-9-2020 18:59:00	Natrium	140	mmol/L	LiHep-Plasma	21	
21	4-14-1982	V	13-9-2020 18:59:00	Total Eiwit	70	g/L	LiHep-Plasma	22	
22	4-14-1982	V	13-9-2020 18:59:00	Uraat	500	umol/L	LiHep-Plasma	23	
23	4-14-1982	V	13-9-2020 18:59:00	Ureum	10	mmol/L	LiHep-Plasma	24	
24	4-14-1982	V	13-9-2020 18:59:00	HbA1c	50	mmol/mol	EDTA	25	
25	4-14-1982	V	13-9-2020 18:59:00	Hemoglobine	7	mmol/L	EDTA	26	

view uit SKML Oracle database - Het 9e record (Chloride) is uit de labdata gefilterd

The screenshot shows the PL/SQL Developer interface with a query window displaying the results of a SELECT * query from the NUMBER_TEMP_R table. The results are ordered by recnum. The table has columns: PTP_ID, DATE_OF_BIRTH, SEX, COLLECTION_DATE, ANALYTE, RESULT, UNIT, MATRIX, RECNUM, ANL_ID, RESULT_PREF, and UNIT_PREF. The data includes various laboratory parameters like ALAT, Albumine, Alk. Fosfatase, Amylase, Anorg. Fosfaat, Bilirubine, Calcium, Chloride, CK, Creatinine, Gamma-GT, Glucose (N), Glucose (NN), Total Eiwit, Uraat, Ureum, HbA1c, and Hemoglobine, along with their respective values and units. The 9th record (Chloride) is highlighted in green.

PTP_ID	DATE_OF_BIRTH	SEX	COLLECTION_DATE	ANALYTE	RESULT	UNIT	MATRIX	RECNUM	ANL_ID	RESULT_PREF	UNIT_PREF
1	4-14-1982	V	13-9-2020 18:59:00	ALAT	50	U/L	LiHep-Plasma	2	13	50	U/L
2	4-14-1982	V	13-9-2020 18:59:00	Albumine	40	g/L	LiHep-Plasma	3	25	40	g/L
3	4-14-1982	V	13-9-2020 18:59:00	Alk. Fosfatase	150	U/L	LiHep-Plasma	4	11	150	U/L
4	4-14-1982	V	13-9-2020 18:59:00	Amylase	250	U/L	LiHep-Plasma	5	29	250	U/L
5	4-14-1982	V	13-9-2020 18:59:00	Anorg. Fosfaat	1	mmol/L	LiHep-Plasma	6	4	1	mmol/L
6	4-14-1982	V	13-9-2020 18:59:00	ASAT	50	U/L	LiHep-Plasma	7	12	50	U/L
7	4-14-1982	V	13-9-2020 18:59:00	Bilirubine	20	umol/L	LiHep-Plasma	8	17	20	umol/L
8	4-14-1982	V	13-9-2020 18:59:00	Calcium	2,5	mmol/L	LiHep-Plasma	9	2	2,5	mmol/L
9	4-14-1982	V	13-9-2020 18:59:00	Chloride	100	mmol/L	NaF	11	28	150	U/L
10	4-14-1982	V	13-9-2020 18:59:00	Creatinine	150	umol/L	LiHep-Plasma	12	27	50	U/L
11	4-14-1982	V	13-9-2020 18:59:00	Glucose (N)	10	mmol/L	NaF	13	9	10	mmol/L
12	4-14-1982	V	13-9-2020 18:59:00	Glucose (NN)	10	mmol/L	NaF	14	9	10	mmol/L
13	4-14-1982	V	13-9-2020 18:59:00	Izera	30	umol/L	LiHep-Plasma	15	15	30	umol/L
14	4-14-1982	V	13-9-2020 18:59:00	Kalium	4	mmol/L	LiHep-Plasma	16	1	4	mmol/L
15	4-14-1982	V	13-9-2020 18:59:00	Kreatinine	100	umol/L	LiHep-Plasma	17	6	100	umol/L
16	4-14-1982	V	13-9-2020 18:59:00	Lipase	500	U/L	LiHep-Plasma	18	14	500	U/L
17	4-14-1982	V	13-9-2020 18:59:00	Uraat	25	U/L	LiHep-Plasma	19	56	25	U/L
18	4-14-1982	V	13-9-2020 18:59:00	Magnesium	1	mmol/L	LiHep-Plasma	20	21	1	mmol/L
19	4-14-1982	V	13-9-2020 18:59:00	Natrium	140	mmol/L	LiHep-Plasma	21	0	140	mmol/L
20	4-14-1982	V	13-9-2020 18:59:00	Total Eiwit	70	g/L	LiHep-Plasma	22	10	70	g/L
21	4-14-1982	V	13-9-2020 18:59:00	Ureum	500	umol/L	LiHep-Plasma	23	7	500	umol/L
22	4-14-1982	V	13-9-2020 18:59:00	HbA1c	50	mmol/mol	EDTA	24	5	10	mmol/L
23	4-14-1982	V	13-9-2020 18:59:00	Hemoglobine	7	mmol/L	EDTA	25	1807	50	mmol/mol
24	4-14-1982	V	13-9-2020 18:59:00	Hemoglobine	7	mmol/L	EDTA	26	132	7	mmol/L

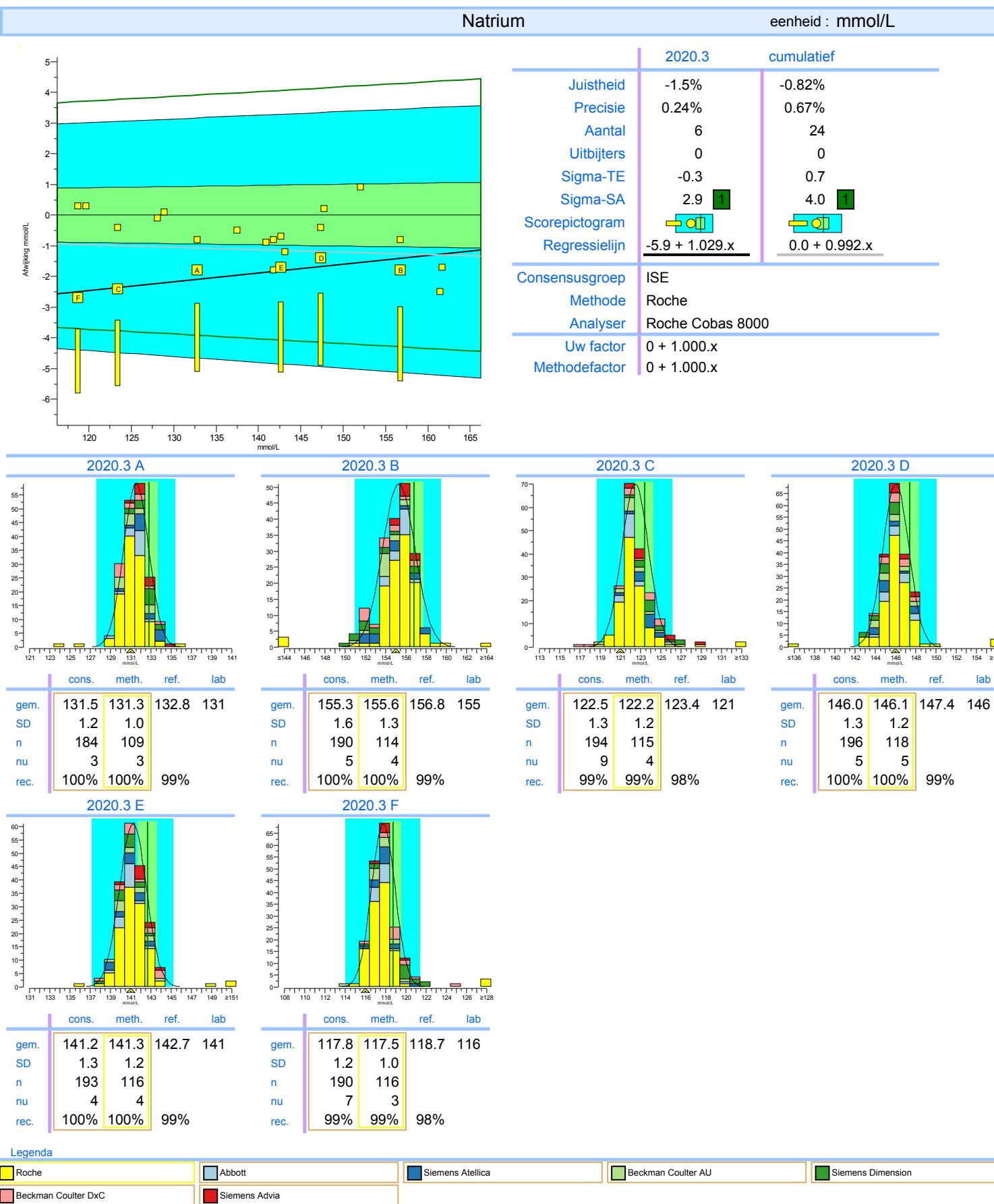
Klinische Chemie, bloed 2020.3

Rondzingend Periode	Klinische Chemie, bloed 2020.3 1 juli 2020 - 30 september 2020
Rapport voor	
Aantal deelnemers Coördinatie en rapportautorisatie	115 dr. C. Weykamp (Coördinator) te bereiken via office@skml.nl
Naslag	<u>MUSE-handleiding</u> en <u>Bepalingsspecificaties</u> Op de SKML-website vindt u de MUSE-handleiding en een overzicht van alle bepalingen van alle rondzingingen. Het overzicht toont per bepaling de bron van de doelwaarde, de tolerantie en waarop die is gebaseerd. Ook het soort materiaal en de specificatie van de commuteerbaarheid, homogeniteit en stabiliteit zijn opgenomen.

Klinische Chemie, bloed 2020.3

Bepaling	Eenheid	Juistheid				Precisie		Performance			
		uw gem.	ref.	cons.	SDtl	uw SD	SDbl	deze ronde	PS	cumulatief	PSc
Natrium	mmol/L	134.5	136.5	135.3	1.3	0.9	1.0		1		1
Kalium	mmol/L	4.50	4.56	4.55	0.09	0.06	0.05		1		1
Chloride	mmol/L	100.4	105.2	102.8	2.3	1.4	1.2		0		1
Magnesium	mmol/L	1.480	1.453	1.470	0.041	0.015	0.027		2		2
Calcium	mmol/L	2.56	2.57	2.57	0.05	0.04	0.04		2		1
IJzer	umol/L	50.7	49.7	49.5	1.4	0.9	0.8		2		2
Ureum	mmol/L	10.37	10.68	10.69	0.44	0.37	0.26		2		2
Kreatinine	umol/L	141.9	138.7	139.7	3.6	2.8	2.7		1		1
eGFR (V, 55, blank)	mL/min/{1.73_m2}	37.7	38.9	38.0	1.7	1.0	1.1		1		1
Uraat	umol/L	404	408	412	13	5	7		2		2
Bilirubine	umol/L	28.9	31.3	30.6	2.1	1.1	1.1		2		2
Bilirubine direct	umol/L		6.1	6.2	1.1	0.5	0.6		2		2
Alk. Fosfatase	U/L	186	182	180	10	3	4		2		2
ASAT	U/L	85.1	85.7	85.7	4.6	3.4	2.9		1		1
ALAT	U/L	76.2	74.5	73.2	4.3	1.6	2.2		2		2
Gamma-GT	U/L	99.0	99.8	102.4	3.5	1.1	1.9		2		2
CK	U/L	227	226	228	8	3	4		2		2
Amylase	U/L	238	247	238	9	2	4		2		2
Albumine	g/L	41.9		43.2	1.3	0.7	0.8		1		2
Totaal Eiwit	g/L	60.7	62.4	61.7	1.5	1.0	1.1		1		1
Glucose	mmol/L	13.45	13.24	13.30	0.47	0.26	0.30		2		1
LD	U/L	624	631	646	31	26	16		2		2
Lithium	mmol/L	1.400	1.454	1.425	0.048	0.046	0.040		1		1
Anorg. Fosfaat	mmol/L	1.361	1.403	1.402	0.042	0.037	0.030		1		2
Ammoniak	umol/L		761	778	50	21	32		1		1
Lipase	U/L		28.4	27.6	2.0	1.4	1.7		2		2

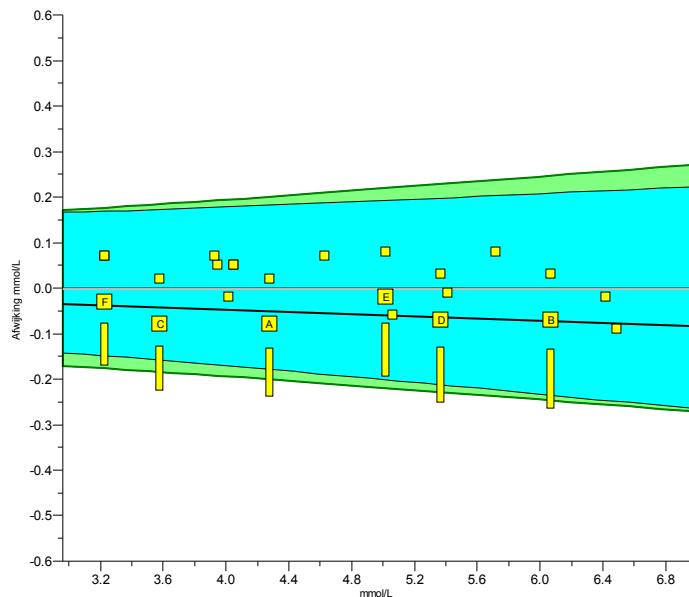
Klinische Chemie, bloed 2020.3



Klinische Chemie, bloed 2020.3

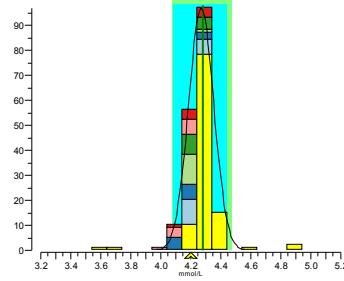
Kalium

eenheid : mmol/L

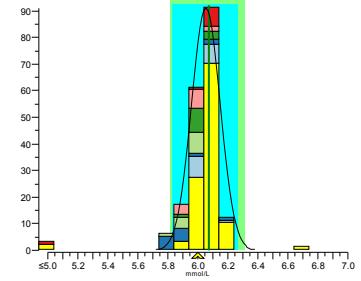


	2020.3	cumulatief
Juistheid	-1.2%	+0.01%
Precisie	0.79%	1.2%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	4.1	4.3
Sigma-SA	3.6	3.8
Scorepictogram		
Regressielijn	$0.00 + 0.988 \cdot x$	$0.00 + 1.000 \cdot x$
Consensusgroep	ISE	
Methode	Roche	
Analysator	Roche Cobas 8000	
Uw factor	$0.0 + 1.000 \cdot x$	
Methodefactor	$0.1 + 1.000 \cdot x$	

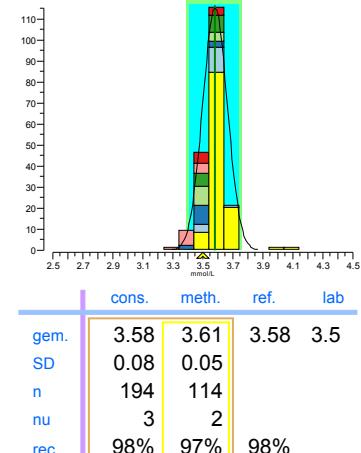
2020.3 A



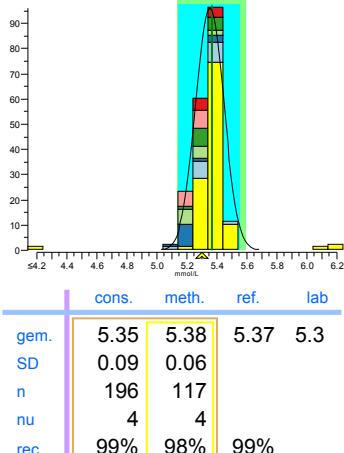
2020.3 B



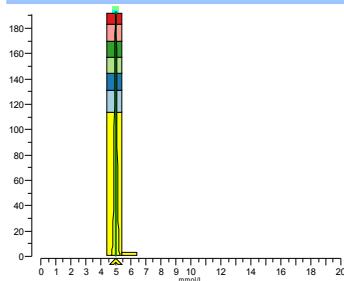
2020.3 C



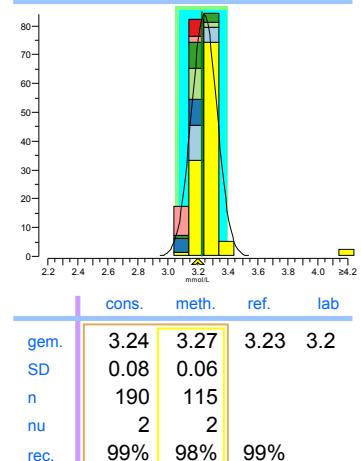
2020.3 D



2020.3 E



2020.3 F



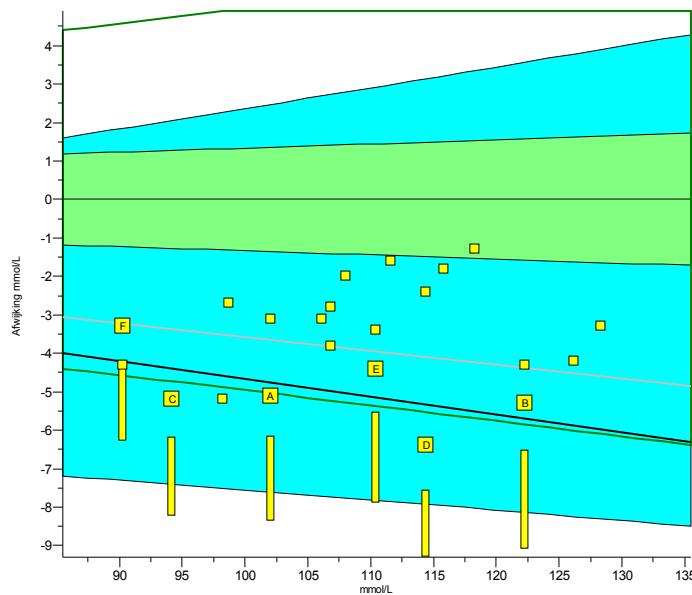
Legenda

Roche	Abbott	Siemens Atellica	Beckman Coulter AU	Siemens Dimension
Beckman Coulter DxC	Siemens Advia			

Klinische Chemie, bloed 2020.3

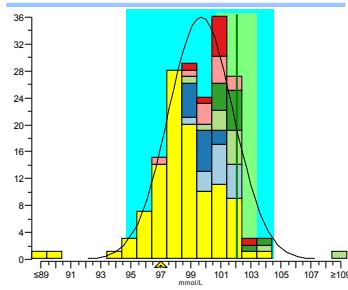
Chloride

eenheid : mmol/L

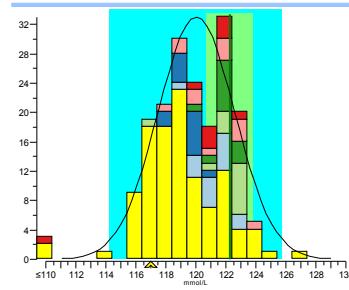


	2020.3	cumulatief
Juistheid	-4.7%	-3.6%
Precisie	0.93%	1.3%
Aantal	6	23
Uitbijters	0	0
Sigma-TE	-2.6	-1.4
Sigma-SA	1.1	2.5
Scorepictogram		
Regressielijn	$0.0 + 0.953 \cdot x$	$0.0 + 0.964 \cdot x$
Consensusgroep	ISE	
Methode	Roche	
Analysator	Roche Cobas 8000	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.006 \cdot x$	

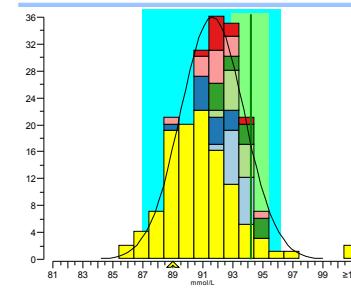
2020.3 A



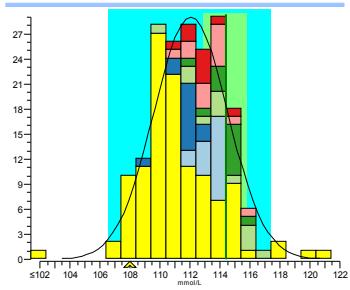
2020.3 B



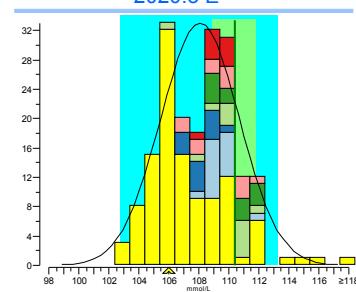
2020.3 C



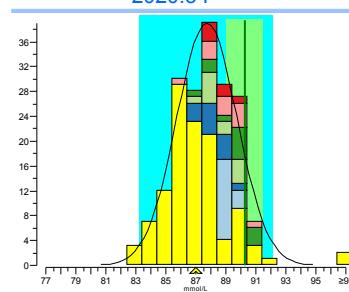
2020.3 D



2020.3 E



2020.3 F



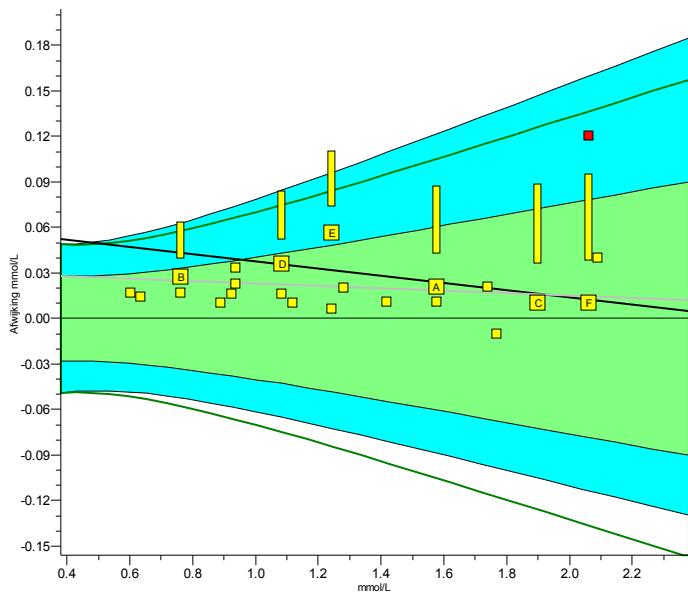
Legenda

Roche	Abbott	Beckman Coulter AU	Siemens Dimension	Siemens Atellica
Beckman Coulter DxC	Siemens Advia			

Klinische Chemie, bloed 2020.3

Magnesium

eenheid : mmol/L



	2020.3	cumulatief
Juistheid	+1.9%	+1.6%
Precisie	1.3%	1.1%
Aantal	6	24
Uitbijters	0	1
Sigma-TE	2.4	2.6
Sigma-SA	5.2 [2]	5.1 [2]
Scorepictogram		
Regressielijn	$0.062 + 0.976 \cdot x$	$0.031 + 0.992 \cdot x$
Consensusgroep	Colorimetrisch	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0.00 + 1.000 \cdot x$	
Methodefactor	$0.00 + 1.002 \cdot x$	

2020.3 A

2020.3 B

2020.3 C

2020.3 D

cons. meth. ref. lab

cons. meth. ref. lab

cons. meth. ref. lab

cons. meth. ref. lab

	gem.	SD	n	nu	rec.
gem.	1.595	0.030	171	15	100%
SD	1.599	0.028	105	4	100%
n					101%
nu					
rec.					

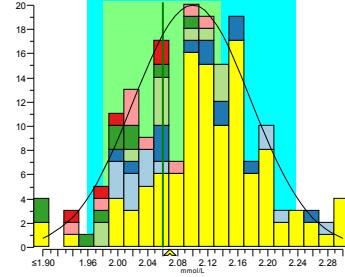
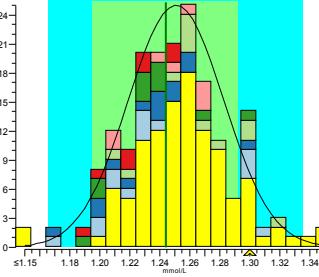
	gem.	SD	n	nu	rec.
gem.	0.776	0.021	176	8	102%
SD	0.777	0.019	110	3	102%
n					104%
nu					
rec.					

	gem.	SD	n	nu	rec.
gem.	1.905	0.033	179	12	100%
SD	1.909	0.033	111	3	100%
n					101%
nu					
rec.					

	gem.	SD	n	nu	rec.
gem.	1.098	0.023	181	12	102%
SD	1.101	0.022	113	6	102%
n					103%
nu					
rec.					

2020.3 E

2020.3 F



	cons.	meth.	ref.	lab
gem.	1.251	1.258	1.244	1.30
SD	0.032	0.028		
n	178	111		
nu	4	4		
rec.	104%	103%	105%	

	cons.	meth.	ref.	lab
gem.	2.099	2.123	2.060	2.07
SD	0.078	0.065		
n	175	111		
nu	6	5		
rec.	99%	98%	100%	

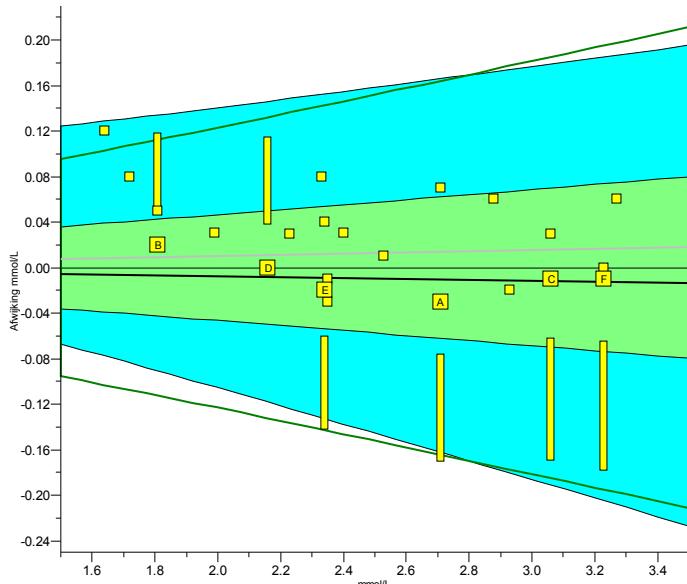
Legenda

Roche	Siemens Atellica	Abbott	Siemens Dimension	Beckman Coulter DxC
Beckman Coulter AU	Siemens Advia			

Klinische Chemie, bloed 2020.3

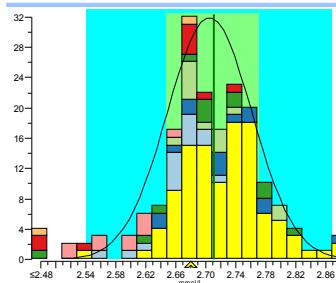
Calcium

eenheid : mmol/L



	2020.3	cumulatief
Juistheid	-0.33%	+0.61%
Precisie	0.65%	1.4%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	2.0	1.3
Sigma-SA	4.7 [2]	4.0 [1]
Scorepictogram		
Regressielijn	$0.00 + 0.996 \cdot x$	$0.00 + 1.005 \cdot x$
Consensusgroep	Colorimetrie en ISE	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0.00 + 1.000 \cdot x$	
Methodefactor	$0.00 + 1.000 \cdot x$	

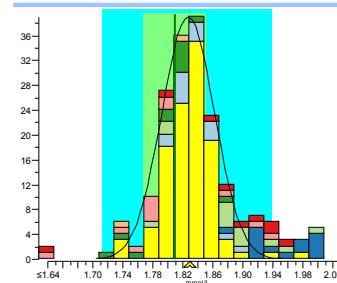
2020.3 A



cons. meth. ref. lab

gem.	2.70	2.72	2.71	2.68
SD	0.06	0.05		
n	182	109		
nu	9	2		
rec.	99%	99%	99%	

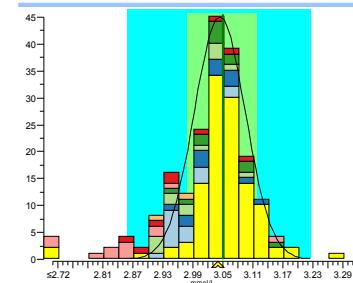
2020.3 B



cons. meth. ref. lab

gem.	1.827	1.826	1.81	1.83
SD	0.035	0.030		
n	189	114		
nu	25	4		
rec.	100%	100%	101%	

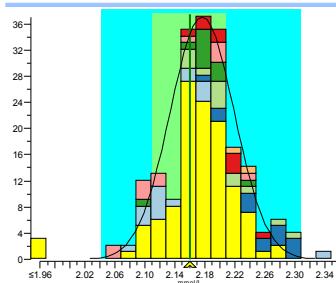
2020.3 C



cons. meth. ref. lab

gem.	3.05	3.07	3.06	3.05
SD	0.05	0.05		
n	192	115		
nu	17	4		
rec.	100%	99%	100%	

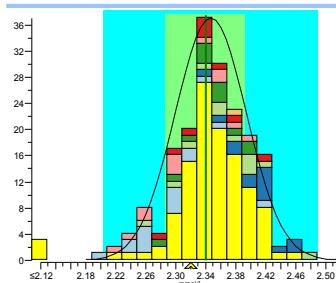
2020.3 D



cons. meth. ref. lab

gem.	2.18	2.17	2.16	2.16
SD	0.04	0.04		
n	192	116		
nu	4	3		
rec.	99%	99%	100%	

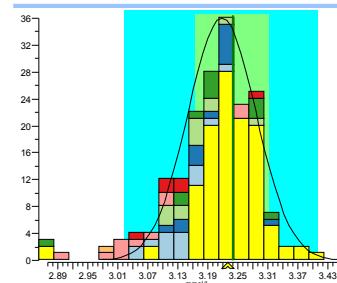
2020.3 E



cons. meth. ref. lab

gem.	2.35	2.35	2.34	2.32
SD	0.05	0.04		
n	189	114		
nu	4	3		
rec.	99%	99%	99%	

2020.3 F



cons. meth. ref. lab

gem.	3.21	3.23	3.23	3.22
SD	0.07	0.05		
n	186	114		
nu	6	2		
rec.	100%	100%	100%	

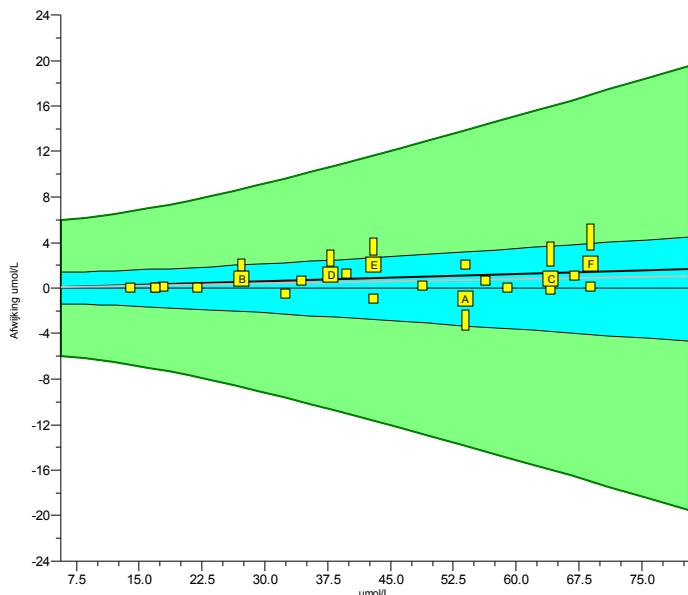
Legenda

Roche	Abbott	Siemens Atellica	Beckman Coulter AU	Siemens Dimension
Beckman Coulter DxC	Siemens Advia	Overige methoden		

Klinische Chemie, bloed 2020.3

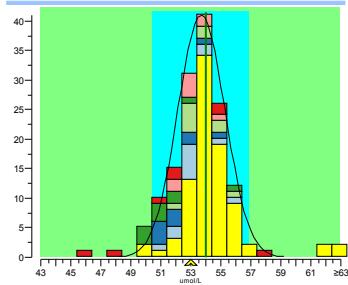
IJzer

eenheid : umol/L

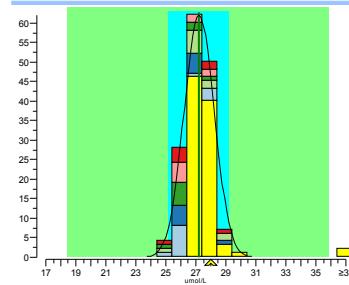


	2020.3	cumulatief
Juistheid	+2.1%	+1.3%
Precisie	2.1%	2.1%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	6.0 [2]	6.0 [2]
Sigma-SA	3.2	4.0
Scorepictogram	[Green box]	[Green box]
Regressielijn	0.0 + 1.020.x	0.0 + 1.013.x
Consensusgroep	Colorimetrisch	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.000.x	

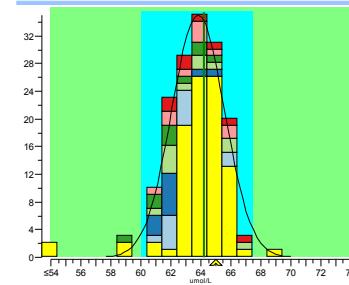
2020.3 A



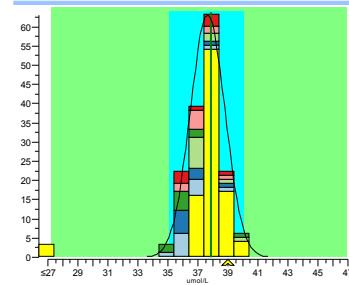
2020.3 B



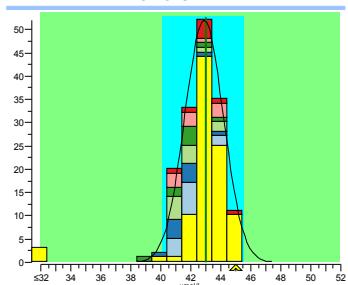
2020.3 C



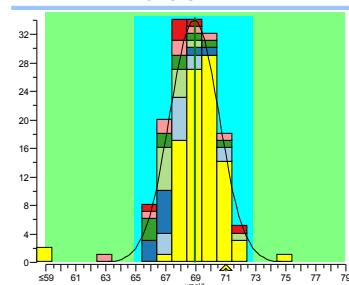
2020.3 D



2020.3 E



2020.3 F



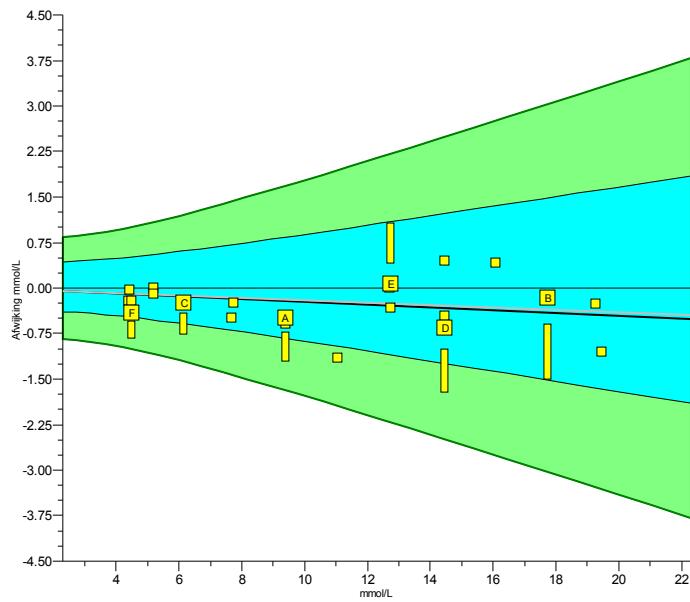
Legenda

Roche	Siemens Atellica	Siemens Dimension	Abbott	Beckman Coulter AU
Beckman Coulter DxC	Siemens Advia			

Klinische Chemie, bloed 2020.3

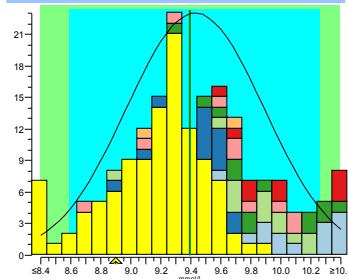
Ureum

eenheid : mmol/L



	2020.3	cumulatief
Juistheid	-2.9%	-2.4%
Precisie	2.4%	3.5%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	6.0 [2]	6.0 [2]
Sigma-SA	3.2	3.3
Scorepictogram	[Green box]	[Green box]
Regressielijn	$0.00 + 0.977 \cdot x$	$0.00 + 0.980 \cdot x$
Consensusgroep	Urease-GDLH en geleidbaarheid	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0.0 + 1.000 \cdot x$	
Methodefactor	$0.0 + 1.000 \cdot x$	

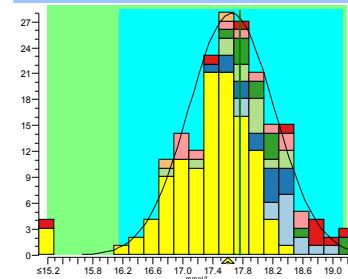
2020.3 A



cons. meth. exp. lab

gem.	9.43	9.18	9.39	8.9
SD	0.46	0.33		
n	183	110		
nu	3	3		
rec.	94%	97%	95%	

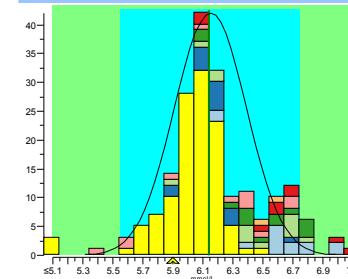
2020.3 B



cons. meth. exp. lab

gem.	17.65	17.39	17.76	17.6
SD	0.57	0.45		
n	189	115		
nu	4	3		
rec.	100%	101%	99%	

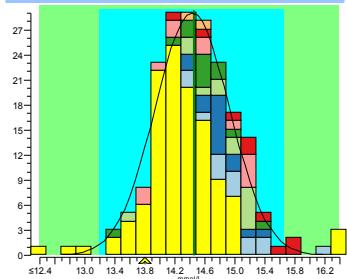
2020.3 C



cons. meth. exp. lab

gem.	6.15	6.05	6.14	5.9
SD	0.24	0.16		
n	192	116		
nu	8	3		
rec.	96%	97%	96%	

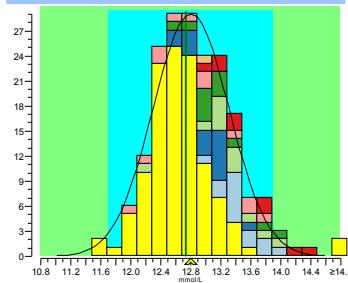
2020.3 D



cons. meth. exp. lab

gem.	14.43	14.23	14.46	13.8
SD	0.50	0.38		
n	192	117		
nu	6	5		
rec.	96%	97%	95%	

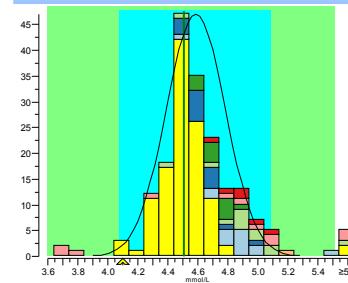
2020.3 E



cons. meth. exp. lab

gem.	12.80	12.59	12.73	12.8
SD	0.51	0.37		
n	189	115		
nu	2	2		
rec.	100%	102%	101%	

2020.3 F



cons. meth. exp. lab

gem.	4.59	4.50	4.51	4.1
SD	0.20	0.14		
n	186	115		
nu	9	2		
rec.	89%	91%	91%	

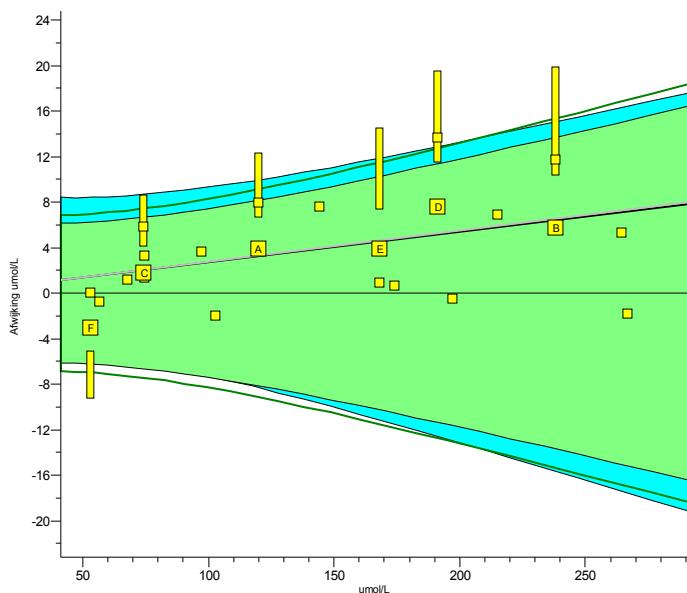
Legenda

 Roche	 Siemens Atellica	 Abbott	 Beckman Coulter AU	 Siemens Dimension
 Beckman Coulter DxC	 Siemens Advia		 Overige methoden	

Klinische Chemie, bloed 2020.3

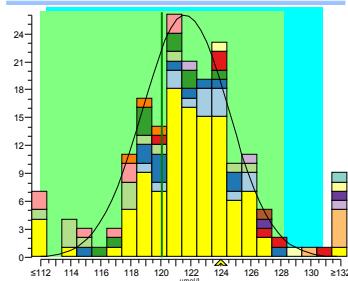
Kreatinine

eenheid : umol/L

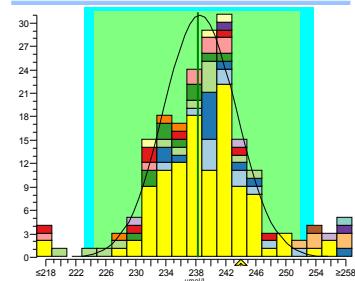


	2020.3	cumulatief
Juistheid	+2.3%	+2.6%
Precisie	1.1%	2.0%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	2.8	2.9
Sigma-SA	3.2	3.3
Scorepictogram		
Regressielijn	$0.0 + 1.027 \cdot x$	$0.0 + 1.027 \cdot x$
Consensusgroep	Enzymatisch	
Methode	Roche enzymatisch	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.001 \cdot x$	

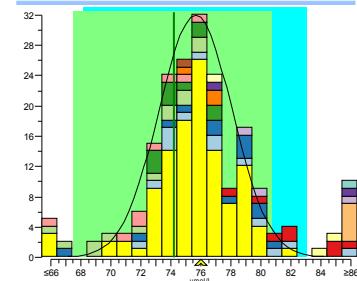
2020.3 A



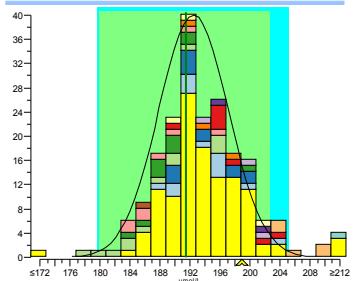
2020.3 B



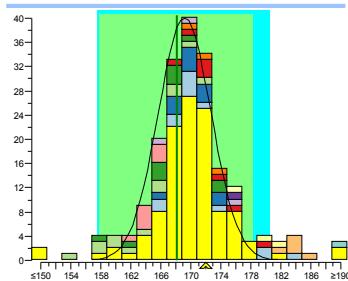
2020.3 C



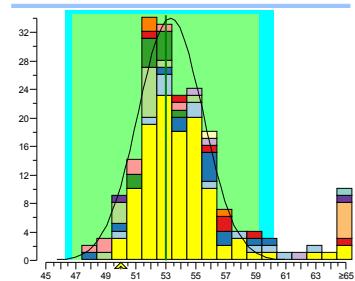
2020.3 D



2020.3 E



2020.3 F



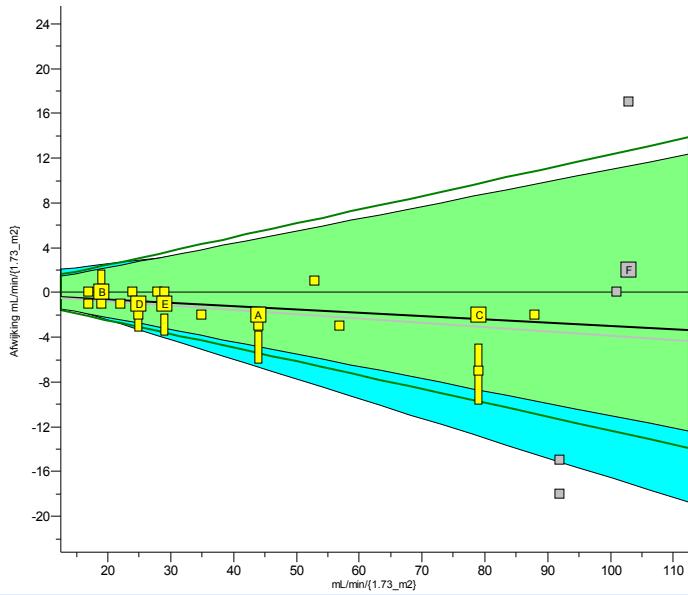
Legenda

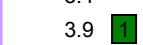
Roche enzymatisch	Siemens Dimension enzymatisch	Beckman Coulter AU enzymatisch	Siemens Atellica	Abbot enzymatisch
Siemens Advia enzymatisch	Beckman Coulter Dx C Jaffe	Abbott Jaffe	Beckman Coulter Dx C enzymatisch	Roche Jaffe
Beckman Coulter AU Jaffe	Siemens Advia Jaffe	Overige methoden	Overigen enzymatisch	Siemens Dimension Jaffe

Klinische Chemie, bloed 2020.3

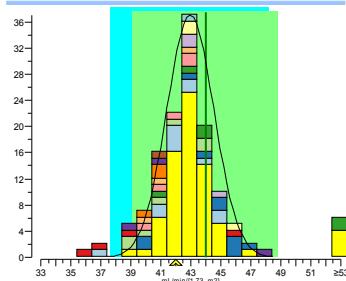
eGFR (V, 55, blank)

eenheid : mL/min/{1.73_m2}



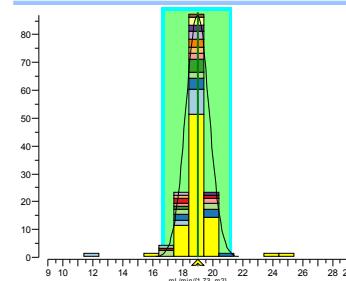
	2020.3	cumulatief
Juistheid	-3.1%	-3.7%
Precisie	1.5%	2.8%
Aantal	5	19
Uitbijters	0	0
Sigma-TE	3.7	3.4
Sigma-SA	4.2	3.9
Scorepictogram		
Regressielijn	$0.0 + 0.970 \cdot x$	$0.0 + 0.961 \cdot x$
Consensusgroep	CKD-EPI	
Methode	Roche CKD-EPI	
Analysator	Roche Cobas 8000	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.000 \cdot x$	

2020.3 A



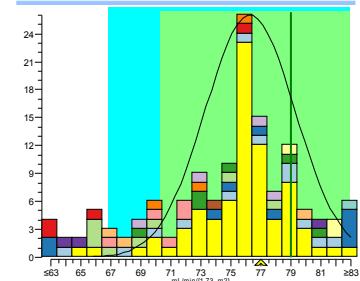
	cons.	meth.	ref.	lab
gem.	43.0	42.9	44	42
SD	1.6	1.3		
n	118	73		
nu	9	4		
rec.	98%	98%	95%	

2020.3 B



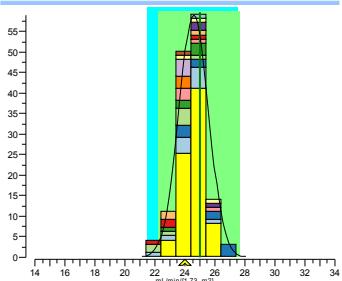
	cons.	meth.	ref.	lab
gem.	19.0	19.0	19	19
SD	0.8	0.6		
n	126	79		
nu	4	3		
rec.	100%	100%	100%	

2020.3 C



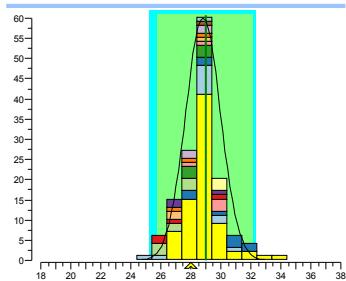
	cons.	meth.	ref.	lab
gem.	76.3	76.0	79	77
SD	3.0	2.5		
n	124	77		
nu	15	3		
rec.	101%	101%	97%	

2020.3 D



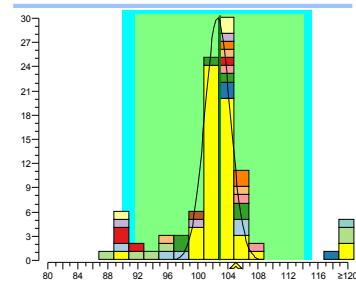
	cons.	meth.	ref.	lab
gem.	24.6	24.7	25	24
SD	1.0	0.7		
n	125	78		
nu	0	0		
rec.	98%	97%	96%	

2020.3 E



	cons.	meth.	ref.	lab
gem.	28.8	28.9	29	28
SD	1.2	1.0		
n	125	78		
nu	3	2		
rec.	97%	97%	97%	

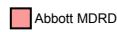
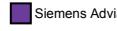
2020.3 F



	cons.	meth.	ref.	lab
gem.	102.6	102.5	103	105
SD	1.7	1.4		
n	85	55		
nu	21	4		
rec.	102%	102%	102%	

Uitgesloten

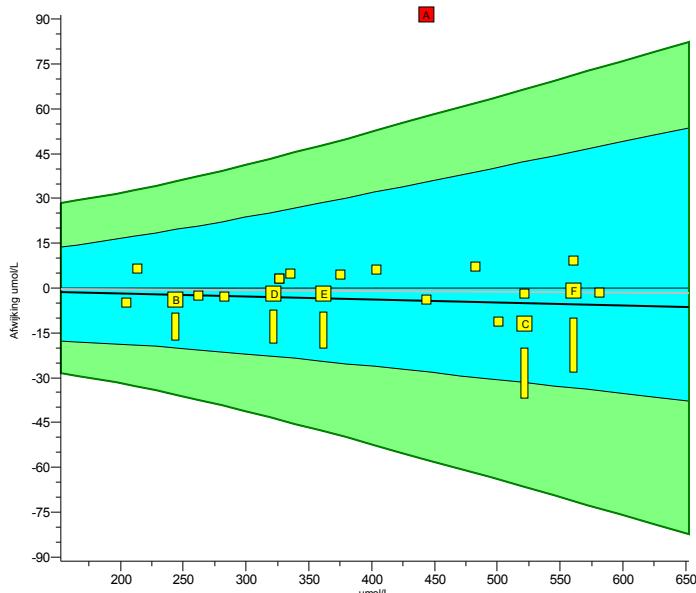
Legenda

 Roche CKD-EPI	 Siemens Dimension CKD-EPI	 Siemens Atelica CKD-EPI	 Beckman Coulter DxC CKD-EPI	 Beckman Coulter AU CKD-EPI
 Abbott MDRD	 Abbott CKD-EPI	 Roche MDRD	 Overigen MDRD	 Overigen CKD-EPI
 Siemens Advia 1800 MDRD	 Siemens Advia 1800 CKD-EPI		 Beckman Coulter AU MDRD	 Beckman Coulter DxC MDRD

Klinische Chemie, bloed 2020.3

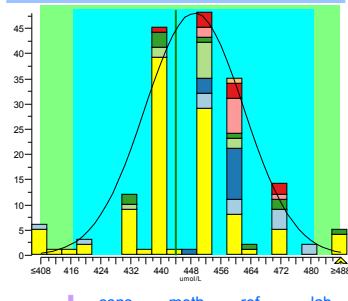
Uraat

eenheid : umol/L



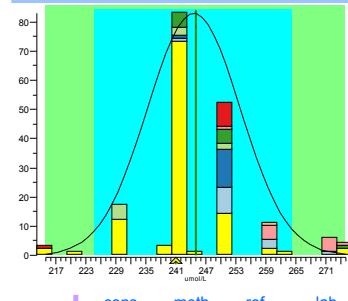
	2020.3	cumulatief
Juistheid	-1.0%	-0.27%
Precisie	1.1%	1.4%
Aantal	6	24
Uitbijters	1	1
Sigma-TE	6.0 [2]	6.0 [2]
Sigma-SA	4.1	4.9
Scorepictogram	[Green box]	[Green box]
Regressielijn	$0 + 0.990 \cdot x$	$0 + 0.998 \cdot x$
Consensusgroep	Uricase-colorimetrie en differentiële UV	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.000 \cdot x$	

2020.3 A



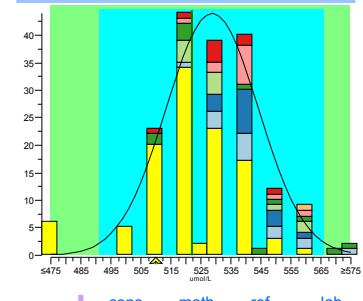
	cons.	meth.	ref.	lab
gem.	449	444	444449670	
SD	13	11		
n	176	106		
nu	11	9		
rec.	0160%	1164%	1277%	

2020.3 B



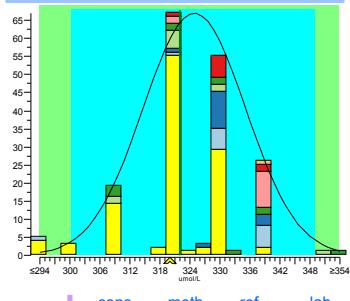
	cons.	meth.	ref.	lab
gem.	244	241	244	240
SD	9	6		
n	181	111		
nu	7	4		
rec.	99%	100%	98%	

2020.3 C



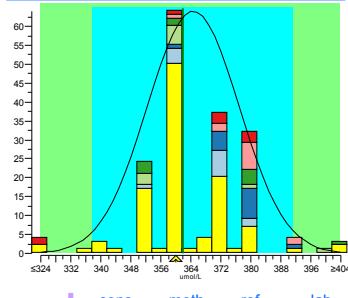
	cons.	meth.	ref.	lab
gem.	529	524	522	510
SD	15	12		
n	183	111		
nu	8	6		
rec.	96%	97%	98%	

2020.3 D



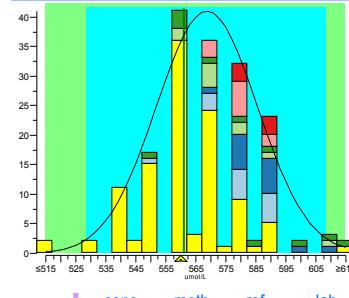
	cons.	meth.	ref.	lab
gem.	325	321	322	320
SD	10	8		
n	183	112		
nu	6	4		
rec.	98%	100%	99%	

2020.3 E



	cons.	meth.	ref.	lab
gem.	365	361	362	360
SD	12	10		
n	181	111		
nu	7	4		
rec.	99%	100%	99%	

2020.3 F



	cons.	meth.	ref.	lab
gem.	569	562	561	560
SD	17	13		
n	179	112		
nu	4	3		
rec.	98%	100%	100%	

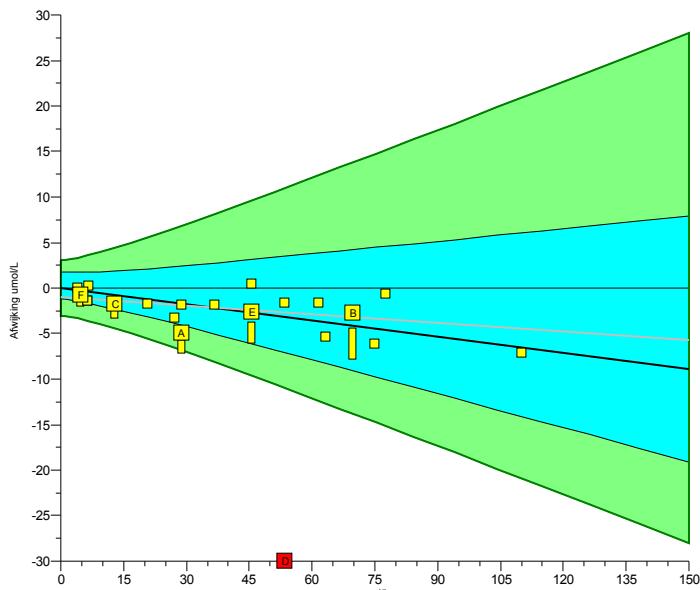
Legenda

Roche	Siemens Atellica	Abbott	Siemens Dimension	Beckman Coulter AU
Beckman Coulter DxC	Siemens Advia	Overige methoden		

Klinische Chemie, bloed 2020.3

Bilirubine

eenheid : umol/L



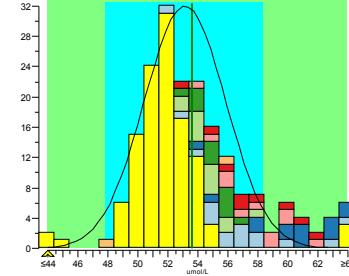
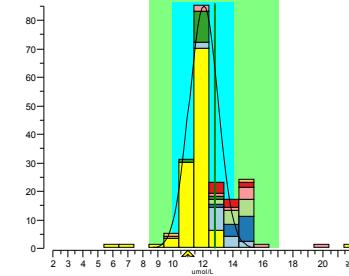
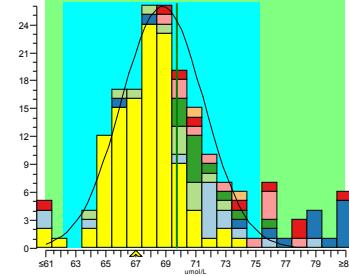
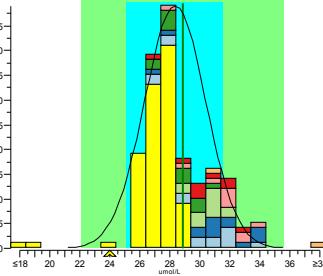
	2020.3	cumulatief
Juistheid	-7.8%	-6.0%
Precisie	5.2%	3.4%
Aantal	6	24
Uitbijters	1	1
Sigma-TE	5.1 [2]	6.0 [2]
Sigma-SA	1.1	2.5
Scorepictogram	[Colorimetrie alle reagentia]	[Colorimetrie alle reagentia]
Regressielijn	$0.0 + 0.941 \cdot x$	$-1.0 + 0.969 \cdot x$
Consensusgroep	Colorimetrie alle reagentia	Colorimetrie alle reagentia
Methode	Roche	Roche
Analysator	Roche cobas c702	Roche cobas c702
Uw factor	$0 + 1.000 \cdot x$	$0 + 1.002 \cdot x$
Methodefactor		

2020.3 A

2020.3 B

2020.3 C

2020.3 D



	cons.	meth.	ref.	lab
gem.	28.4	27.4	28.9	24
SD	2.0	0.9		
n	179	105		
nu	2	2		
rec.	85%	88%		83%

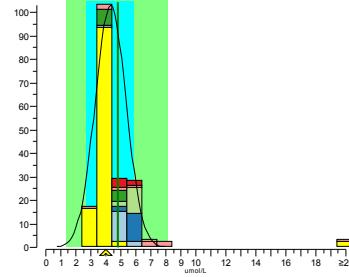
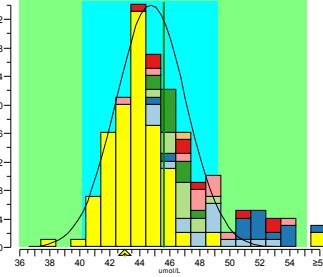
	cons.	meth.	ref.	lab
gem.	68.8	67.8	69.7	67
SD	2.7	2.0		
n	186	112		
nu	24	2		
rec.	97%	99%		96%

	cons.	meth.	ref.	lab
gem.	12.1	11.7	12.8	11
SD	1.0	0.6		
n	189	113		
nu	29	4		
rec.	91%	94%		86%

	cons.	meth.	ref.	lab
gem.	53.1	51.7	53.6	10
SD	2.7	1.6		
n	189	114		
nu	14	5		
rec.	19%	19%		19%

2020.3 E

2020.3 F



	cons.	meth.	ref.	lab
gem.	44.7	43.7	45.6	43
SD	2.3	1.7		
n	186	112		
nu	21	2		
rec.	96%	98%		94%

	cons.	meth.	ref.	lab
gem.	4.3	3.9	4.8	4
SD	1.0	0.4		
n	184	113		
nu	5	2		
rec.	93%	103%		83%

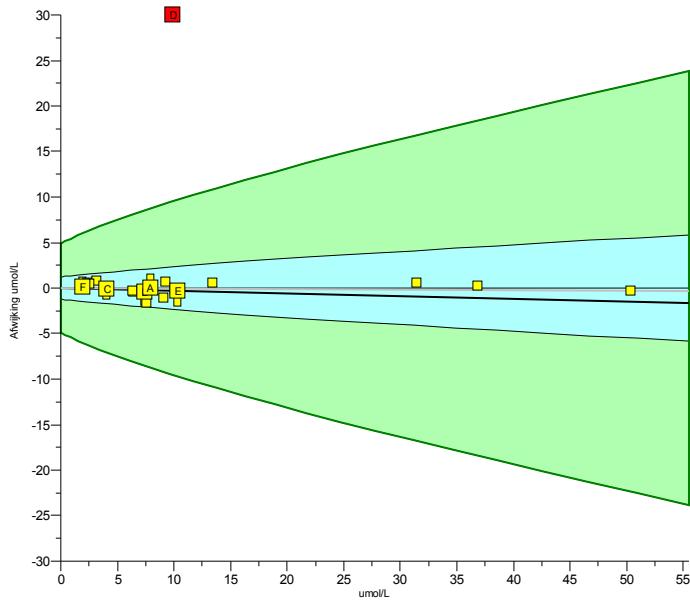
Legenda

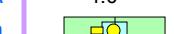
Roche	Abbott	Siemens Atellica	Beckman Coulter AU	Siemens Dimension
Beckman Coulter DxC	Siemens Advia	Overige methoden		

Klinische Chemie, bloed 2020.3

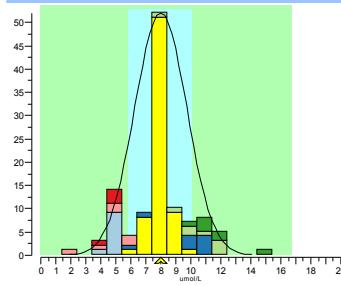
Bilirubine direct

eenheid : umol/L

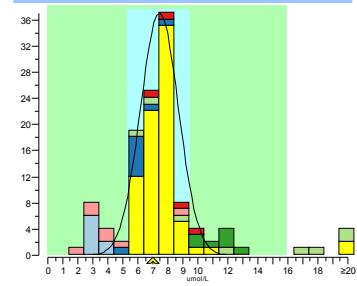


	2020.3	cumulatief
Juistheid	-2.4%	-1.1%
Precisie	2.7%	6.3%
Aantal	6	24
Uitbijters	1	1
Sigma-TE	6.0	6.0
Sigma-SA	4.0	4.6
Scorepictogram		
Regressielijn	$0.0 + 0.971 \cdot x$	$0.0 + 0.994 \cdot x$
Consensusgroep	Colorimetrie alle reagentia	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.001 \cdot x$	

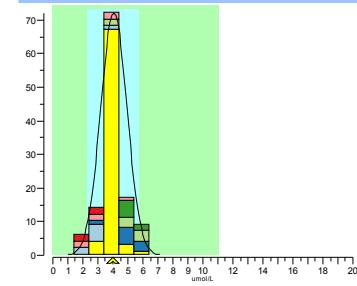
2020.3 A



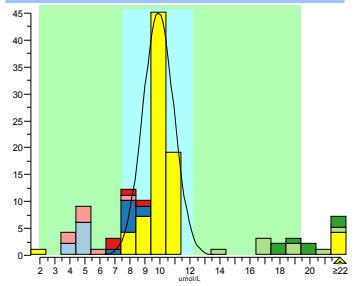
2020.3 B



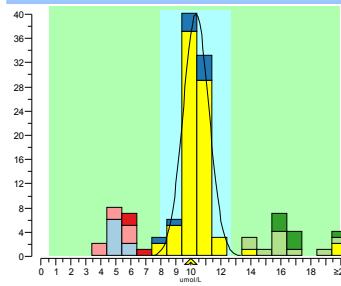
2020.3 C



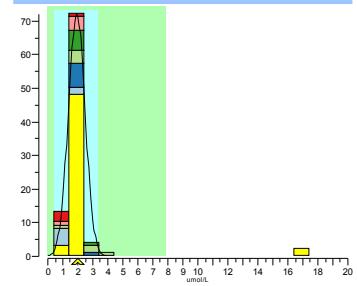
2020.3 D



2020.3 E



2020.3 F



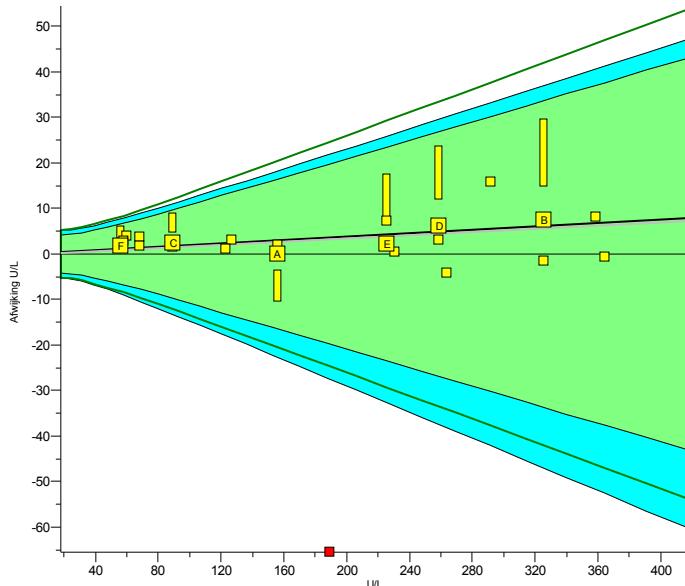
Legenda

Roche	Siemens Dimension	Abbott	Siemens Advia
Beckman Coulter DxC	Beckman Coulter AU		Siemens Atellica

Klinische Chemie, bloed 2020.3

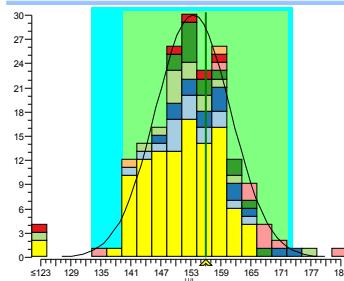
Alk. Fosfatase

eenheid : U/L

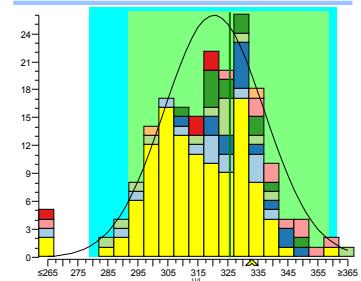


	2020.3	cumulatief
Juistheid	+1.8%	+1.9%
Precisie	1.0%	1.9%
Aantal	6	24
Uitbijters	0	1
Sigma-TE	5.6	5.0
Sigma-SA	6.0 [2]	6.0 [2]
Scorepictogram		
Regressielijn	0 + 1.019.x	0 + 1.017.x
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c501, c502	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.027.x	

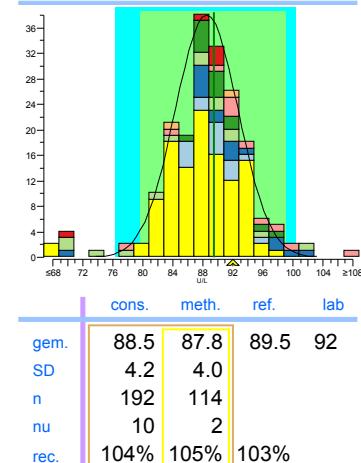
2020.3 A



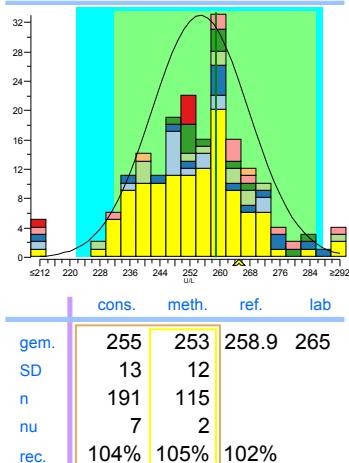
2020.3 B



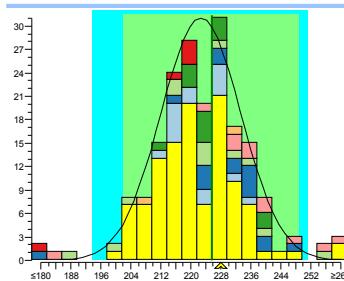
2020.3 C



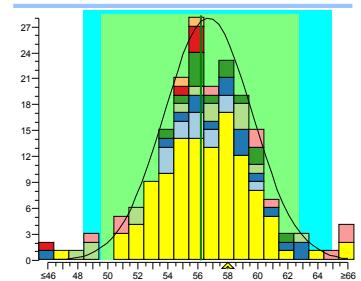
2020.3 D



2020.3 E



2020.3 F



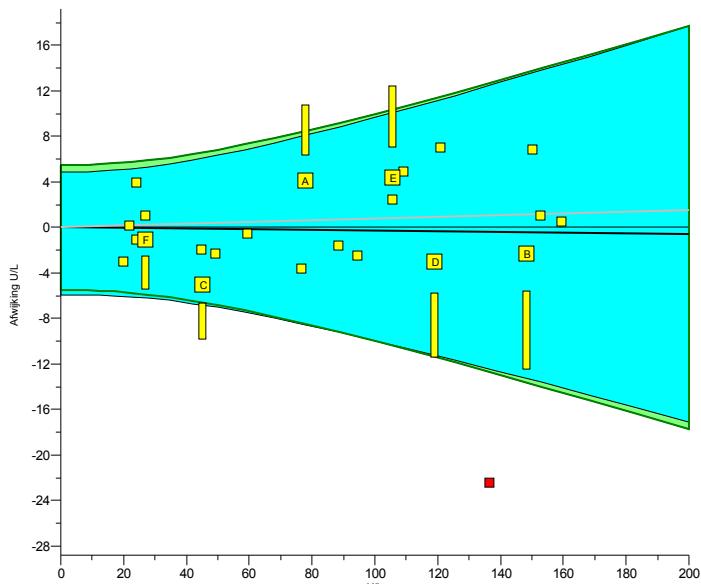
Legenda

Roche IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Abbott IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar	Siemens Dimension IFCC traceerbaar
Beckman Coulter DxC IFCC traceerbaar	Siemens Atellica IFCC traceerbaar	Overigen IFCC traceerbaar		

Klinische Chemie, bloed 2020.3

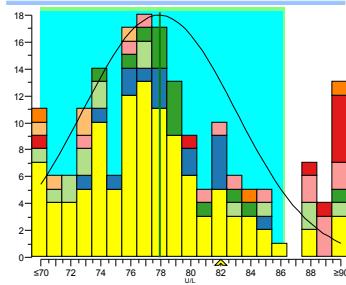
ASAT

eenheid : U/L



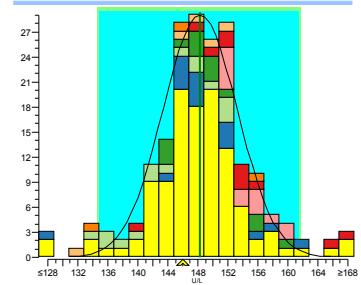
	2020.3	cumulatief
Juistheid	-0.62%	+0.35%
Precisie	4.5%	4.2%
Aantal	6	24
Uitbijters	0	1
Sigma-TE	3.8	3.8
Sigma-SA	3.7	3.7
Scorepictogram		
Regressielijn	0.0 + 0.997.x	0.0 + 1.008.x
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c702	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 0.999.x	

2020.3 A



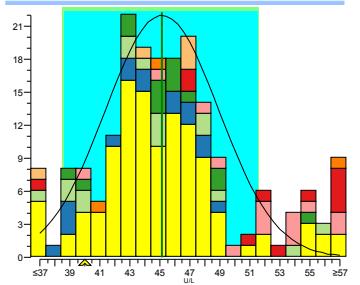
	cons.	meth.	exp.	lab
gem.	77.9	77.3	77.9	82
SD	5.1	4.4		
n	184	108		
nu	8	5		
rec.	105%	106%	105%	

2020.3 B



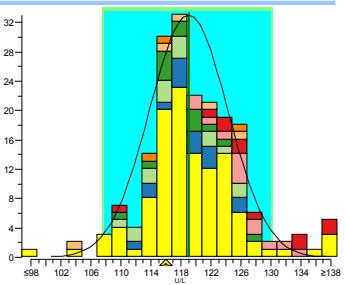
	cons.	meth.	exp.	lab
gem.	148.3	147.7	148.3	146
SD	5.0	4.7		
n	190	113		
nu	10	6		
rec.	98%	99%	98%	

2020.3 C



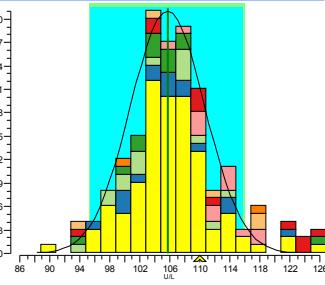
	cons.	meth.	exp.	lab
gem.	45.1	45.0	45.1	40
SD	3.8	3.7		
n	193	114		
nu	11	4		
rec.	89%	89%	89%	

2020.3 D



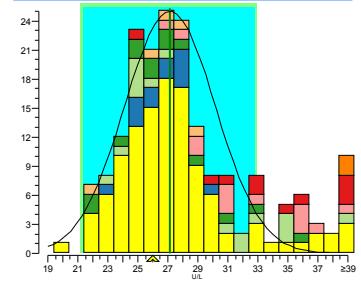
	cons.	meth.	exp.	lab
gem.	119.0	118.6	119.0	116
SD	5.2	4.6		
n	193	115		
nu	8	6		
rec.	97%	98%	97%	

2020.3 E



	cons.	meth.	exp.	lab
gem.	105.7	105.5	105.7	110
SD	5.0	4.4		
n	189	113		
nu	10	4		
rec.	104%	104%	104%	

2020.3 F



	cons.	meth.	exp.	lab
gem.	27.1	26.8	27.1	26
SD	3.0	2.8		
n	187	114		
nu	15	7		
rec.	96%	97%	96%	

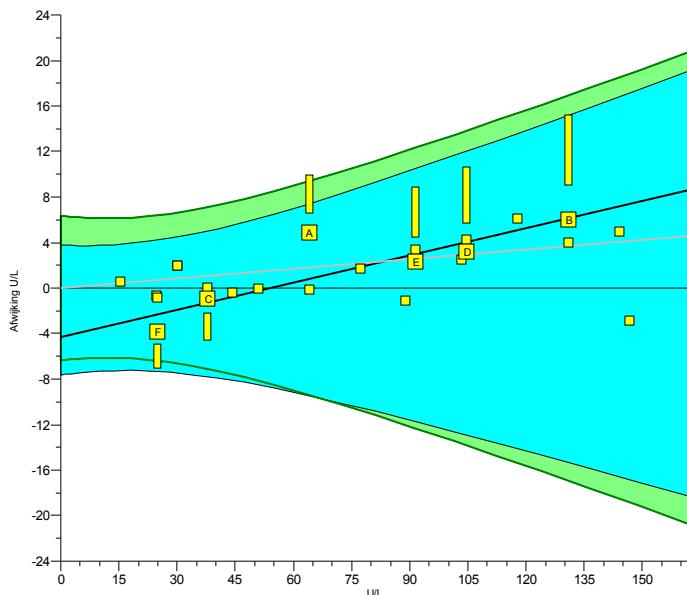
Legenda

Roche IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Abbott IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar	Siemens Dimension IFCC traceerbaar
Beckman Coulter DxC IFCC traceerbaar	Siemens Atellica IFCC traceerbaar	Overigen IFCC traceerbaar		

Klinische Chemie, bloed 2020.3

ALAT

eenheid : U/L



	2020.3	cumulatief
Juistheid	+2.2%	+2.3%
Precisie	2.2%	2.2%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	5.5 [2]	6.0 [2]
Sigma-SA	4.8	5.7
Scorepictogram	[Color-coded histogram]	[Color-coded histogram]
Regressielijn	$-4.3 + 1.080 \cdot x$	$0.0 + 1.028 \cdot x$
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.006 \cdot x$	

2020.3 A

2020.3 B

2020.3 C

2020.3 D

cons. meth. ref. lab

cons. meth. ref. lab

cons. meth. ref. lab

cons. meth. ref. lab

	gem.	SD	n	nu	rec.
cons.	63.2	3.9	187	14	109%
meth.	63.0	3.6	109	4	110%
ref.	64.2				107%
lab	69				

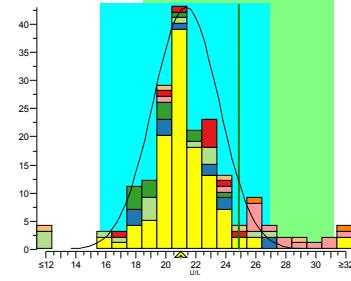
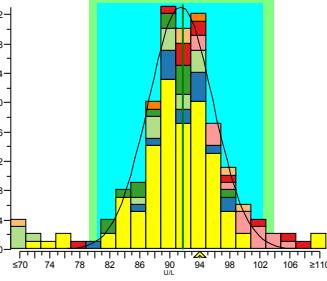
	gem.	SD	n	nu	rec.
cons.	131	6	193	16	104%
meth.	130	6	114	10	106%
ref.	131.0				105%
lab	137				

	gem.	SD	n	nu	rec.
cons.	35.6	2.3	196	25	104%
meth.	35.4	2.1	115	3	105%
ref.	38.0				97%
lab	37				

	gem.	SD	n	nu	rec.
cons.	104.3	4.9	196	13	104%
meth.	103.2	4.7	116	7	105%
ref.	104.8				103%
lab	108				

2020.3 E

2020.3 F



	cons.	meth.	ref.	lab
gem.	91.5	90.9	91.7	94
SD	4.3	3.9		
n	192	114		
nu	15	6		
rec.	103%	103%	103%	

	cons.	meth.	ref.	lab
gem.	21.3	21.2	24.9	21
SD	2.2	1.8		
n	190	115		
nu	15	2		
rec.	98%	99%	84%	

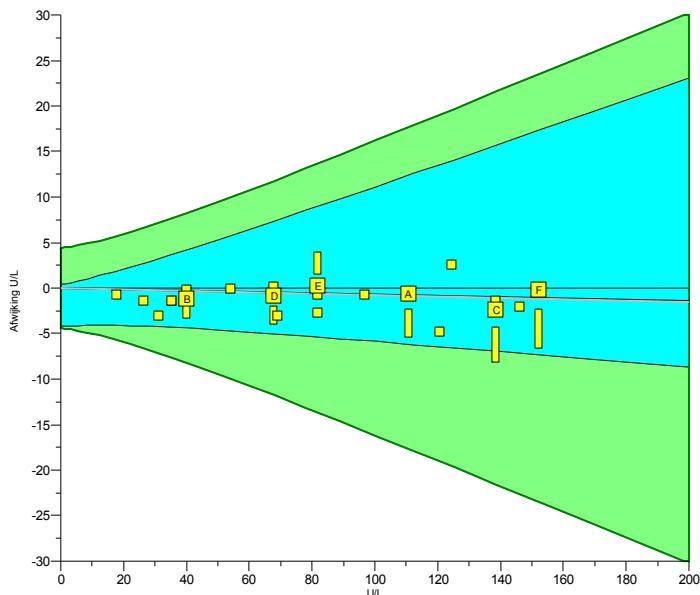
Legenda

Roche IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Abbott IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar	Siemens Dimension IFCC traceerbaar
Beckman Coulter DxC IFCC traceerbaar	Siemens Atellica IFCC traceerbaar	Overigen IFCC traceerbaar		

Klinische Chemie, bloed 2020.3

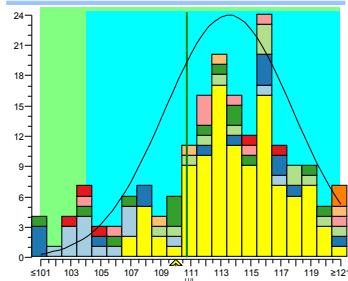
Gamma-GT

eenheid : U/L



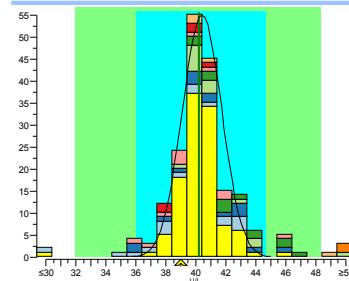
	2020.3	cumulatief
Juistheid	-0.83%	-1.0%
Precisie	1.2%	1.2%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	6.0 [2]	6.0 [2]
Sigma-SA	6.0	6.0
Scorepictogram	[Green box]	[Green box]
Regressielijn	$0.0 + 0.993.x$	$0.0 + 0.992.x$
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000.x$	
Methodefactor	$0 + 1.001.x$	

2020.3 A



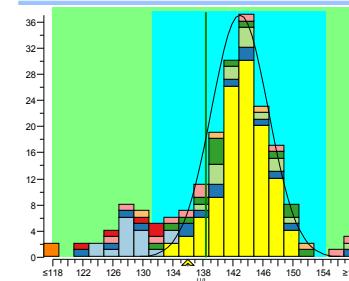
	cons.	meth.	ref.	lab
gem.	113.5	114.3	110.7	110
SD	4.3	3.3		
n	183	106		
nu	5	0		
rec.	97%	96%	99%	

2020.3 B



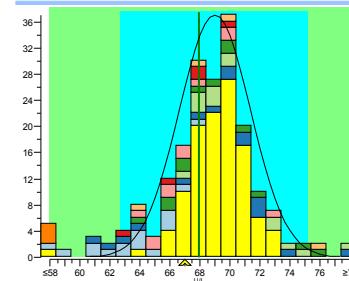
	cons.	meth.	ref.	lab
gem.	40.4	40.4	40.2	39
SD	1.3	1.2		
n	189	111		
nu	15	2		
rec.	97%	97%	97%	

2020.3 C



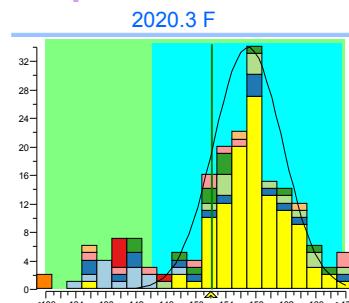
	cons.	meth.	ref.	lab
gem.	142.9	143.1	138.4	136
SD	3.8	3.3		
n	192	112		
nu	34	0		
rec.	95%	95%	98%	

2020.3 D



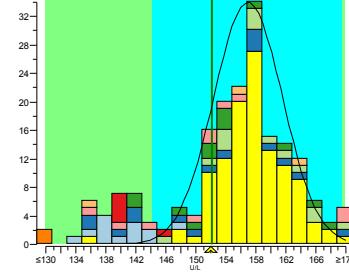
	cons.	meth.	ref.	lab
gem.	69.0	69.3	67.9	67
SD	2.4	1.7		
n	191	112		
nu	8	1		
rec.	97%	97%	99%	

2020.3 E



	cons.	meth.	ref.	lab
gem.	83.3	84.1	81.8	82
SD	3.5	2.3		
n	188	111		
nu	4	0		
rec.	98%	98%	100%	

2020.3 F



	cons.	meth.	ref.	lab
gem.	157.0	157.4	152.2	152
SD	4.6	4.0		
n	186	112		
nu	35	2		
rec.	97%	97%	100%	

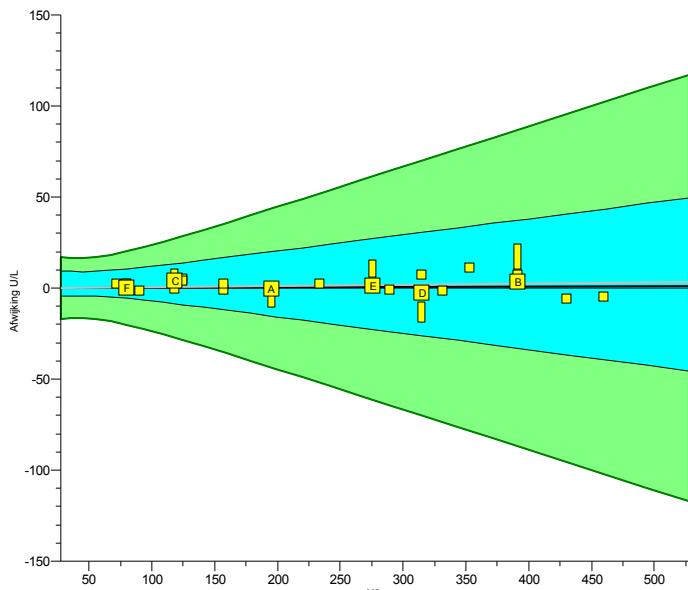
Legenda

Roche IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Abbott IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar	Siemens Dimension IFCC traceerbaar
Beckman Coulter DxC IFCC traceerbaar	Siemens Atelica IFCC traceerbaar	Overigen IFCC traceerbaar	Roche niet-IFCC traceerbaar	

Klinische Chemie, bloed 2020.3

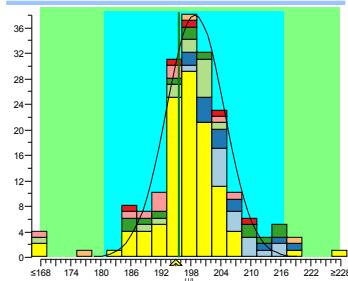
CK

eenheid : U/L



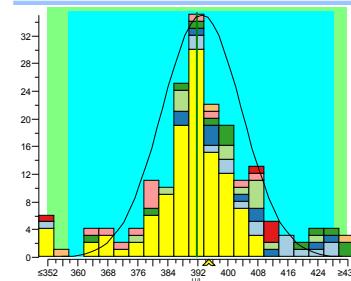
	2020.3	cumulatief
Juistheid	+0.33%	+0.73%
Precisie	1.3%	1.5%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	6.0 [2]	6.0 [2]
Sigma-SA	6.0	6.0
Scorepictogram	[Green Box]	[Green Box]
Regressielijn	$0 + 1.003 \cdot x$	$0 + 1.006 \cdot x$
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 0.996 \cdot x$	

2020.3 A



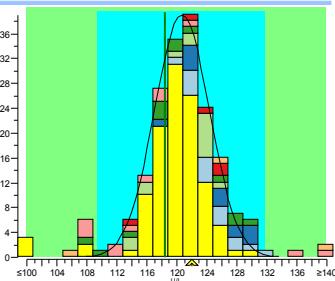
	cons.	meth.	ref.	lab
gem.	199	198	195.5	195
SD	6	5		
n	183	108		
nu	11	4		
rec.	98%	99%	100%	

2020.3 B



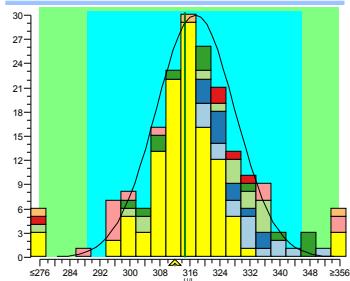
	cons.	meth.	ref.	lab
gem.	393	390	391.7	395
SD	11	9		
n	188	113		
nu	15	4		
rec.	100%	101%	101%	

2020.3 C



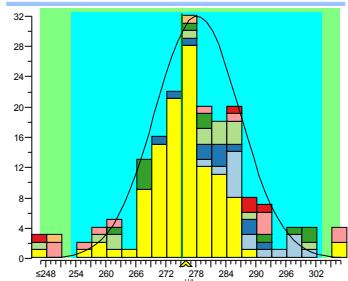
	cons.	meth.	ref.	lab
gem.	120.7	120.1	118.4	122
SD	3.7	2.8		
n	190	113		
nu	15	5		
rec.	101%	102%	103%	

2020.3 D



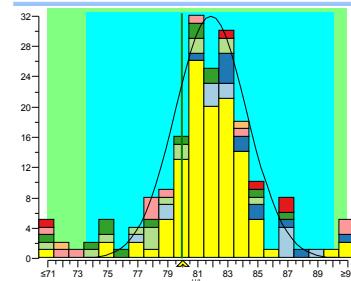
	cons.	meth.	ref.	lab
gem.	317	315	314.6	312
SD	11	7		
n	190	114		
nu	14	6		
rec.	98%	99%	99%	

2020.3 E



	cons.	meth.	ref.	lab
gem.	279	277	276.1	277
SD	8	6		
n	187	113		
nu	10	3		
rec.	99%	100%	100%	

2020.3 F



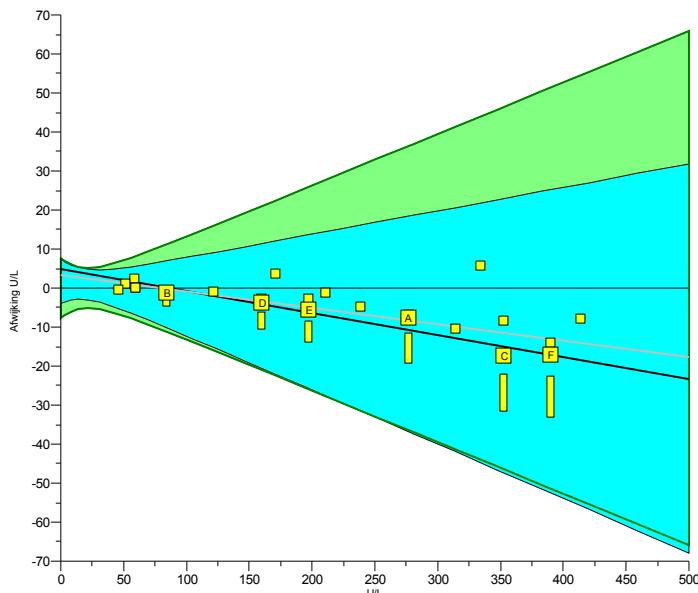
	cons.	meth.	ref.	lab
gem.	81.9	81.8	79.9	80
SD	2.4	2.0		
n	185	114		
nu	16	4		
rec.	98%	98%	100%	

Legenda

Roche IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Siemens Dimension IFCC traceerbaar	Abbott IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar
Beckman Coulter Dx/C IFCC traceerbaar	Siemens Atelica IFCC traceerbaar	Overigen IFCC traceerbaar		

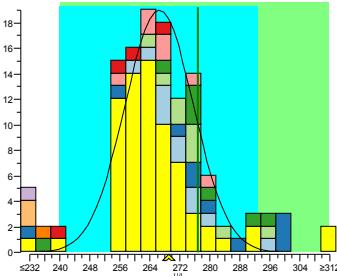
Klinische Chemie, bloed 2020.3

Amylase eenheid : U/L



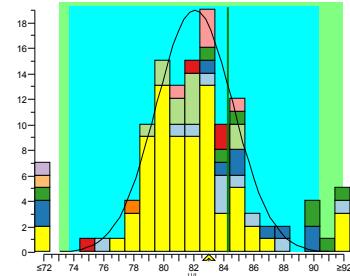
	2020.3	cumulatief
Juistheid	-3.7%	-2.6%
Precisie	0.91%	1.2%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	6.0 [2]	6.0 [2]
Sigma-SA	6.0	6.0
Scorepictogram	[Scorepictogram image]	[Scorepictogram image]
Regressielijn	$5 + 0.943 \cdot x$	$3 + 0.958 \cdot x$
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.002 \cdot x$	

2020.3 A



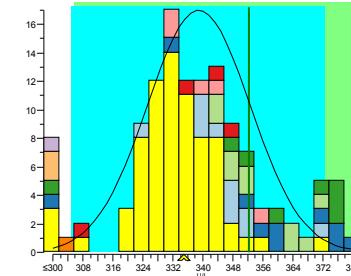
	cons.	meth.	ref.	lab
gem.	267	265	276.8	269
SD	9	8		
n	119	70		
nu	12	4		
rec.	101%	102%	97%	

2020.3 B



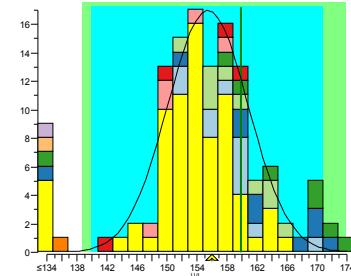
	cons.	meth.	ref.	lab
gem.	82.1	81.5	84.3	83
SD	2.6	2.2		
n	122	73		
nu	15	5		
rec.	101%	102%	98%	

2020.3 C



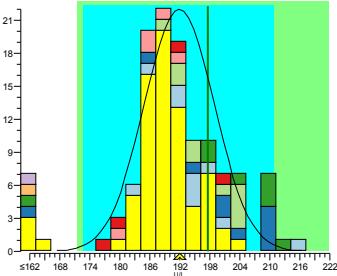
	cons.	meth.	ref.	lab
gem.	339	334	352.4	335
SD	14	10		
n	121	73		
nu	5	3		
rec.	99%	100%	95%	

2020.3 D



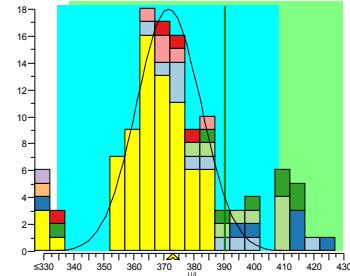
	cons.	meth.	ref.	lab
gem.	155	154	159.9	156
SD	5	4		
n	122	74		
nu	10	5		
rec.	100%	101%	98%	

2020.3 E



	cons.	meth.	ref.	lab
gem.	192	190	197.7	192
SD	7	5		
n	120	73		
nu	7	4		
rec.	100%	101%	97%	

2020.3 F



	cons.	meth.	ref.	lab
gem.	372	369	390.2	373
SD	11	9		
n	116	72		
nu	22	4		
rec.	100%	101%	96%	

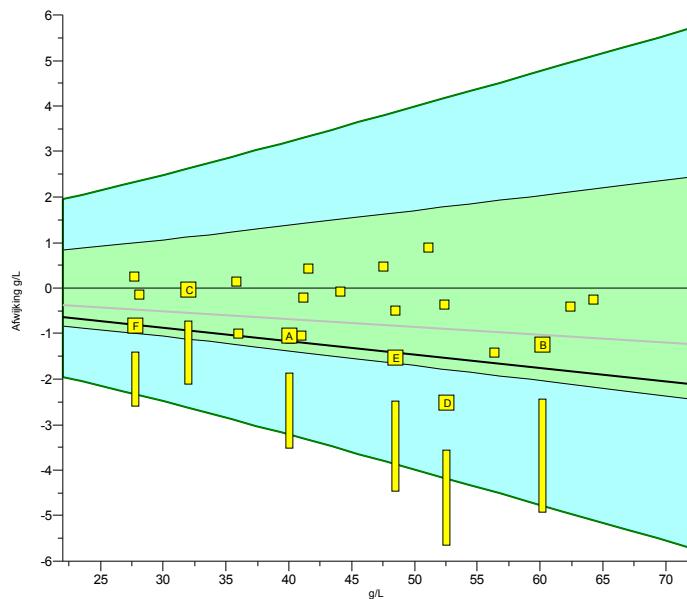
Legenda

Roche IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Beckman Coulter DxC IFCC traceerbaar	Siemens Atellica IFCC traceerbaar
Siemens Dimension IFCC traceerbaar	Abbott IFCC traceerbaar	Siemens Dimension niet-IFCC traceerbaar	Overigen niet-IFCC traceerbaar	Beckman Coulter DxC niet-IFCC traceerbaar

Klinische Chemie, bloed 2020.3

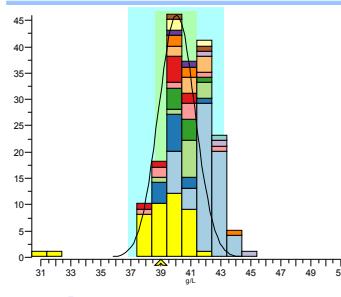
Albumine

eenheid : g/L



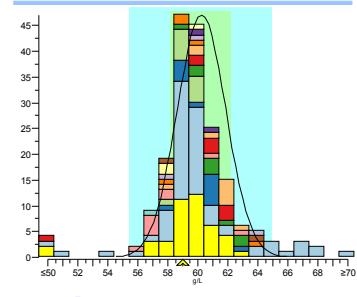
	2020.3	cumulatief
Juistheid	-2.8%	-1.7%
Precisie	1.5%	1.7%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	1.3	1.9
Sigma-SA	3.9	4.6
Scorepictogram	1	2
Regressielijn	$0.0 + 0.971 \cdot x$	$0.0 + 0.983 \cdot x$
Consensusgroep	Broomkresolpurper	
Methode	Roche Broomkresolpurper	
Analysier	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.000 \cdot x$	

2020.3 A



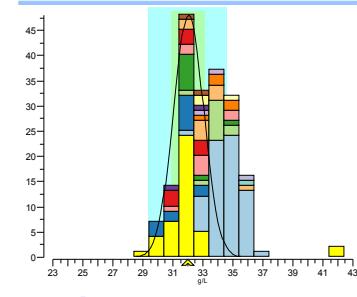
	cons.	meth.	ALTM	lab
gem.	40.1	39.6	41.0	39
SD	1.2	1.1	1.6	
n	86	42	183	
nu	2	2	2	
rec.	97%	98%	95%	

2020.3 B



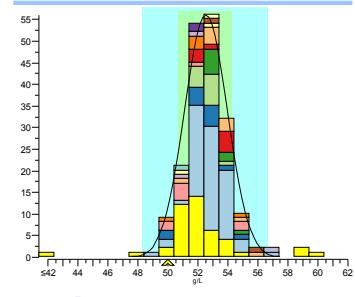
	cons.	meth.	ALTM	lab
gem.	60.2	59.8	59.8	59
SD	1.6	1.4	1.6	
n	87	42	189	
nu	3	2	16	
rec.	98%	99%	99%	

2020.3 C



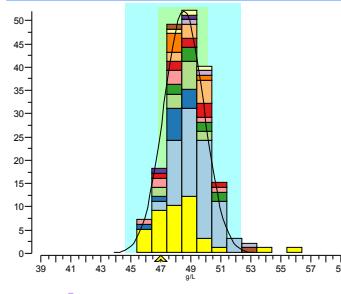
	cons.	meth.	ALTM	lab
gem.	32.1	31.8	33.3	32
SD	1.0	0.8	1.8	
n	89	43	191	
nu	4	3	2	
rec.	100%	101%	96%	

2020.3 D



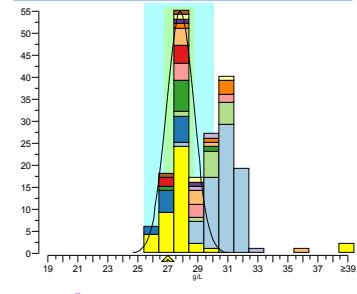
	cons.	meth.	ALTM	lab
gem.	52.5	52.0	52.6	50
SD	1.4	1.2	1.3	
n	89	44	192	
nu	5	5	7	
rec.	95%	96%	95%	

2020.3 E



	cons.	meth.	ALTM	lab
gem.	48.5	48.0	48.9	47
SD	1.3	1.3	1.4	
n	87	42	188	
nu	2	2	2	
rec.	97%	98%	96%	

2020.3 F



	cons.	meth.	ALTM	lab
gem.	27.8	27.7	29.3	27
SD	0.9	0.8	2.1	
n	83	42	186	
nu	3	2	3	
rec.	97%	98%	92%	

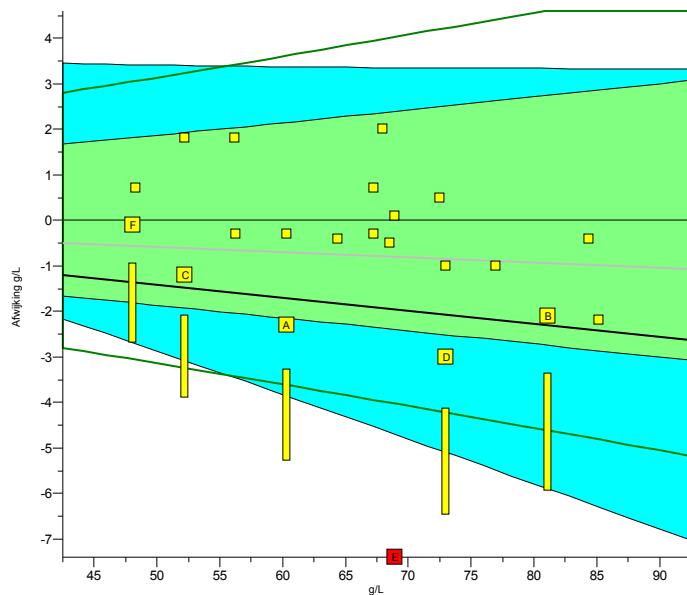
Legenda

Roche Broomkresolpurper	Roche Broomkresolgroen	Siemens Dimension Broomkresolpurper	Abbott Broomkresolgroen	Siemens Atellica Broomkresolpurper
Beckman Coulter AU Broomkresolgroen	Beckman Coulter Dx C Broomkresolpurper	Beckman Coulter Dx C Broomkresolpurper	Beckman Coulter AU Broomkresolgroen	Beckman Coulter AU Broomkresolpurper
Beckman Coulter Dx Immunochemisch	Abbott Broomkresolpurper	Roche Immunochemisch	Overige methoden	Overigen Broomkresolgroen
Beckman Coulter Dx/C Broomkresolgroen				

Klinische Chemie, bloed 2020.3

Totaal Eiwit

eenheid : g/L



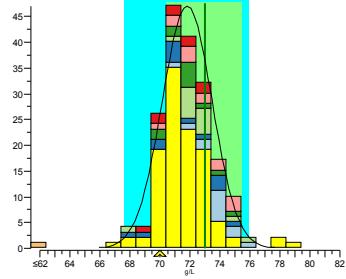
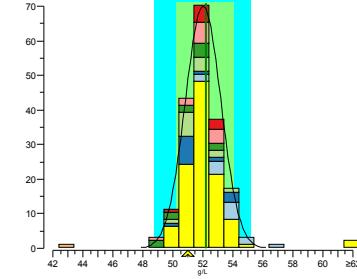
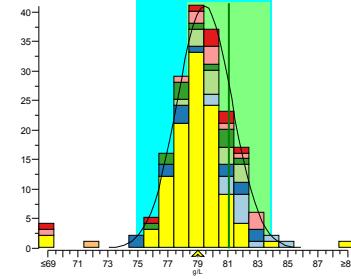
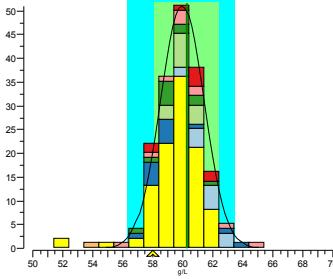
	2020.3	cumulatief
Juistheid	-2.7%	-1.0%
Precisie	1.3%	1.5%
Aantal	6	24
Uitbijters	1	1
Sigma-TE	0.7	2.0
Sigma-SA	2.2	3.7
Scorepictogram		
Regressielijn	$0.0 + 0.972 \cdot x$	$0.0 + 0.988 \cdot x$
Consensusgroep	Biureet	
Methode	Roche	
Analysator	Roche cobas c501, c502	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.001 \cdot x$	

2020.3 A

2020.3 B

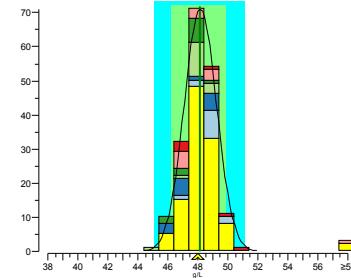
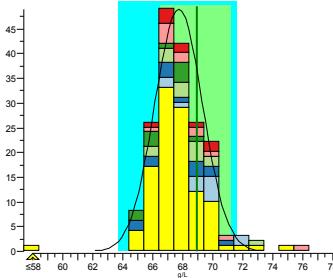
2020.3 C

2020.3 D



2020.3 E

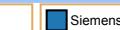
2020.3 F



	cons.	meth.	ref.	lab
gem.	60.0	59.8	60.3	58
SD	1.5	1.2		
n	178	105		
nu	4	3		
rec.	97%	97%	96%	

	cons.	meth.	ref.	lab
gem.	79.4	79.1	81.1	79
SD	1.8	1.4		
n	184	110		
nu	6	3		
rec.	99%	100%	97%	

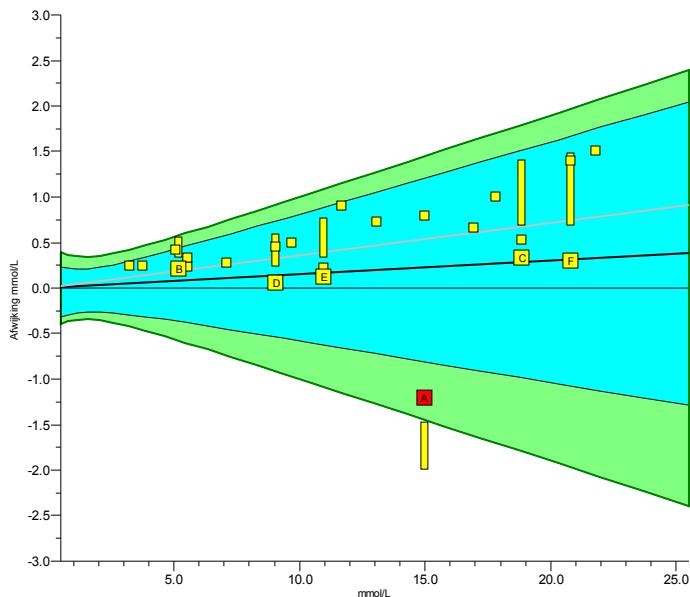
Legenda

 Roche	 Siemens Dimension	 Siemens Atellica	 Abbott	 Beckman Coulter AU
 Beckman Coulter DxC	 Siemens Advia	 Overige methoden		

Klinische Chemie, bloed 2020.3

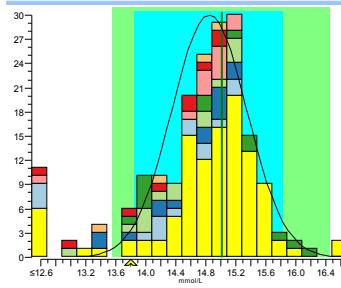
Glucose

eenheid : mmol/L



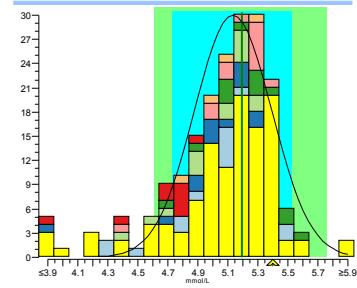
	2020.3	cumulatief
Juistheid	+1.5%	+3.6%
Precisie	1.2%	2.2%
Aantal	6	24
Uitbijters	1	1
Sigma-TE	5.3 [2]	4.2 [1]
Sigma-SA	3.4	2.3
Scorepictogram	[Color-coded box]	[Color-coded box]
Regressielijn	$0.00 + 1.015 \cdot x$	$0.00 + 1.036 \cdot x$
Consensusgroep	Hexokinase, Glucoseoxidase en Glucosedehydrogena	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0.0 + 1.000 \cdot x$	
Methodefactor	$0.0 + 0.998 \cdot x$	

2020.3 A



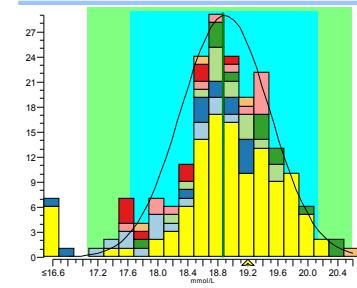
	cons.	meth.	ref.	lab
gem.	14.85	14.94	15.01	13.8
SD	0.50	0.47		
n	185	109		
nu	16	9		
rec.	93%	92%	92%	

2020.3 B



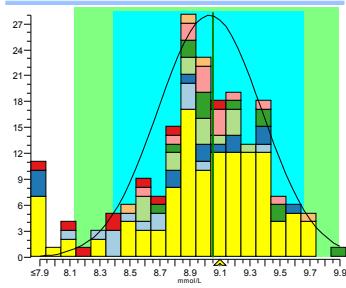
	cons.	meth.	ref.	lab
gem.	5.13	5.14	5.19	5.4
SD	0.26	0.25		
n	190	114		
nu	13	9		
rec.	105%	105%	104%	

2020.3 C



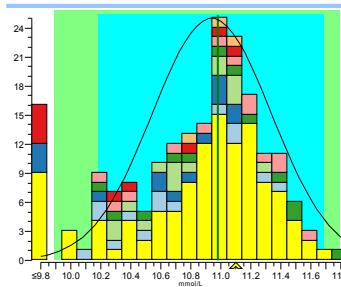
	cons.	meth.	ref.	lab
gem.	18.90	19.02	18.87	19.2
SD	0.59	0.55		
n	194	115		
nu	8	6		
rec.	102%	101%	102%	

2020.3 D



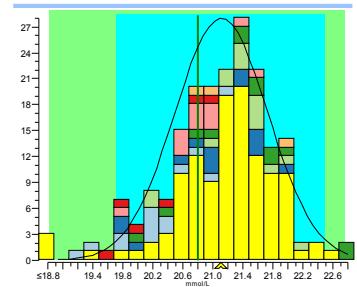
	cons.	meth.	ref.	lab
gem.	9.03	9.07	9.05	9.1
SD	0.35	0.35		
n	196	118		
nu	11	7		
rec.	101%	100%	101%	

2020.3 E



	cons.	meth.	ref.	lab
gem.	10.94	10.97	10.98	11.1
SD	0.40	0.37		
n	193	116		
nu	15	9		
rec.	101%	101%	101%	

2020.3 F



	cons.	meth.	ref.	lab
gem.	21.11	21.20	20.8	21.1
SD	0.62	0.55		
n	191	117		
nu	4	3		
rec.	100%	100%	101%	

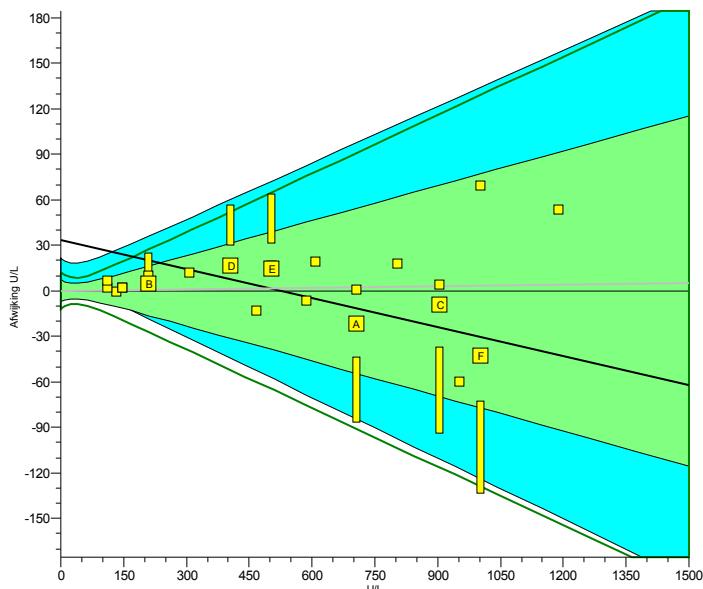
Legenda

 Roche	 Siemens Dimension	 Siemens Atellica	 Abbott	 Beckman Coulter AU
 Beckman Coulter DxC	 Siemens Advia	 Overige methoden		

Klinische Chemie, bloed 2020.3

LD

eenheid : U/L



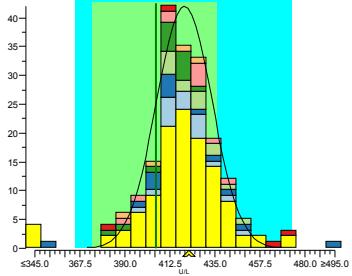
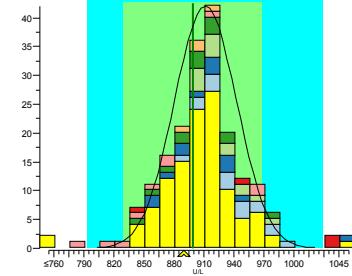
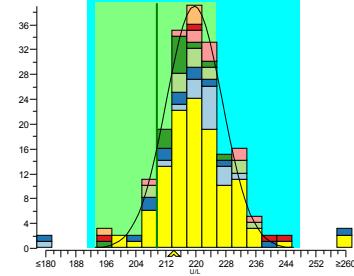
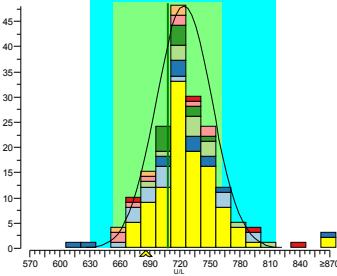
	2020.3	cumulatief
Juistheid	-1.1%	+0.70%
Precisie	2.7%	4.6%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	2.7	2.7
Sigma-SA	4.7	4.7
Scorepictogram		
Regressielijn	$34 + 0.936 \cdot x$	$0 + 1.003 \cdot x$
Consensusgroep	IFCC traceerbaar	
Methode	Roche IFCC traceerbaar	
Analysator	Roche cobas c702	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 0.987 \cdot x$	

2020.3 A

2020.3 B

2020.3 C

2020.3 D



	cons.	meth.	ref.	lab
gem.	724	727	708.2	686
SD	28	26		
n	183	109		
nu	6	2		
rec.	95%	94%	97%	

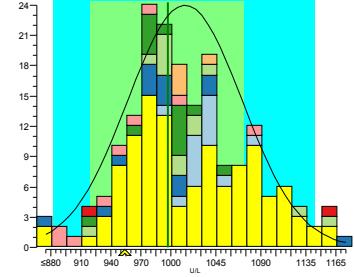
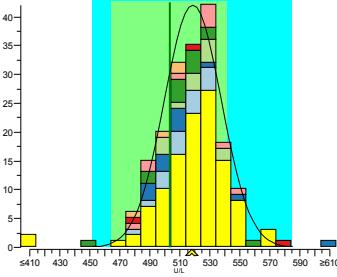
	cons.	meth.	ref.	lab
gem.	220	220	209.5	214
SD	8	8		
n	189	114		
nu	9	3		
rec.	97%	97%	102%	

	cons.	meth.	ref.	lab
gem.	917	912	904.1	895
SD	31	30		
n	192	115		
nu	8	3		
rec.	98%	98%	99%	

	cons.	meth.	ref.	lab
gem.	420	421	405.4	422
SD	14	14		
n	192	116		
nu	10	6		
rec.	101%	100%	104%	

2020.3 E

2020.3 F



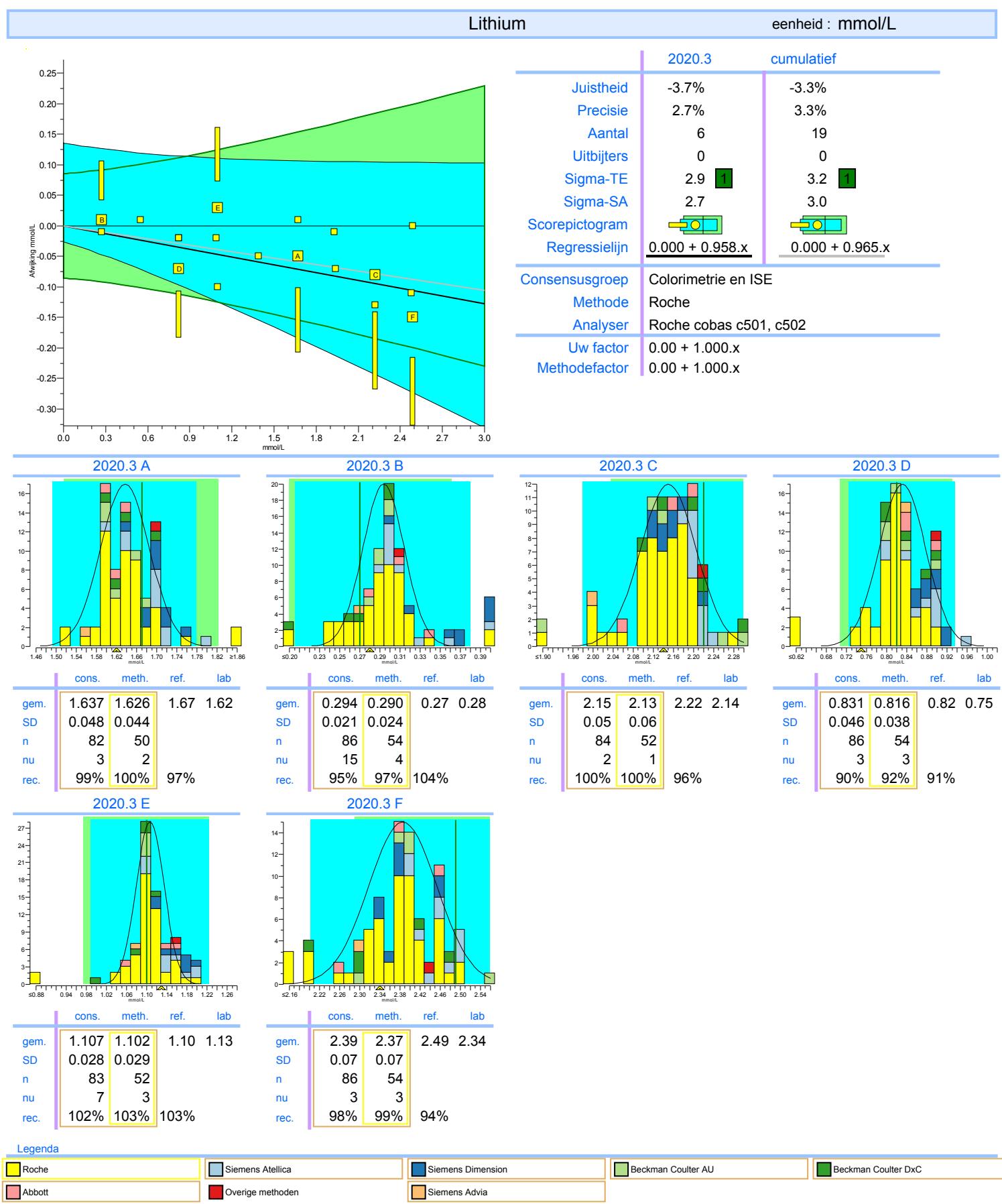
	cons.	meth.	ref.	lab
gem.	519	522	503.4	518
SD	19	18		
n	188	114		
nu	5	2		
rec.	100%	99%	103%	

	cons.	meth.	ref.	lab
gem.	1019	1033	1002.0	959
SD	57	60		
n	185	115		
nu	3	2		
rec.	94%	93%	96%	

Legenda

Roche IFCC traceerbaar	Siemens Advia IFCC traceerbaar	Beckman Coulter AU IFCC traceerbaar	Siemens Dimension IFCC traceerbaar	Abbott IFCC traceerbaar
Beckman Coulter DxC IFCC traceerbaar	Overigen IFCC traceerbaar	Siemens Atellica IFCC traceerbaar		

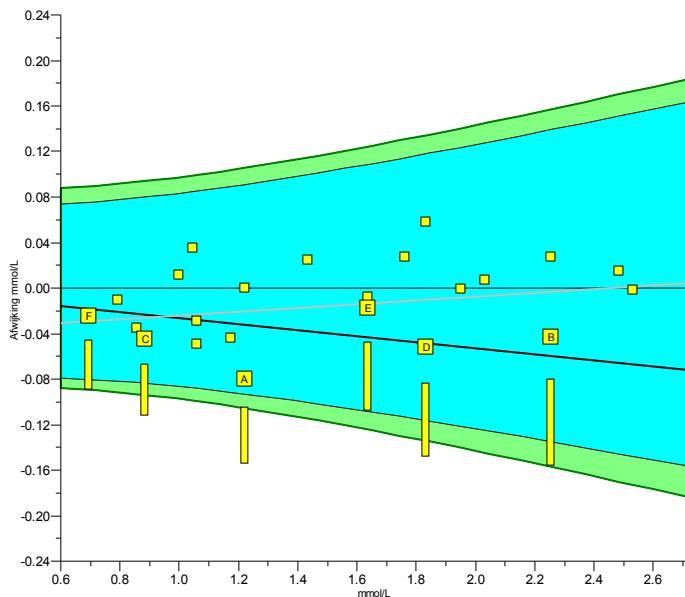
Klinische Chemie, bloed 2020.3



Klinische Chemie, bloed 2020.3

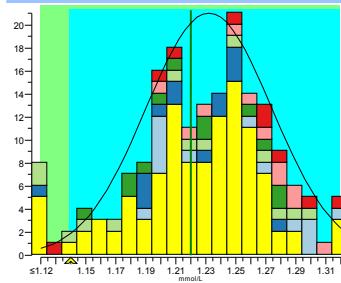
Anorg. Fosfaat

eenheid : mmol/L



	2020.3	cumulatief
Juistheid	-3.0%	-1.2%
Precisie	1.9%	2.6%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	3.9 [1]	4.6 [2]
Sigma-SA	3.2	3.9
Scorepictogram		
Regressielijn	$0.000 + 0.973 \cdot x$	$-0.041 + 1.017 \cdot x$
Consensusgroep	Zonder en met reductie	
Methode	Roche	
Analysator	Roche cobas c702	
Uw factor	$0.00 + 1.000 \cdot x$	
Methodefactor	$0.00 + 1.001 \cdot x$	

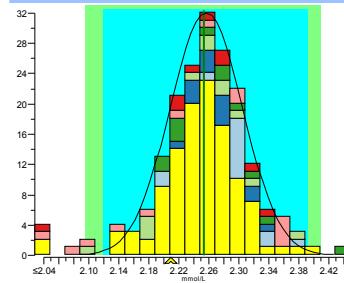
2020.3 A



cons. meth. exp. lab

	cons.	meth.	exp.	lab
gem.	1.232	1.226	1.220	1.14
SD	0.042	0.035		
n	182	109		
nu	9	7		
rec.	93%	93%	93%	

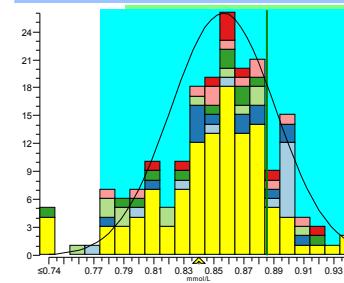
2020.3 B



cons. meth. exp. lab

	cons.	meth.	exp.	lab
gem.	2.257	2.249	2.253	2.21
SD	0.049	0.046		
n	188	114		
nu	8	2		
rec.	98%	98%	98%	

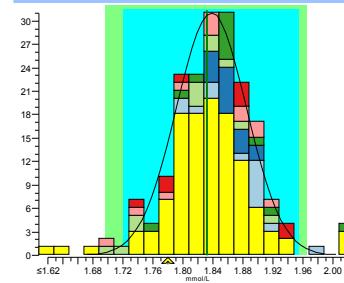
2020.3 C



cons. meth. exp. lab

	cons.	meth.	exp.	lab
gem.	0.856	0.852	0.885	0.84
SD	0.035	0.031		
n	190	115		
nu	7	6		
rec.	98%	99%	95%	

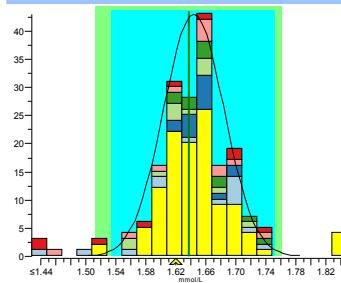
2020.3 D



cons. meth. exp. lab

	cons.	meth.	exp.	lab
gem.	1.838	1.832	1.832	1.78
SD	0.047	0.042		
n	190	116		
nu	8	6		
rec.	97%	97%	97%	

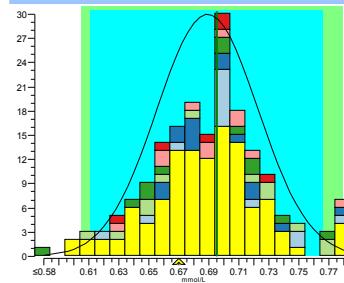
2020.3 E



cons. meth. exp. lab

	cons.	meth.	exp.	lab
gem.	1.644	1.640	1.638	1.62
SD	0.040	0.036		
n	187	114		
nu	12	6		
rec.	99%	99%	99%	

2020.3 F



cons. meth. exp. lab

	cons.	meth.	exp.	lab
gem.	0.689	0.685	0.695	0.67
SD	0.034	0.032		
n	184	114		
nu	8	4		
rec.	97%	98%	96%	

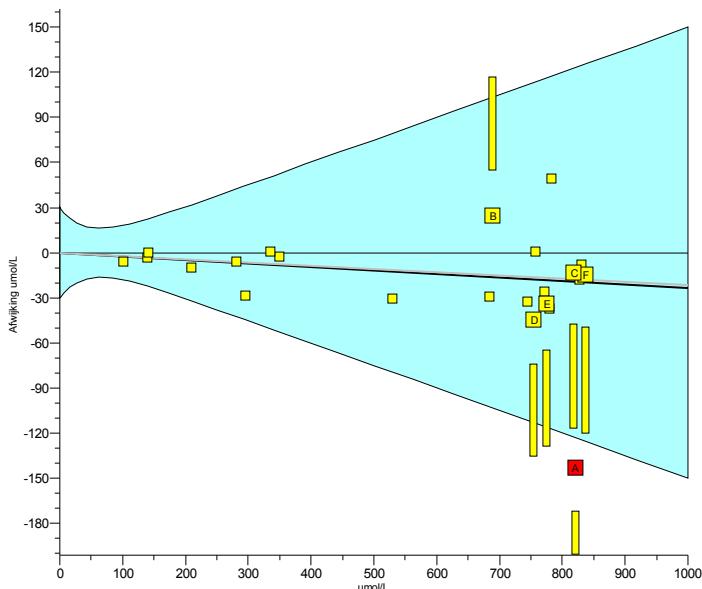
Legenda

Roche	Siemens Atellica	Abbott	Siemens Dimension	Beckman Coulter AU
Beckman Coulter DxC	Siemens Advia			

Klinische Chemie, bloed 2020.3

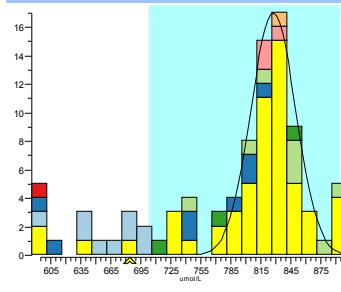
Ammoniak

eenheid : umol/L



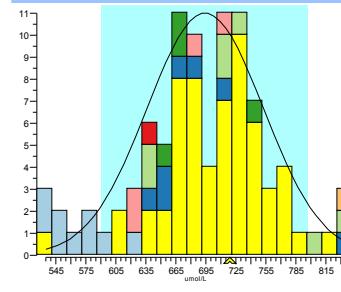
	2020.3	cumulatief
Juistheid	-2.3%	-2.2%
Precisie	3.2%	3.4%
Aantal	6	23
Uitbijters	1	1
Sigma-TE		
Sigma-SA	4.1	4.0
Scorepictogram		
Regressielijn	$0 + 0.977 \cdot x$	$0 + 0.978 \cdot x$
Consensusgroep	Enzymatisch	
Methode	Roche	
Analysator	Roche cobas c501, c502	
Uw factor	$0 + 1.000 \cdot x$	
Methodefactor	$0 + 1.001 \cdot x$	

2020.3 A



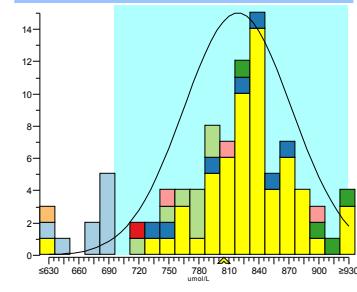
	cons.	meth.	ALTM	lab
gem.	822	821	823	679
SD	22	22	22	
n	88	56	89	
nu	29	12	29	
rec.	83%	83%	83%	

2020.3 B



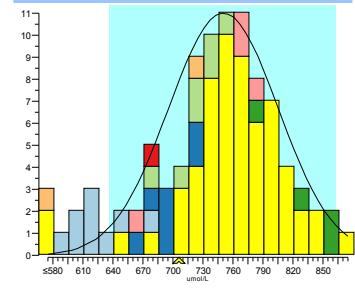
	cons.	meth.	ALTM	lab
gem.	689	706	691	714
SD	58	44	60	
n	91	59	92	
nu	2	1	1	
rec.	104%	101%	103%	

2020.3 C



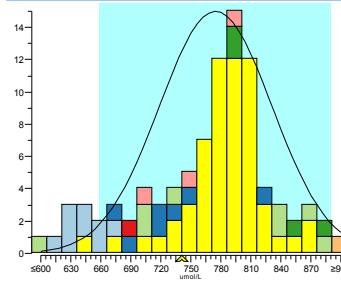
	cons.	meth.	ALTM	lab
gem.	819	831	819	805
SD	54	38	54	
n	92	60	93	
nu	5	3	6	
rec.	98%	97%	98%	

2020.3 D



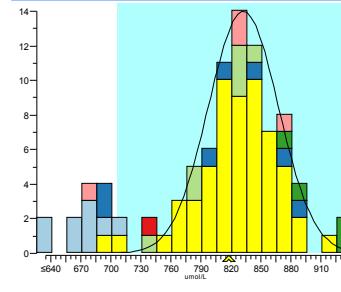
	cons.	meth.	ALTM	lab
gem.	755	772	758	711
SD	55	39	51	
n	92	60	94	
nu	3	3	7	
rec.	94%	92%	94%	

2020.3 E



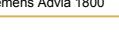
	cons.	meth.	ALTM	lab
gem.	775	785	775	741
SD	56	39	56	
n	91	59	92	
nu	1	0	2	
rec.	96%	94%	96%	

2020.3 F



	cons.	meth.	ALTM	lab
gem.	838	837	838	823
SD	35	34	35	
n	90	58	90	
nu	16	2	16	
rec.	98%	98%	98%	

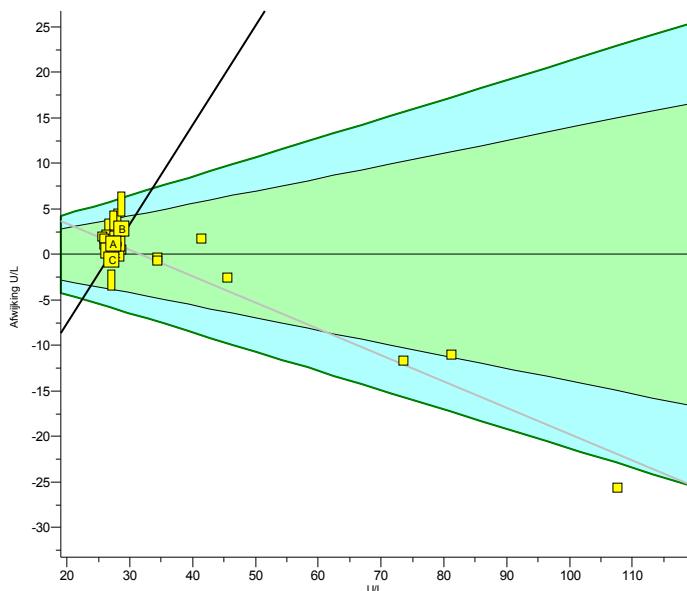
Legenda

 Roche	 Abbott	 Siemens Dimension	 Siemens Atellica	 Beckman Coulter AU
 Beckman Coulter DxC	 Siemens Advia 1800	 Overige methoden		

Klinische Chemie, bloed 2020.3

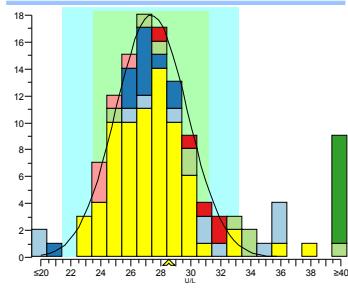
Lipase

eenheid : U/L



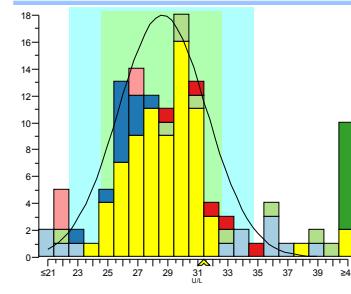
	2020.3	cumulatief
Juistheid	+2.8%	-0.82%
Precisie	2.9%	4.2%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	3.8	3.1
Sigma-SA	5.9 [2]	5.2 [2]
Scorepictogram		
Regressielijn	$-29.3 + 2.088 \cdot x$	$9.2 + 0.711 \cdot x$
Consensusgroep	Colorimetrisch	
Methode	Roche	
Analysator	Roche cobas c501, c502	
Uw factor	$0.0 + 1.000 \cdot x$	
Methodefactor	$0.0 + 1.003 \cdot x$	

2020.3 A



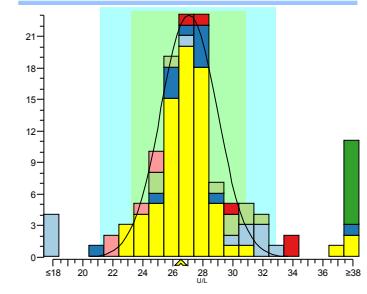
	cons.	meth.	ALTM	lab
gem.	27.4	27.2	27.4	28.5
SD	2.4	2.1	2.4	
n	124	73	124	
nu	17	2	17	
rec.	104%	105%	104%	

2020.3 B



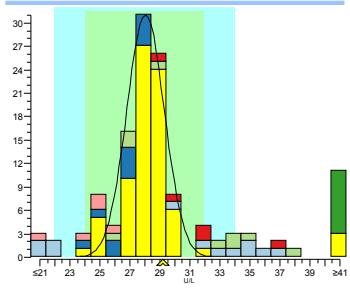
	cons.	meth.	ALTM	lab
gem.	28.6	28.6	28.6	31.4
SD	2.9	2.0	2.9	
n	125	74	125	
nu	16	3	16	
rec.	110%	110%	110%	

2020.3 C



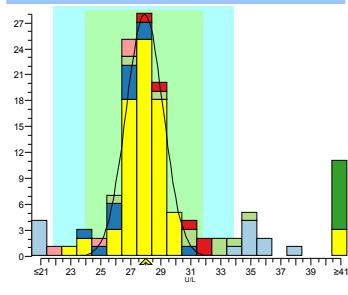
	cons.	meth.	ALTM	lab
gem.	27.1	26.8	27.1	26.5
SD	1.9	1.6	1.9	
n	126	75	126	
nu	20	3	20	
rec.	98%	99%	98%	

2020.3 D



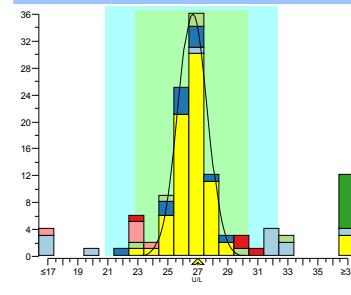
	cons.	meth.	ALTM	lab
gem.	28.0	28.2	28.1	29.2
SD	1.3	1.2	1.4	
n	128	77	128	
nu	36	5	28	
rec.	104%	104%	104%	

2020.3 E



	cons.	meth.	ALTM	lab
gem.	27.9	28.1	27.9	28
SD	1.2	0.9	1.2	
n	125	75	125	
nu	34	6	34	
rec.	100%	100%	100%	

2020.3 F



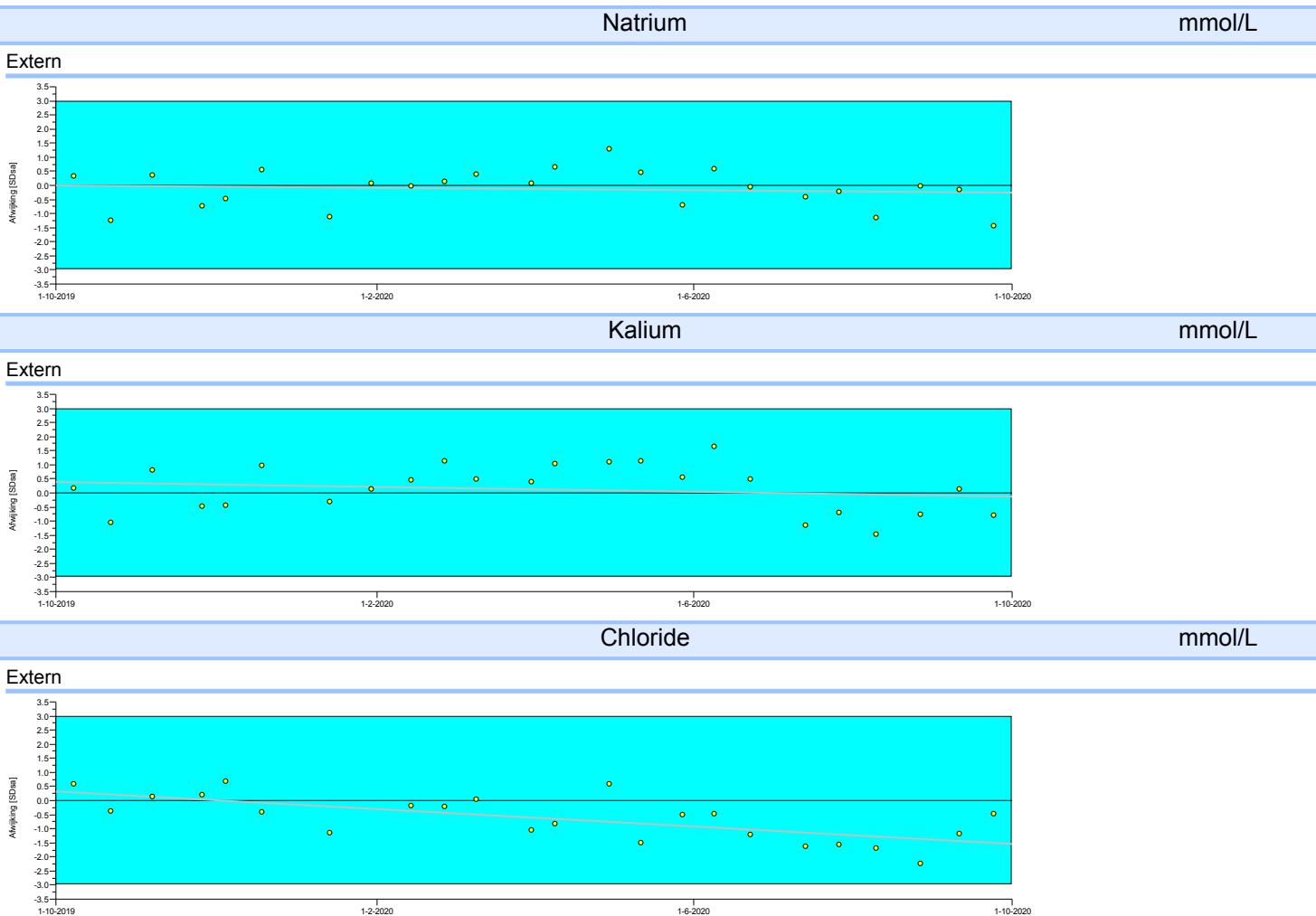
	cons.	meth.	ALTM	lab
gem.	26.6	26.7	26.6	27.0
SD	1.0	0.9	1.0	
n	122	75	122	
nu	37	4	35	
rec.	101%	101%	101%	

Legenda

Roche	Siemens Atellica	Abbott	Siemens Advia	Siemens Dimension
Beckman Coulter AU	Beckman Coulter DxC			

Klinische Chemie, bloed 2020.3

Tijddiagrammen

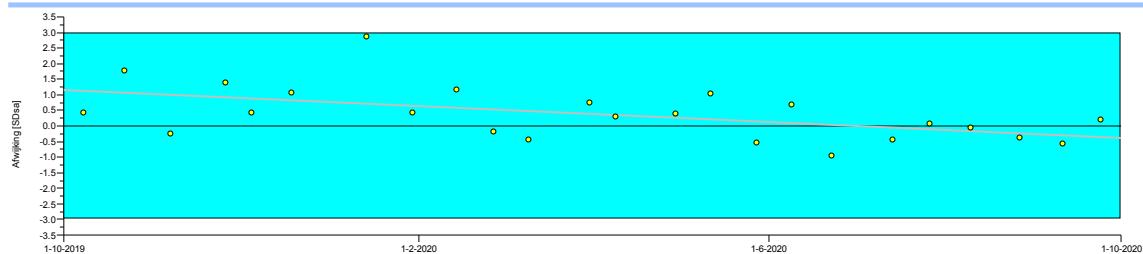


Klinische Chemie, bloed 2020.3

Calcium

mmol/L

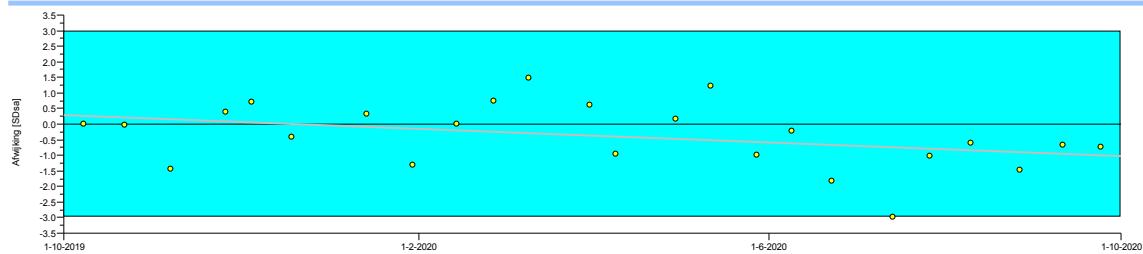
Extern



Anorg. Fosfaat

mmol/L

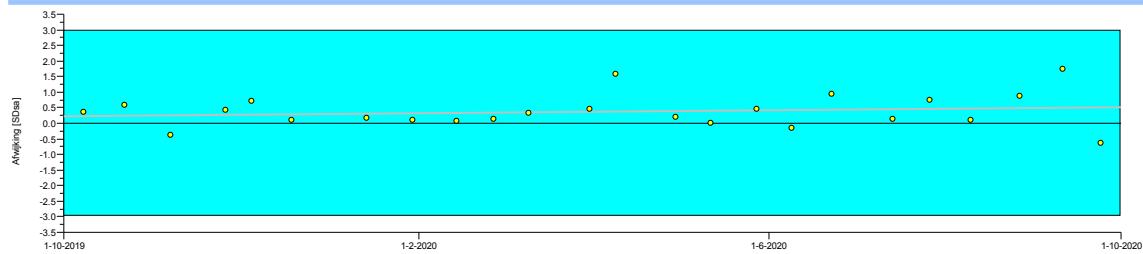
Extern



Magnesium

mmol/L

Extern

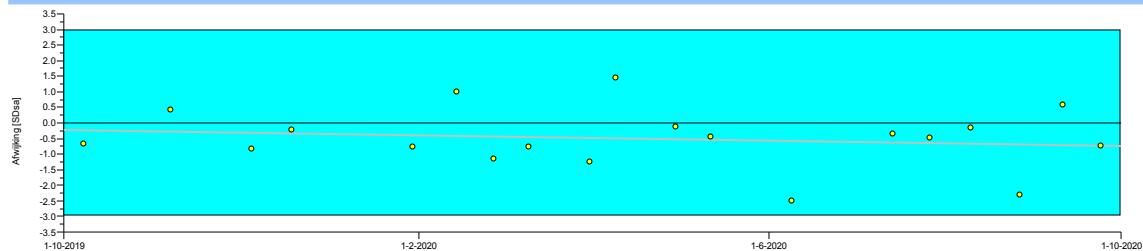


Klinische Chemie, bloed 2020.3

Lithium

mmol/L

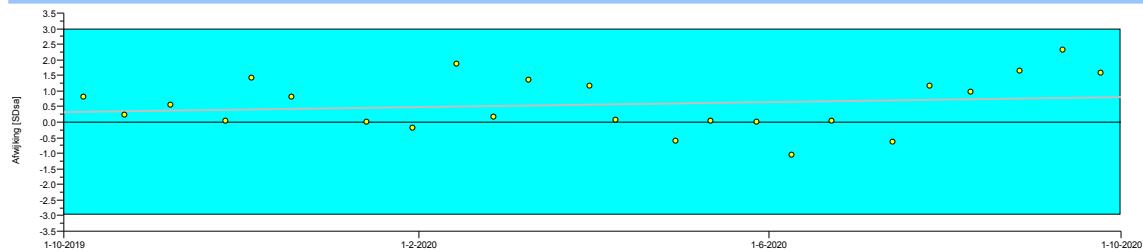
Extern



IJzer

umol/L

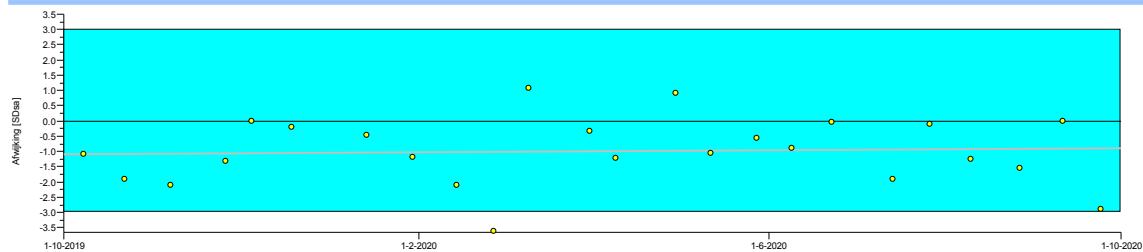
Extern



Ureum

mmol/L

Extern

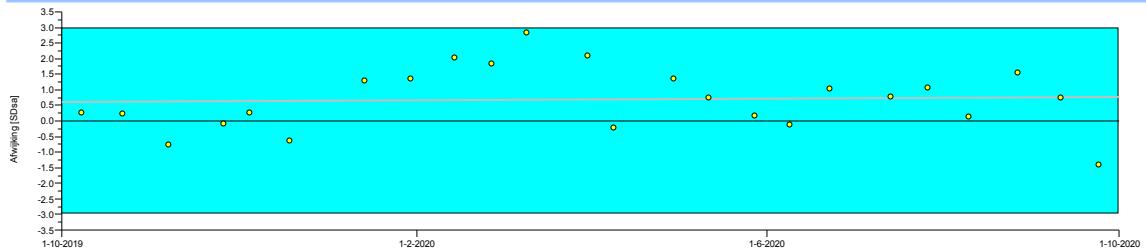


Klinische Chemie, bloed 2020.3

Kreatinine

umol/L

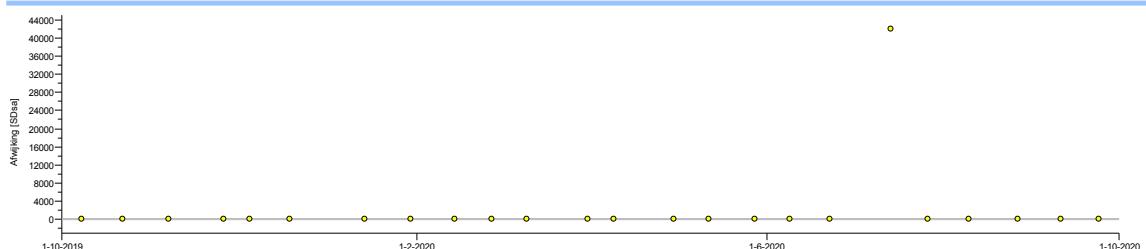
Extern



Uraat

umol/L

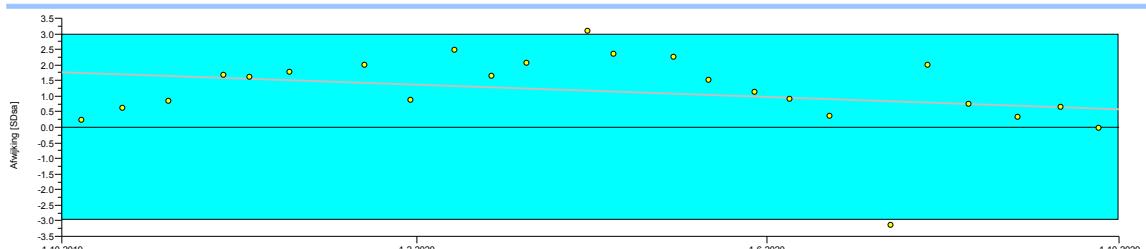
Extern



Glucose

mmol/L

Extern

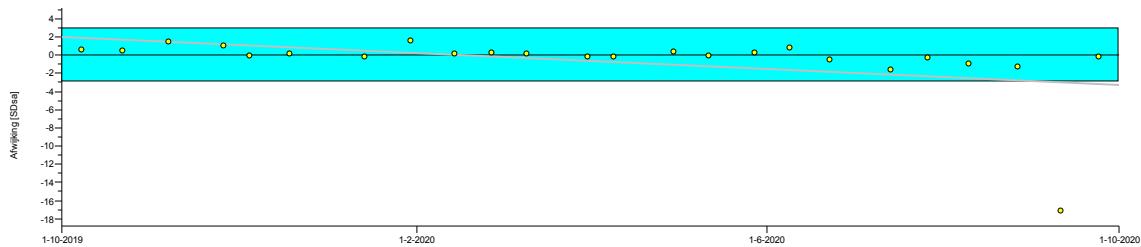


Klinische Chemie, bloed 2020.3

Totaal Eiwit

g/L

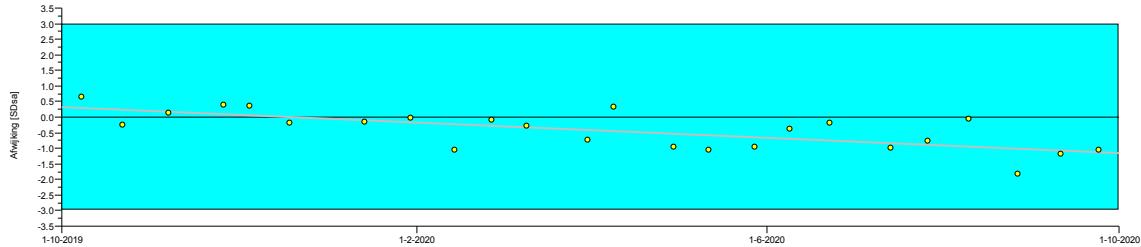
Extern



Albumine

g/L

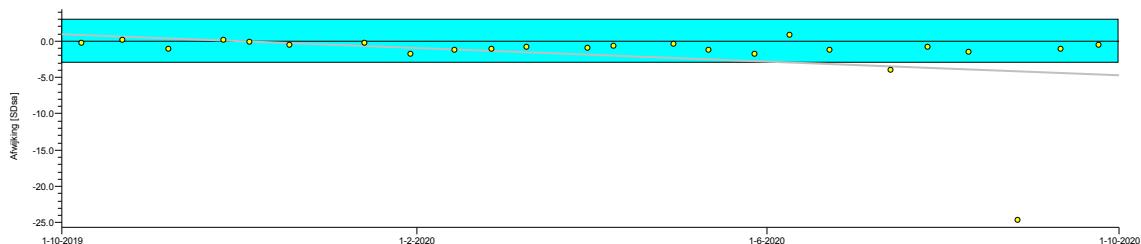
Extern



Bilirubine

umol/L

Extern

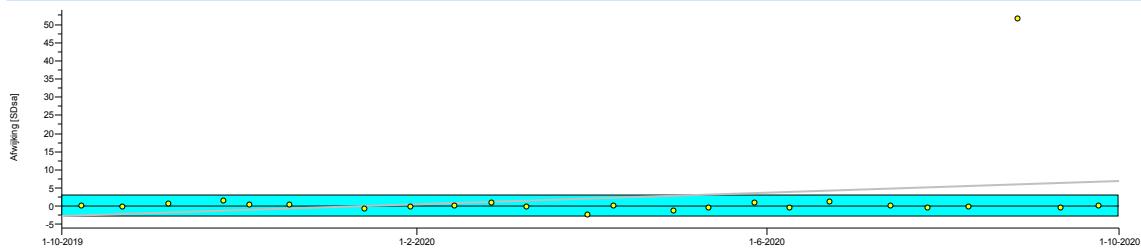


Klinische Chemie, bloed 2020.3

Bilirubine direct

umol/L

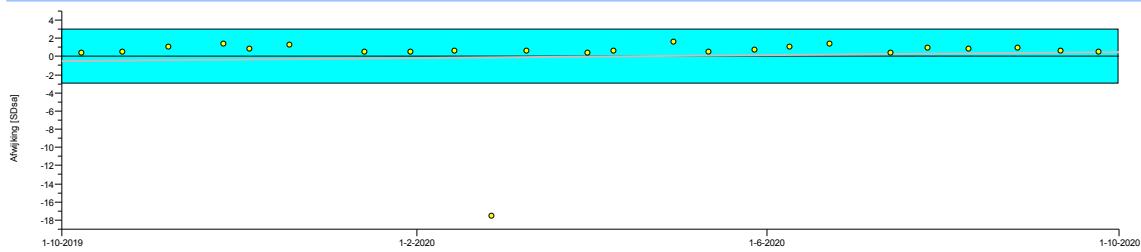
Extern



Alk. Fosfatase

U/L

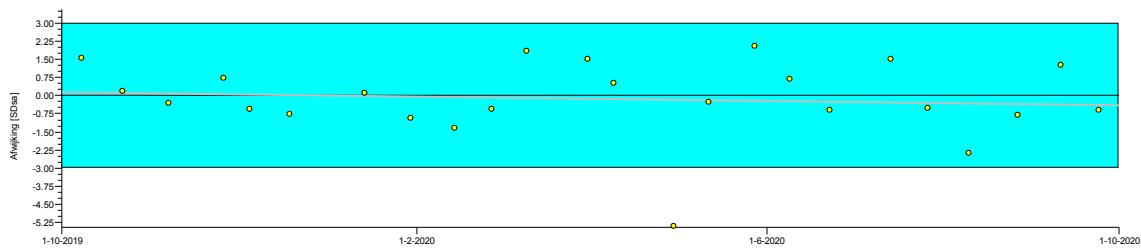
Extern



ASAT

U/L

Extern

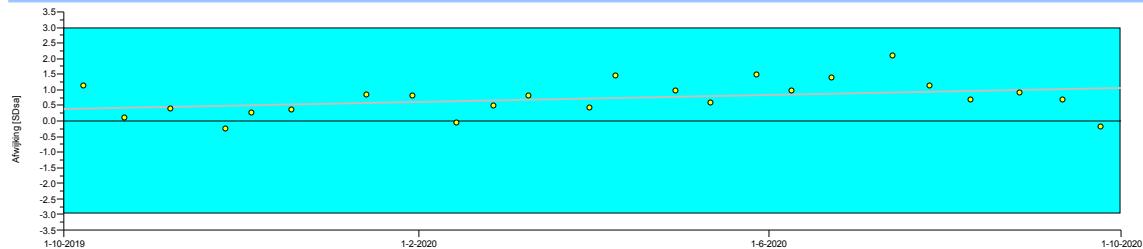


Klinische Chemie, bloed 2020.3

ALAT

U/L

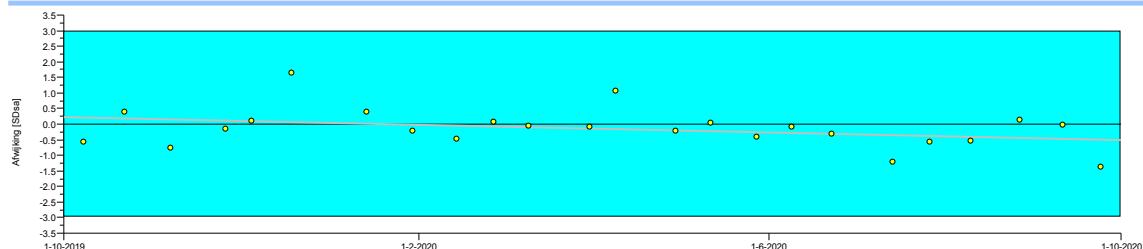
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LD

U/L

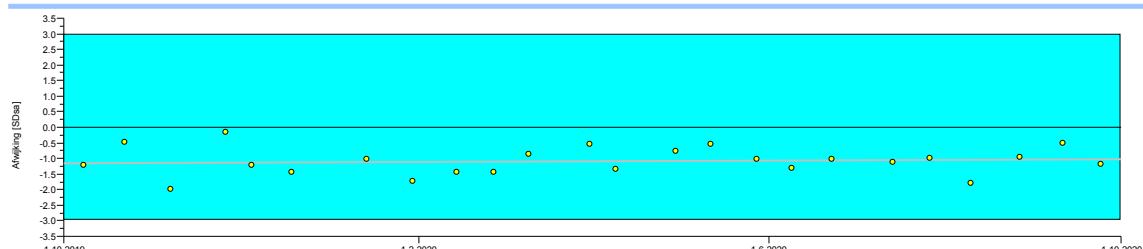
Extern



Gamma-GT

U/L

Extern

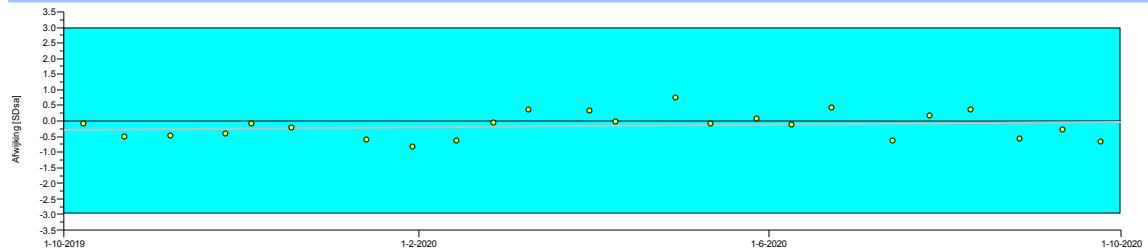


Klinische Chemie, bloed 2020.3

CK

U/L

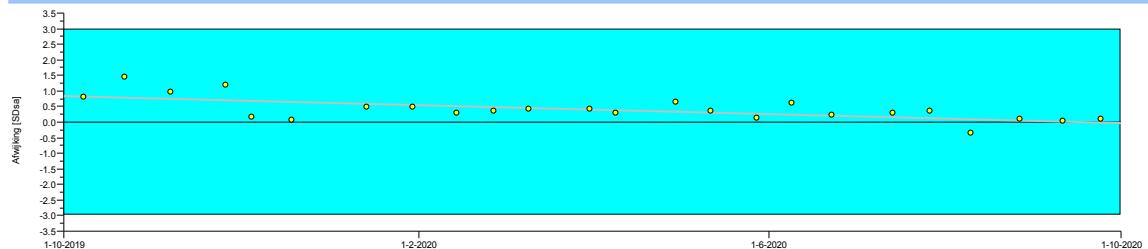
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Amylase

U/L

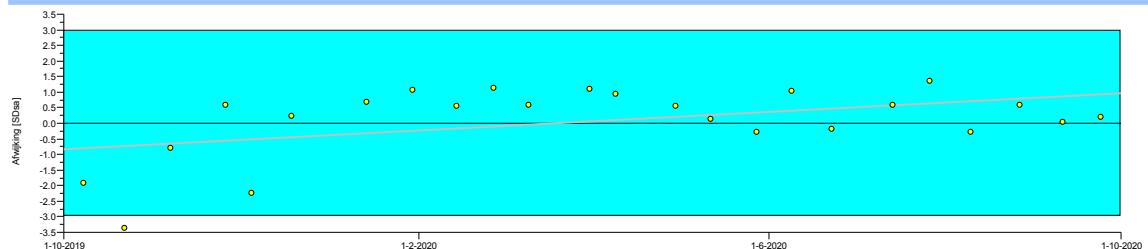
Extern



Lipase

U/L

Extern

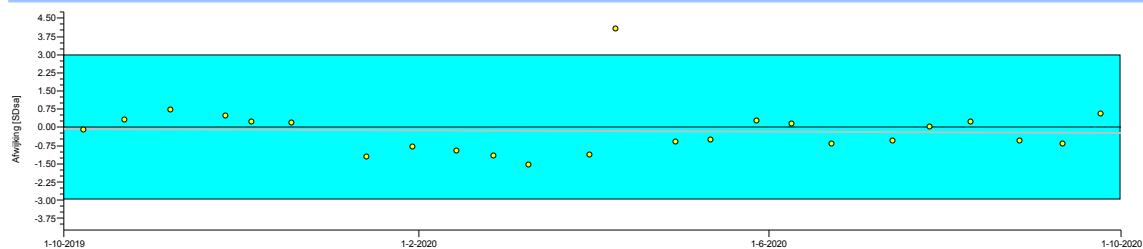


Klinische Chemie, bloed 2020.3

eGFR (V, 55, blank)

mL/min/{1.73_m2}

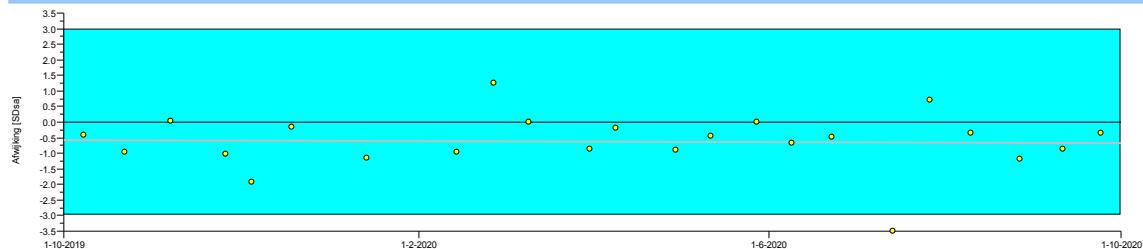
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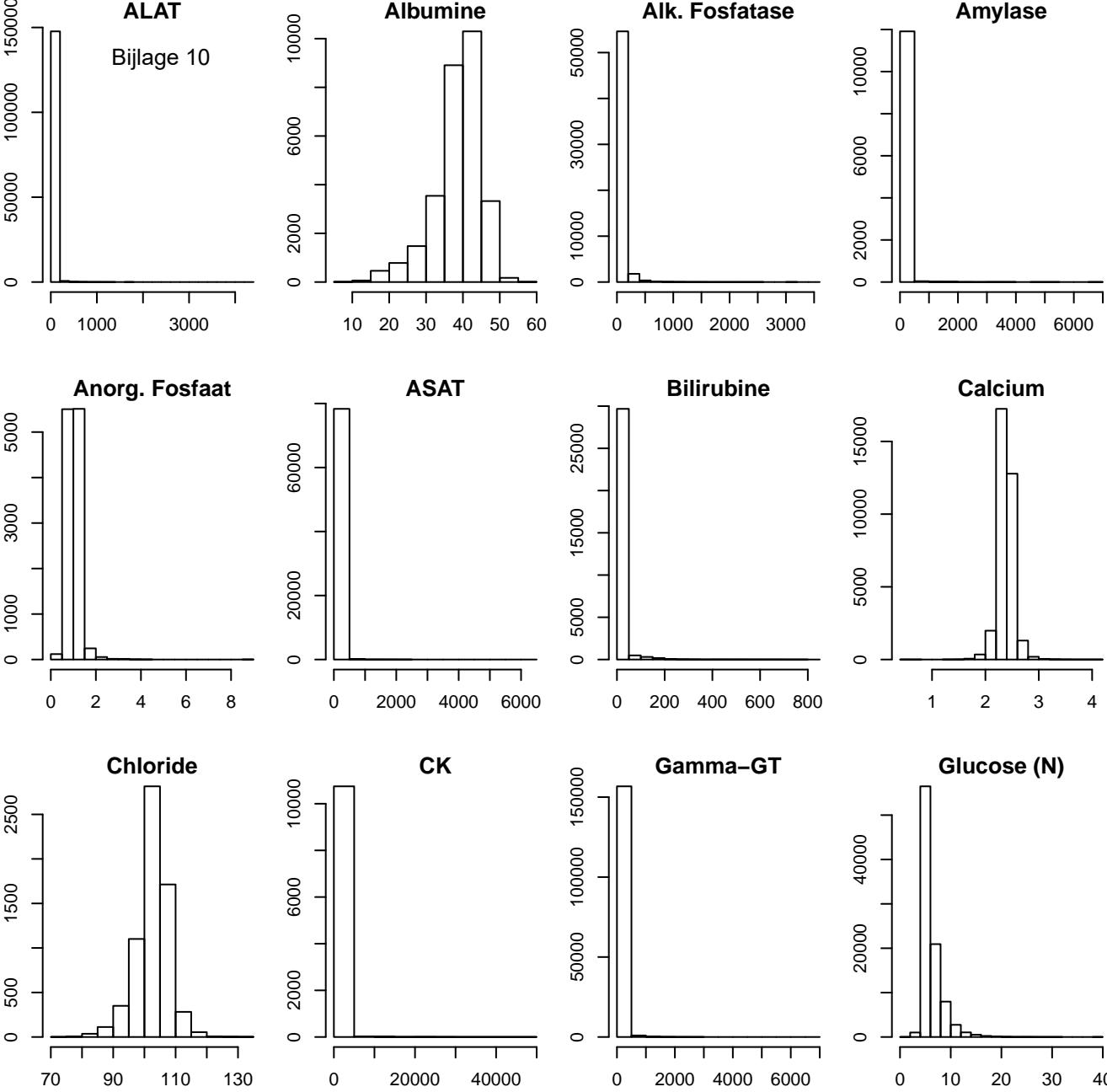


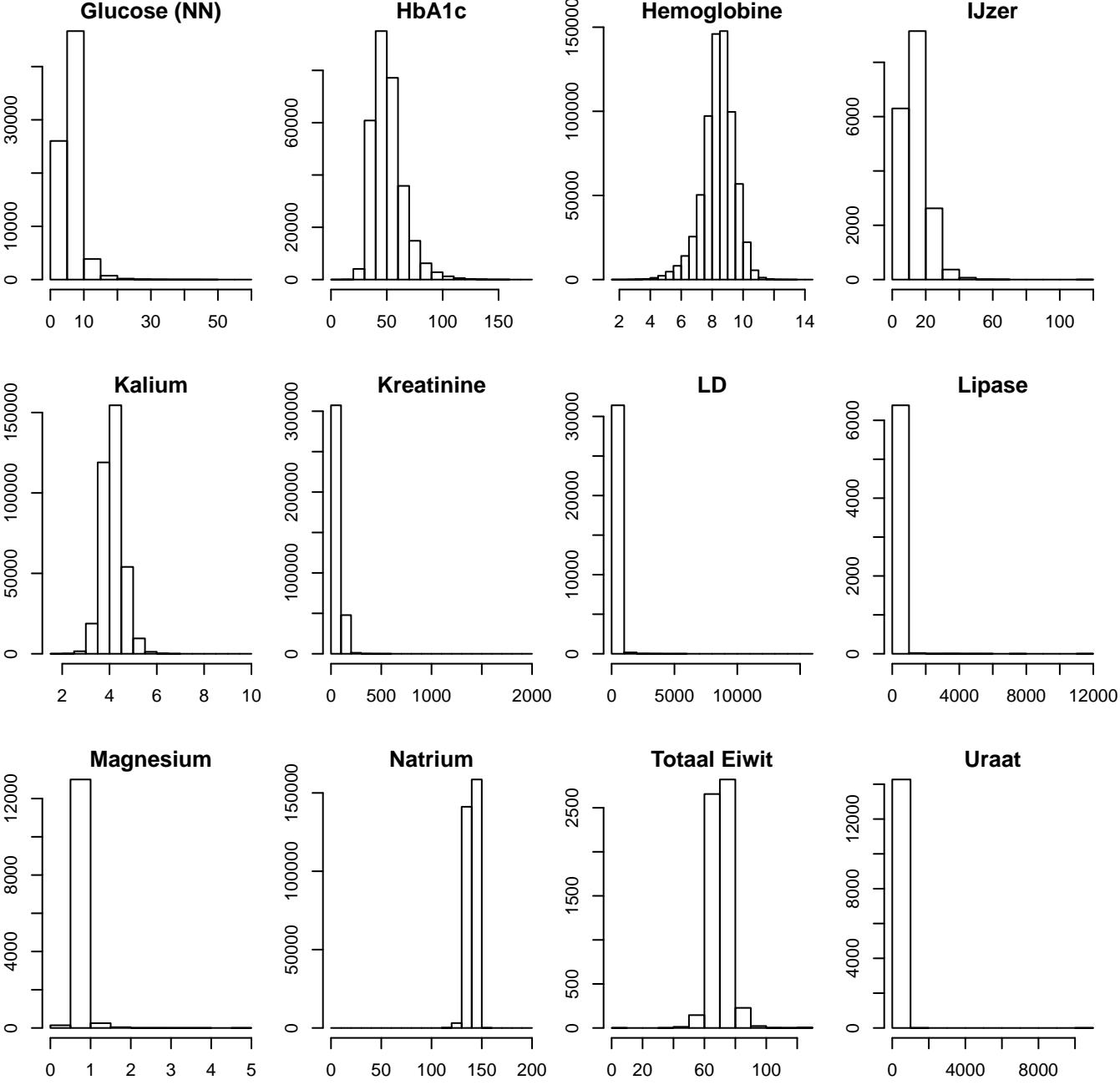
Ammoniak

umol/L

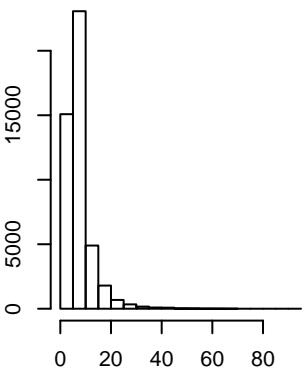
Extern







Ureum



Bijlage 11

variable	PERIOD	SEX	AGE	MEAN	SD	MIN
ALAT	TOTAL	ALL	ALL	26,88611	9,777237	3
ALAT	TOTAL	MEN	ALL	29,69385	10,11816	3
ALAT	TOTAL	WOMEN	ALL	24,87038	9,000179	3
ALAT	PERIOD_1	ALL	ALL	NaN	NA	Inf
ALAT	PERIOD_1	MEN	ALL	NaN	NA	Inf
ALAT	PERIOD_1	WOMEN	ALL	NaN	NA	Inf
ALAT	PERIOD_2	ALL	ALL	NaN	NA	Inf
ALAT	PERIOD_2	MEN	ALL	NaN	NA	Inf
ALAT	PERIOD_2	WOMEN	ALL	NaN	NA	Inf
ALAT	PERIOD_3	ALL	ALL	26,13173	9,890925	3
ALAT	PERIOD_3	MEN	ALL	28,87845	10,28859	3
ALAT	PERIOD_3	WOMEN	ALL	24,19264	9,114888	3
ALAT	PERIOD_4	ALL	ALL	27,70296	9,585985	3
ALAT	PERIOD_4	MEN	ALL	30,55903	9,860858	5
ALAT	PERIOD_4	WOMEN	ALL	25,61505	8,81266	3
ALAT	ALL	ALL	AGE_1	NaN	NA	Inf
ALAT	ALL	MEN	AGE_1	NaN	NA	Inf
ALAT	ALL	WOMEN	AGE_1	NaN	NA	Inf
ALAT	ALL	ALL	AGE_2	32,97692	10,75905	13,6
ALAT	ALL	MEN	AGE_2	33,56522	11,27715	13,6
ALAT	ALL	WOMEN	AGE_2	32,13125	10,26819	17
ALAT	ALL	ALL	AGE_3	22,88934	7,762512	7
ALAT	ALL	MEN	AGE_3	23,3705	8,397183	7
ALAT	ALL	WOMEN	AGE_3	22,25238	6,81967	9
ALAT	ALL	ALL	AGE_4	23,14327	7,355755	7
ALAT	ALL	MEN	AGE_4	23,68093	7,31487	7,6
ALAT	ALL	WOMEN	AGE_4	22,57446	7,363926	7
ALAT	ALL	ALL	AGE_5	21,76192	8,00922	5
ALAT	ALL	MEN	AGE_5	23,37937	8,075963	6
ALAT	ALL	WOMEN	AGE_5	20,94018	7,850264	5
ALAT	ALL	ALL	AGE_6	26,33975	10,1915	3
ALAT	ALL	MEN	AGE_6	31,5758	10,49858	5
ALAT	ALL	WOMEN	AGE_6	23,53009	8,823529	3
ALAT	ALL	ALL	AGE_7	29,09508	9,845797	4
ALAT	ALL	MEN	AGE_7	31,69475	9,893659	4
ALAT	ALL	WOMEN	AGE_7	27,05588	9,313594	4
ALAT	ALL	ALL	AGE_8	26,79701	9,231319	3
ALAT	ALL	MEN	AGE_8	28,33559	9,559084	3
ALAT	ALL	WOMEN	AGE_8	25,43663	8,708152	4
ALAT	ALL	ALL	AGE_9	23,46225	8,405066	3
ALAT	ALL	MEN	AGE_9	24,29322	8,701884	3
ALAT	ALL	WOMEN	AGE_9	22,8309	8,116345	3
log10_ALAT	TOTAL	ALL	ALL	1,422215	0,172683	0,991226
log10_ALAT	TOTAL	MEN	ALL	1,471869	0,171248	0,991226
log10_ALAT	TOTAL	WOMEN	ALL	1,384795	0,164113	0,991226
log10_ALAT	PERIOD_1	ALL	ALL	NaN	NA	Inf
log10_ALAT	PERIOD_1	MEN	ALL	NaN	NA	Inf
log10_ALAT	PERIOD_1	WOMEN	ALL	NaN	NA	Inf
log10_ALAT	PERIOD_2	ALL	ALL	NaN	NA	Inf

log10_ALAT	PERIOD_2	MEN	ALL	NaN	NA	Inf
log10_ALAT	PERIOD_2	WOMEN	ALL	NaN	NA	Inf
log10_ALAT	PERIOD_3	ALL	ALL	1,409171	0,176347	0,991226
log10_ALAT	PERIOD_3	MEN	ALL	1,458028	0,17605	0,991226
log10_ALAT	PERIOD_3	WOMEN	ALL	1,372979	0,167626	0,991226
log10_ALAT	PERIOD_4	ALL	ALL	1,436081	0,167591	0,991226
log10_ALAT	PERIOD_4	MEN	ALL	1,48629	0,164868	0,991226
log10_ALAT	PERIOD_4	WOMEN	ALL	1,397549	0,159257	0,991226
log10_ALAT	ALL	ALL	AGE_1	NaN	NA	Inf
log10_ALAT	ALL	MEN	AGE_1	NaN	NA	Inf
log10_ALAT	ALL	WOMEN	AGE_1	NaN	NA	Inf
log10_ALAT	ALL	ALL	AGE_2	1,50111	0,159857	1,133539
log10_ALAT	ALL	MEN	AGE_2	1,499086	0,162428	1,133539
log10_ALAT	ALL	WOMEN	AGE_2	1,503848	0,161239	1,230449
log10_ALAT	ALL	ALL	AGE_3	1,352766	0,151701	1
log10_ALAT	ALL	MEN	AGE_3	1,362051	0,159935	1
log10_ALAT	ALL	WOMEN	AGE_3	1,340324	0,13971	1
log10_ALAT	ALL	ALL	AGE_4	1,349156	0,145654	1
log10_ALAT	ALL	MEN	AGE_4	1,360991	0,142181	1
log10_ALAT	ALL	WOMEN	AGE_4	1,336531	0,148385	1
log10_ALAT	ALL	ALL	AGE_5	1,332898	0,161697	0,995635
log10_ALAT	ALL	MEN	AGE_5	1,364887	0,164487	1
log10_ALAT	ALL	WOMEN	AGE_5	1,315985	0,157638	0,995635
log10_ALAT	ALL	ALL	AGE_6	1,415463	0,183213	0,991226
log10_ALAT	ALL	MEN	AGE_6	1,506954	0,174647	0,995635
log10_ALAT	ALL	WOMEN	AGE_6	1,361589	0,165957	0,991226
log10_ALAT	ALL	ALL	AGE_7	1,459345	0,166743	0,991226
log10_ALAT	ALL	MEN	AGE_7	1,503873	0,161706	0,991226
log10_ALAT	ALL	WOMEN	AGE_7	1,422678	0,161831	0,991226
log10_ALAT	ALL	ALL	AGE_8	1,418959	0,162197	0,991226
log10_ALAT	ALL	MEN	AGE_8	1,446093	0,162864	0,991226
log10_ALAT	ALL	WOMEN	AGE_8	1,39446	0,157634	0,991226
log10_ALAT	ALL	ALL	AGE_9	1,358461	0,158156	0,995635
log10_ALAT	ALL	MEN	AGE_9	1,374178	0,160475	0,995635
log10_ALAT	ALL	WOMEN	AGE_9	1,34648	0,155313	1

MAX	N
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55,8	57225
55,8	79710
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55,8	71190
55,8	29460
55,7	41730
55,8	65745
55,8	27765
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55,2	39
55,2	23
54	16
50	244
50	139
42	105
55	959
52	493
55	466
55	3280
55	1105
55	2175
55,8	42404
55,8	14808
55,6	27596
55,8	39075
55,8	17177
55,8	21898
55,8	39696
55,8	18628
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1,8750613 11289
1,8750613 4883
1,8750613 6406

RESEARCH COLLABORATION AGREEMENT

- (1) **Academisch Ziekenhuis Leiden**, also acting under the name Leiden University Medical Centre, having its offices at Albinusdreef 2, 2333 ZA Leiden, the Netherlands, hereinafter referred to as "Leiden";
- (2) **Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek (SKML)**, having its offices at Mercator 1, Toernooiveld 214, 6525 EC Nijmegen, hereinafter referred to as "Partner".

each herein individually also referred to as a "Party" and collectively as the "Parties".

WHEREAS:

- A. Leiden, and specifically its Department of Clinical Chemistry and Laboratory Medicine and the Department of Internal Medicine, section Gerontology and Geriatrics, has developed the methodology and R scripts to 1) collect and process anonymous laboratory test results from clinical laboratories and 2) calculate (standardized) pooled reference intervals.
- B. Partner has developed methodology to automatically exclude laboratory test results for periods of poor performance from datasets with anonymous laboratory test results;
- C. Partner and Leiden wish to collaborate in performing research in setting up a database and infrastructure to determine and monitor uniform reference intervals in the Netherlands (SKMS project 59943982 Database + infrastructuur voor vaststellen uniforme referentie-intervallen in NL)] as further described in the Schedule annexed hereto (hereinafter the "Research");

Therefore, the Parties have agreed to the following:

1. COLLABORATION

- 1.1 Parties agree to use their reasonable endeavours to undertake the Research.
- 1.2 At Leiden, the Research shall be carried out under the supervision of Prof.dr. C.M. Cobbaert and dr. W.P.J. den Elzen or such other suitably qualified personnel as Leiden may see fit to appoint. At Nijmegen, the Research shall be carried out under the supervision of Prof.dr. M.H.M. Thelen or such other suitably qualified personnel as Partner may see fit to appoint.

2. TERM

The Research shall commence on 1 September 2020 and run for a period of two years ("the Period") or until completed, whichever is the sooner.

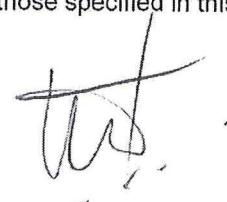
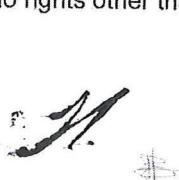
3. RESEARCH FUNDING

Funding support for the Research shall be the responsibility of each Party with regard to its own activities. Parties agree that they shall not be liable towards each other for any breach of any subject funding conditions.

4. RESULTS AND INTELLECTUAL PROPERTY RIGHTS

Background and Background IP

- 4.1 For the purposes of this Agreement, "Results" are all and any results of the Research, and "Background Information" is all non-publicly available information, including Confidential Information and know-how and intellectual property rights, which a Party possessed or controlled before it entered into this Agreement, or which a Party has acquired or will generate or acquire outside the scope of this Agreement and which is necessary for the execution of the Research.
- 4.2 Use of Background Information in the Research shall create no rights other than those specified in this Agreement and will not affect control or ownership thereof.



1

4.3 Each Party hereby grants to the other Party, and the other Party hereby accepts, a non-exclusive, royalty free, non-transferable licence to use its Background Information to the extent necessary for the purpose of carrying out the Research.

Foreground and Foreground IP

4.4 Results generated by members of staff of a Party shall be owned by the Party employing such staff, including all intellectual property and related rights. The exploitation of said Results shall be the responsibility of that Party and all revenue generated will remain the property of that Party. Each Party hereby grants to the other Party and the other Parties hereby accept, a non-exclusive, royalty free, non-transferable licence to use its Results to the extent necessary for the purpose of carrying out the Research and to use its Results for the purposes of (academic) research and education and clinical patient care, solely or jointly with third parties.

4.5 Results generated by members of staff of the Parties jointly ("Joint Inventions") shall be jointly owned by the Parties. The Parties hereby agree to co-operate fully in the protection and exploitation of such Joint Inventions. No Party shall be entitled to use such Joint Inventions for commercial purposes without the prior written consent of the other Party. The Parties agree to enter into good faith negotiations and aim to agree no later than ninety (90) days after completion of the Research on the exploitation strategy, together with any joint ownership and revenue-sharing arrangements which will reflect the contribution of the relevant Parties to the Joint Inventions. All liabilities and revenue relating thereto shall be distributed pro rata upon inventorship or as may otherwise be mutually agreed upon in writing.

5. DATA

A Party ("Providing Party") may provide to the other Party ("Receiving Party") data specified and to be used in carrying out the Research ("Data"). The Receiving Party will be free to use Data provided by the Providing Party for the Research only. Under no condition may the Data be transferred by the Receiving Party to any third party without prior written approval of the Providing Party. The Receiving Party agrees to comply with all laws, regulations and rules applicable to the handling of the Data. Where the European General Data Protection Regulation 2016 ((EU) 2016/679) ("GDPR") applies, each party agrees, at its own cost:

- (a) to provide the other party with such information and documents about its Processing of Personal Data, and its Processors' Processing of Personal Data, and such assistance as the other party may request from time to time to allow the other party to meet its obligations under the GDPR, and to allow the other party to be able to demonstrate compliance with the GDPR;
- (b) to take such other action, or refrain from taking any action, necessary to comply with, or to allow the other party to comply with, the GDPR or the order of any competent Supervisory Authority or court of competent jurisdiction; and
- (c) to co-operate with any competent Supervisory Authority and to allow such Supervisory Authority to audit each party's compliance with the GDPR.

Expressions used in this clause beginning with a capital letter have the meaning given to them in the GDPR. The Receiving Party will be solely responsible for the handling, storage and return of any Data. Upon termination of this Agreement the unused portion of the Data will be returned to the Providing Party, destroyed or otherwise disposed of as mutually agreed by the Providing Party and the Receiving Party. Nothing in this Agreement shall or may be construed as granting the Receiving Party any right or licence to the Data provided by the Providing Party for any use other or further than for the Research. The Receiving Party accepts the Data may not have been completely investigated and therefore may be unknown.

6. RESEARCH SOFTWARE

The Parties may agree that, during the term of the Research, Leiden shall provide Partner with research software as set out in the Research ("Research Software").

For provided Research Software, Leiden grants, or will procure the grant, to Partner a non-exclusive, non-transferable, revocable, royalty free licence, during the term of the Research, to use the Research Software only for the purposes of conducting the relevant Research under this Agreement. Research Software and all copies thereof are proprietary to Leiden and will remain in the true and lawful ownership of Leiden.

Partner agrees that Research Software will be provided by Leiden.

The Parties agree that Research Software is not in general commercial release and constitutes "untested" product of Leiden. Partner shall not nor permit anyone else (including its Affiliates and their personnel) to use the Research Software for any use and/or purpose (including without limitation clinical purposes) other than as expressly granted in this Agreement. Partner understands and acknowledges that Leiden is not obligated to make the Research Software available as commercial product or for general release.

It is understood and agreed that Research Software (including any related documentation and/or materials) is provided "AS IS" and that Leiden makes no representation or warranty of any kind, express or implied, statutory or otherwise, as to merchantability, noninfringement, fitness for a particular purpose or any other matter relating to the Research Software.

Leiden shall not be liable for any loss or damage of any kind incurred as a result of, or arising out of the use by Partner or relying on the Research Software.

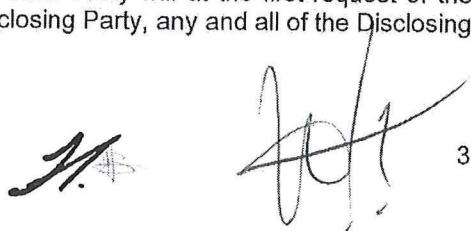
This Agreement does not allow for clinical patient care in any form. Partner assumes full liability for injuries, damages and loss which arises in connection with any clinical patient care or clinical research (except as expressly allowed under this Agreement) and shall indemnify and hold Leiden harmless in relation to any such claims which may be asserted against Leiden's including reasonable attorney's fee.

7. PUBLICATION

It is anticipated that publications arising from the research hereunder will be a joint publication. The following authors shall be included in any publication initiated in a to be discussed order based on effort and responsibilities: Prof. Dr. Christa M Cobbaert, Dr. Raymond Noordam, Dr. Nannette Brouwer, Dr. Wendy PJ den Elzen, Marith van Schrojenstein Lantman, MSc, Guido van Dam, Msc, Ron Meijer, Prof.Dr,Marc Thelen. The initiating Party shall provide a copy of the proposed publication or presentation to the other Party for review at least thirty (30) days prior to submission to a publisher thereof. If that Party requests the removal of Confidential Information (as defined below), the initiating Party agrees to allow the use of sufficient information regarding the identity and properties of the Data to enable the complete and accurate publication of the research results. If the non-initiating Party determines that the proposed publication or presentation contains subject matter requiring patent protection, the initiating Party shall delay publication or presentation for up to an additional sixty (60) days for the filing of patent applications.

8. CONFIDENTIALITY

The Parties shall ensure that any information relating to the Research, Background Information, Results or to the business affairs of the other Parties that has been or will be disclosed by or on behalf of one Party (the "Disclosing Party"), to the other Party (the "Receiving Party"), directly or indirectly, in whatever form, including (without limitation) any data, reports, analyses, specifications, techniques, processes, technical information, ideas, know-how, trade secrets, patents, patent applications and inventions (whether or not patentable), drawings, designs and computer software, and which is, or which should reasonably be expected to be, of a confidential nature ("Confidential Information") shall not be disclosed by the Receiving Party, without the prior written consent of the Disclosing Party. Such confidentiality shall continue for a period of 5 years from expiration or termination of this Agreement and shall not include any information which the Receiving Party can prove by documentary evidence: (a) lies in the public domain; (b) was in its possession prior to the disclosure under this Agreement, provided it was not acquired under confidentiality obligations directly or indirectly from the Disclosing Party; (c) that, after its disclosure under this Agreement, it became part of the public domain by publication or otherwise through no act or omission of the Receiving Party; (d) that, after its disclosure under this Agreement, it was received by the Receiving Party from a third party who did not acquire it directly or indirectly from the Disclosing Party, and who was legally entitled to disclose that information; e) was independently developed without use of the Disclosing Party's Confidential Information; or f) that it is required under a statutory duty and/or Court order to disclose, provided that advance notice is given to the Disclosing Party and the Receiving Party takes all reasonable measures to protect the confidentiality of the information. Upon termination or expiry of this Agreement, each Party will at the first request of the Disclosing Party, return or destroy, at the election of the Disclosing Party, any and all of the Disclosing Party's Confidential Information.



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9. REPRESENTATIONS, WARRANTIES AND LIABILITIES

- 9.1 Each Party will exercise reasonable care to ensure the accuracy of any information provided under the Agreement. However, each Party makes no representations and extends no warranties of any kind, either expressed or implied, in relation to such information. There are no express or implied warranties of merchantability, satisfactory quality or suitability for any particular purpose, nor any warranty that the exercise of the rights granted under this Agreement will not infringe patent, copyright, trademark, or other rights of any third party.
- 9.2 To the extent permitted by law, Parties agree that they shall not be liable towards each other for any breach of this Agreement or for loss or damage of any kind and of whatever nature incurred by the other Party or by third parties which arise as a result of the Research or the use of Background Information or Results, unless the damage was caused by a Party's wilful act or gross negligence. The Parties agree that the maximum aggregate liability of each Party under this Agreement is set at one time the value of any fees or funding received under this Agreement.

10. MISCELLANEOUS.

- 10.1 This Agreement may only be amended by prior written agreement of the Parties hereto.
- 10.2 A waiver by any Party of a breach or default of the other Party under any of the provisions of this Agreement shall not be construed as a waiver of any succeeding breach of the same or other provisions, nor shall any delay or omission on the part of any Party to exercise or avail itself of any right, power or privilege that it has or may have under this Agreement, operate as a waiver of any breach or default by the other Party.

11. GOVERNING LAW AND JURISDICTION

- 11.1 This Agreement shall be governed by the laws of the Netherlands, excluding its conflict of law provisions.
- 11.2 Any dispute arising out of or in connection with this Agreement, which cannot be solved amicably within a reasonable period of time, will be submitted to the competent court in The Hague, The Netherlands.
- 11.3 Upon termination or expiry of this Agreement, the provisions of articles 5.4, 5.5, 6, 7, 9, 10 and 11 shall remain in force.

Leiden

Name: Mrs. Drs. G.E. de Blecourt
Position: Manager of Division IV
Date: November 9, 2020

SKML

Name: Prof.Dr. M.H.M. Thelen
Position: director
Date: November 11, 2020

Leiden

Name: Dhr. H.B.M. Onstein
Position: Manager of Division II
Date:
12-11-2020

Schedule

[Description of the Research]
[if applicable: Description of the Funding]