



instru^{chemie}

Science without f(r)iction since 1979

Catalogue 2024

45 *Years*
ANNIVERSARY
CELEBRATION



InstruChemie is located in Delfzijl, The Netherlands.

Delfzijl is a city and former municipality (which now belongs to the municipality of Eemshaven) with a population of 26.000 in the province of Groningen in the northeast of the Netherlands. Delfzijl was a sluice between the Delf and the Ems, which became fortified settlement in the 16th century. The fortifications were removed in the late 19th century. Delfzijl is the fifth largest seaport in the Netherlands, and the largest port in the North East of the country.





iNstruChemie

Company profile

INstruChemie is a family-owned business, founded in 1979 by Irenus Nieland in The Netherlands.

INstruChemie started as a distributor for in vitro diagnostics with the slogan:

Science without f(r)iction

In 1986 we opened our own research and production facility and started to produce our own line of in vitro diagnostics. Through research and dedication, we grew into a company selling our products worldwide.

In 2014, Fons Nieland became the managing director of INstruChemie. Nowadays we have over 40 years of experience, but our slogan has not changed. If you are looking for an in vitro diagnostic test, please do not hesitate to contact us! We will gladly help you find what you are looking for.

Quality

Quality has always been important to INstruChemie. We use a certified quality management system to ensure each batch is identical and passes strict quality control procedures.

In 1997 we acquired our first ISO quality management certificate and we are currently (EN) ISO 13485:2016 certified. Additionally, all INstruChemie products are CE-marked under the Directive 98/79/EC (EU) on in vitro diagnostic medical devices.

Our quality management team is currently working on complying with the new EU Regulation 2017/746 (EU) on in vitro diagnostic medical devices and are well on their way regarding the current timelines.

Product range

INstruChemie offers an extensive range of assays and control materials for spectrophotometric, (U)HPLC, and LC-MS methods which can be found full in this product catalogue. However, we also offer a wide range of product from other reputable companies, on which we will gladly provide more information.

Additionally, INstruChemie is always working on improving our products and developing new IVD reagent sets. We also offer custom made options, so please feel free to contact us!



CERTIFICATE

Number: 2131911

The management system of:

INstruchemie** B.V.**

Zwet 26
9932 AB Delfzijl
The Netherlands

including the implementation meets the requirements of the standard:

ISO 13485:2016 **EN ISO 13485:2016**

Scope:

The design and development, manufacture and distribution of in-vitro diagnostic reagents, in-vitro diagnostic test kits and calibrators and controls used in the diagnosis, management and detection of disease status or analytes in human bodily fluids, including point of care in-vitro diagnostic devices.

Certificate expiry date: 1 December 2024
Certificate effective date: 1 December 2021
Certified since: 28 January 2008

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



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Regulation 2017/746 (EU) on in vitro diagnostic medical devices

The Regulation 2017/746 (EU) on in vitro diagnostic medical devices, or the IVDR for short, came into force on May 26, 2022 to replace the Directive 98/79/EC (EU) on in vitro diagnostic medical devices. The IVDR assured increased safety and efficiency in the EU in vitro diagnostic medical device market.

Regulation (EU) 2022/112 has extended the transitional period for current IVDD products and states:

Devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that Directive, and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until the following dates:

- (a) 26 May 2025, for class D devices;
- (b) 26 May 2026, for class C devices;
- (c) 26 May 2027, for class B devices;
- (d) 26 May 2027, for class A devices placed on the market in sterile condition

For INstruChemie, a manufacturer of all class B devices, this means that all products must comply to the IVDR on May 26 2027. In the meantime, we will assure to maintain the highest product quality as possible and work towards achieving the CE-mark of the IVDR as soon as possible but of course prior to the date required by the IVDR.

Transport and stability

Per January 1 2023 we are improving our transport conditions to ensure optimum quality of our products. INstruChemie ensures stability of the product for at least 1 week from the date of shipment.*

Storage temperature on label	Storage condition on customer site	Shipping condition
-25 °C to -15 °C	Freezer	Insulation box with cold packs and packing peanuts when needed
2 °C to 8 °C	Fridge	Box with cold packs and packing peanuts
15 °C to 25 °C	Controlled temperature room	Box with packing peanuts

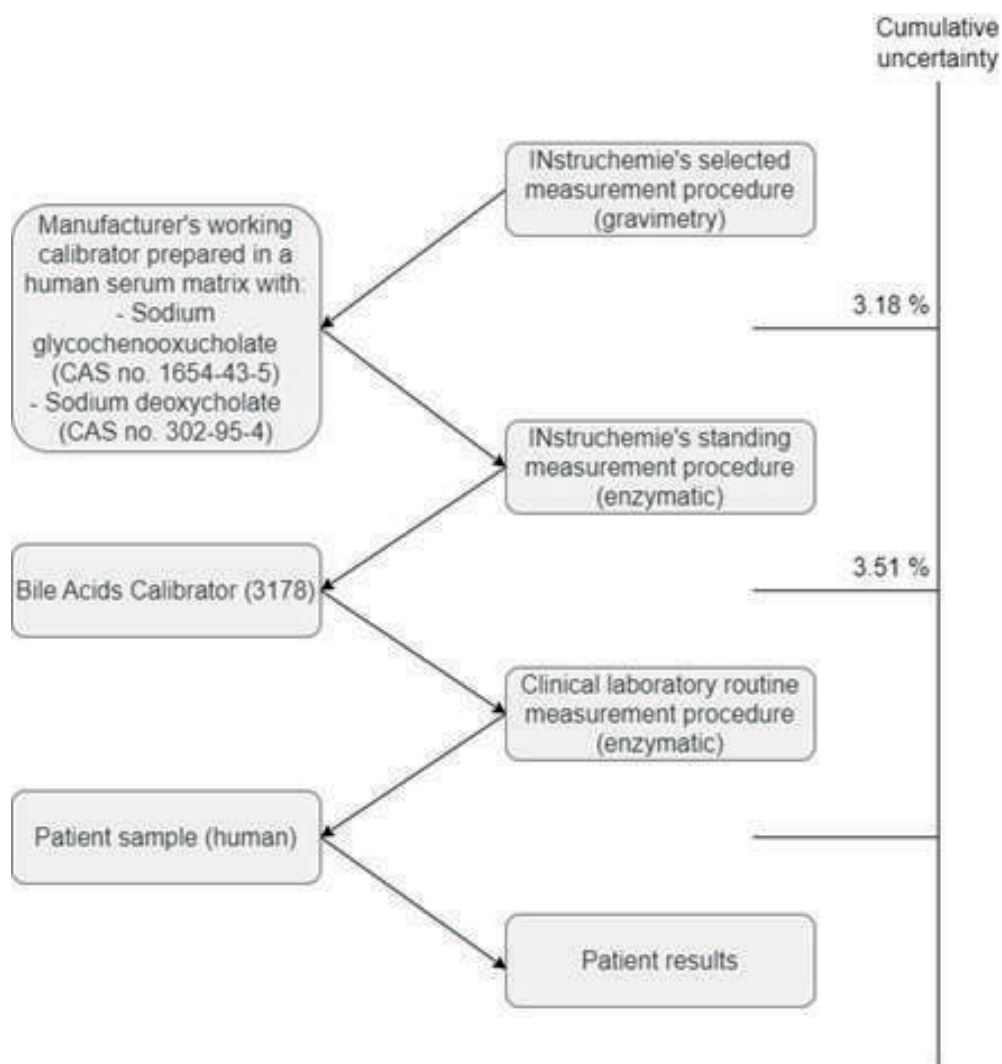
*Conditions are only applicable for products of the InstruChemie brand. Conditions of products distributed by InstruChemie are subject to the guidelines of the manufacturer.

Metrological traceability

The traceability of our calibrators and standards will in the near future be displayed in all of our instructions for use (IFU). By referencing the calibrators and standards to a reference standard of a higher order, INstruChemie ensures optimum accuracy of the patient results.

If necessary and upon request, INstruChemie offers all its customers additional support material by documenting the traceability chain with internal manufacturing documentation, such as a certificate of analysis (CoA), that precisely links the calibrator to the standard of the higher order.

An example of the traceability chain can be found below.



Traceability chain of Bile Acids Calibrator (3178)



Enzymatic Method

Application	Reagent set for the determination of angiotensin-converting enzyme (ACE)
Method	Enzymatic (FAPGG)
Sample material	Serum or heparinized plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3002
Contents	50-250 tests
Calibrator included?	No, can be ordered additionally

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2997	ACE Calibrator Medium Level	10 x 1 ml
2998	ACE Control Low level	10 x 1 ml
2999	ACE Control High level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of acetoacetate
Method	Enzymatic
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C, Calibrator 2 is stored in the freezer and shipped on dry-ice.
Product number	3061
Contents	30-150 tests
Calibrator included?	No, can be ordered additionally

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3060	Acetoacetate AUT Calibrator 2 (on dry-ice)	5 x 1 ml
3062	Acetoacetate AUT Control Medium Level	10 x 1 ml
3063	Acetoacetate AUT Control High Level	10 x 1 ml
3064	Acetoacetate AUT Control Extra High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of aldolase
Method	Enzymatic
Sample material	Serum, heparin plasma or EDTA plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2904
Contents	40-500 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2908	Aldolase Control Normal Level	10 x 1 ml
3007	Aldolase Control High Level	10 x 1 ml

*The expiration date stated on the test kit is only an example.



Enzymatic Method (NADPH)

Application	Reagent set for the determination of ammonia
Method	Enzymatic (NADPH)
Sample material	EDTA plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2230
Contents	24-300 tests
Calibrator included?	Yes

All controls are included in the set



Enzymatic Method

Application	Reagent set for the determination of beta-hydroxybutyric acid (β-HBA)
Method	Enzymatic
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3076
Contents	30-150 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3112	β-HBA & Lactate & Pyruvate AUT Control Low-Normal Level	10 x 1 ml
3113	β-HBA & Lactate & Pyruvate AUT Control High Level	10 x 1 ml
3114	β-HBA & Lactate & Pyruvate AUT Control Extra High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of beta-hydroxybutyric acid (β-HBA)
Method	Enzymatic
Sample material	Serum, heparin plasma or EDTA plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2940
Contents	75-300 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2947	β-HBA Control High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of bile acids
Method	Enzymatic
Sample material	Serum or heparinized plasma
Shelf life	2 years from date of production
Storage	2-8 °C
Product number	3219
Contents	40-160 tests
Calibrator included?	No, can be ordered additionally

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3178	Bile Acids Calibrator	1 x 1 ml
3179	Bile Acids Control Normal Level	1 x 1 ml
3180	Bile Acids Control High Level	1 x 1 ml
3183	Bile Acids Control Extra High Level	1 x 1 ml

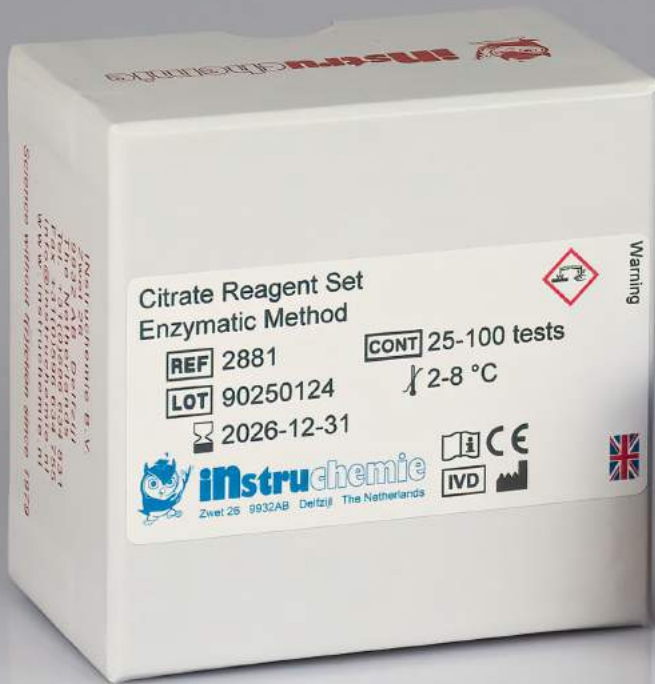


Colorimetric Method

Application	Reagent set for the determination of chymotrypsin
Method	Colorimetric
Sample material	Faeces
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2909
Contents	18-72 tests
Calibrator included?	Yes

Corresponding calibrator(s), control(s) and additional preparation materials

Product no.	Description	Contents
2910	Chymotrypsin Control Low Level	10 x 2 ml
2986	Chymotrypsin Control High Level	10 x 2 ml
2912	Chymotrypsin Solvent Solution	500 ml
2505	Faecal Sample Preparation Set	50 tubes



Enzymatic Method

Application	Reagent set for the determination of citrate
Method	Enzymatic
Sample material	Serum, heparin plasma or urine
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2881
Contents	25-100 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3084	Citrate & Oxalate Control Normal Level	10 x 2 ml
3085	Citrate & Oxalate Control High Level	10 x 2 ml



A collection of our many controls, standards and calibrators





normal/high/extra high level

**Application
Matrix**

Independent control for C-reactive protein (CRP)
Liquid, defibrinated normal human plasma containing stabilisers and spiked with purified CRP.

**Shelf life
Storage**

4 years from date of production
2-8 °C

Suitable for

Routine CRP controls for automated analyzers

Product no.	Description	Contents
2789	CRP Control Extra High Level, approx. 120 mg/l	12 x 1 ml
2790	CRP Control High Level, approx. 47 mg/l	12 x 1 ml
5009	CRP Control Normal Level, approx. 10 mg/l	12 x 1 ml



Point of Care

Application

Independent control for C-reactive protein (CRP) for point-of-care (POC) systems

Matrix

Liquid, defibrinated human plasma containing stabilizers and spiked with purified CRP

Shelf life

4 years from date of production

Storage

2-8 °C

Suitable for

Alere Afinion™ AS100
QuikRead go®
Turbidimetric methods

Product no.

Description

Contents

3037	CRP Control POC Level 1 (approx. 20 mg/l)	12 x 1 ml
3038	CRP Control POC Level 2 (approx. 94 mg/l)	12 x 1 ml
3215	CRP Control POC Level 3 (approx. 66 mg/l)	12 x 1 ml
3118	CRP Control POC Level 1 (approx. 20 mg/l)	10 x 200 µl
3119	CRP Control POC Level 2 (approx. 94 mg/l)	10 x 200 µl
3216	CRP Control POC Level 3 (approx. 66 mg/l)	10 x 200 µl



Enzymatic Method

Application	Reagent set for the determination of free fatty acids (non-esterified fatty acids)
Method	Enzymatic
Sample material	Serum or EDTA plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3055
Contents	20-100 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3052	Free Fatty Acids Control High Level	10 x 1 ml
3053	Free Fatty Acids Control Normal Level	10 x 1 ml
3054	Free Fatty Acids Control Extra High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of glucose-6-phosphate dehydrogenase
Method	Enzymatic
Sample material	EDTA or heparin whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2958
Contents	25-300 tests
Calibrator included?	No, can be ordered additionally

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2971	PK & G6PDH Calibrator	1 x 500 µl
3141	PK & G6PDH Control Deficient Level	1 x 500 µl
3142	PK & G6PDH Control Normal Level	1 x 500 µl
3143	PK & G6PDH Control High Level	1 x 500 µl



Enzymatic Method

Application	Reagent set for the determination of galactose
Method	Enzymatic
Sample material	Whole blood or urine
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2935
Contents	30-450 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2939	Galactose Control Normal Level	1 x 5 ml
3022	Galactose Control High Level	1 x 5 ml
2934	Deproteinization Reagent	1 x 100 ml



Cyanide Free Method

Application	Reagent for the determination of hemoglobin
Method	Cyanide free
Sample material	Capillary or EDTA-venous whole blood
Shelf life	4 years from date of production
Storage	15-25 °C
Product number	2488
Contents	500 ml (approx, 160 tests)
Calibrator included?	No

Calibrators and controls distributed by INstruChemie



Enzymatic Method

Application	Reagent set for the determination of lactate
Method	Enzymatic
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3100
Contents	30-150 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3112	β-HBA & Lactate & Pyruvate AUT Control Low-Normal Level	10 x 1 ml
3113	β-HBA & Lactate & Pyruvate AUT Control High Level	10 x 1 ml
3114	β-HBA & Lactate & Pyruvate AUT Control Extra High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of lactate
Method	Enzymatic
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2864
Contents	25-250 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3005	Lactate & Pyruvate Control Low-Normal Level	10 x 5 ml
2896	Lactate & Pyruvate Control High Level	10 x 5 ml
2933	Deproteinization Reagent	6 x 100 ml



Turbidimetric Method

Application	Reagent set for the determination of lysozyme
Method	Turbidimetric
Sample material	Serum, heparin plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2419
Contents	17-200 tests
Calibrator included?	No

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2411	Lysozyme Standard	10 x 5 ml
3003	Lysozyme Control Low Level	10 x 5 ml
3004	Lysozyme Control High Level	10 x 5 ml



LC-MS Method

Application	Reagent set for the determination of methylmalonic acid
Method	LC-MS
Sample material	Serum, EDTA plasma or lithium heparin plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3200
Contents	96 tests
Calibrator included?	No

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3171	Methylmalonic Acid LC-MS Calibrator set	2 x 6 x 1 ml
3192	Methylmalonic Acid LC-MS Control Low Level	10 x 1 ml
3193	Methylmalonic Acid LC-MS Control Normal Level	10 x 1 ml
3194	Methylmalonic Acid LC-MS Control High Level	10 x 1 ml
3196	Methylmalonic Acid LC-MS Deproteinization Reagent	6 x 50 ml



Enzymatic Method

Application	Reagent set for the determination of oxalate
Method	Enzymatic
Sample material	24 h urine
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3098
Contents	30 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3084	Citrate & Oxalate Control Normal Level	10 x 2 ml
3085	Citrate & Oxalate Control High Level	10 x 2 ml



Enzymatic Method

Application	Reagent set for the determination of oxalate
Method	Enzymatic
Sample material	24 h urine
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2401
Contents	15-20 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3084	Citrate & Oxalate Control Normal Level	10 x 2 ml
3085	Citrate & Oxalate Control High Level	10 x 2 ml



Enzymatic Method

Application	Reagent kit for the determination of phospholipids (lecithin, lysolecithin and sphingomyelin)
Method	Enzymatic
Sample material	Serum, heparin plasma or EDTA plasma
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3009
Contents	50-160 tests
Calibrator included?	No

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3012	Phospholipids Calibrator	1 x 2 ml
3013	Phospholipids Control Low Level	10 x 1 ml
3014	Phospholipids Control Normal Level	10 x 1 ml
3015	Phospholipids Control High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of pyruvate
Method	Enzymatic
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	3040
Contents	30-150 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3112	β-HBA & Lactate & Pyruvate AUT Control Low-Normal Level	10 x 1 ml
3113	β-HBA & Lactate & Pyruvate AUT Control High Level	10 x 1 ml
3114	β-HBA & Lactate & Pyruvate AUT Control Extra High Level	10 x 1 ml



Enzymatic Method

Application	Reagent set for the determination of pyruvate kinase
Method	Enzymatic
Sample material	Heparin or EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2926
Contents	25-300 tests
Calibrator included?	No

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2971	PK & G6PDH Calibrator	1 x 500 µl
3141	PK & G6PDH Control Deficient Level	1 x 500 µl
3142	PK & G6PDH Control Normal Level	1 x 500 µl
3143	PK & G6PDH Control High Level	1 x 500 µl



Enzymatic Method

Application	Reagent set for the determination of pyruvate
Method	Enzymatic
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2897
Contents	40-400 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3005	Lactate & Pyruvate Control Low-Normal Level	10 x 5 ml
2896	Lactate & Pyruvate Control High Level	10 x 5 ml
2933	Deproteinization Reagent	6 x 100 ml



Instrunorm & Instrupath

Application	Independent quality control for the accuracy and precision for a variation of parameters in both the low-normal as well as the high range
Matrix	Serum
Shelf life	4 years from date of production
Storage	2-8 °C

Product no.	Description	Contents
2466	Instrunorm, Low-Normal Level	10 x 2 ml
2467	Instrupath, High Level	10 x 2 ml

Parameters included:

α 1-acid glycoprotein, α 1-antitrypsin, α 1-foetoprotein, α 2-macroglobulin, albumin, antithrombin III, apolipoprotein A1, apolipoprotein B, ASL, β 2-microglobuline, CA 125, CA 15.3, CA 19.9, calcium, CEA, ceruloplasmin, cholesterol, complement C3, complement C4, cortisol, creatinine, CRP, cystatin C, ferritin, folic acid, free fatty acids, FSH, FT3, FT4, haptoglobin, HDL-cholesterol, high-sensitive troponin T, IgA, IgG, IgM, iron, kappa light chain, lambda light chain, LDL-cholesterol, LH, lipoprotein (a), magnesium, NT-pro BNP, osmolality, parathormone, phosphate, potassium, prealbumin, prolactin, protein (total), PSA, testosterone, total bile acids, transferrin, triglyceride, TSH, urea, uric acid, vitamin B12, zinc.



Urinorm & Uripath

Application

Independent quality control for the accuracy and precision for a variation of parameters in both the normal and abnormal range

Matrix

Urine

Shelf life

4 years from date of production

Storage

-20 °C

Product no.	Description	Contents
2170	Urinorm	10 x 10 ml
2171	Uripath	10 x 10 ml

Parameters included:

albumin, amylase, calcium, adrenaline, noradrenaline, dopamine, chloride, creatinin, δ -ALA, glucose, 5-HIAA, HVA, hydroxyproline, 17-ketosteroids, magnesium, metanephrines, 17-OH-steroid, osmolality, phosphorus, porphobilinogen, porphyrins, potassium, protein (total), sodium, urea, uric acid, VMA, blood, protein, glucose



HPLC Method

Application	Reagent set for the determination of vitamin A (retinol) and E (α -tocopherol)
Method	HPLC - UPLC
Sample material	Serum
Shelf life	4 years from date of production
Storage	2-8 °C
Product number	2795
Contents	50-70 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
2840	Vitamin A & E Control Low Level	1 x 1 ml
2841	Vitamin A & E Control Normal Level	1 x 1 ml
2842	Vitamin A & E Control High Level	1 x 1 ml
3209	Vitamin A, Internal Standard	1 x 2 ml
3210	Vitamin E, Internal Standard	1 x 2 ml



LC-MS method

Application	Reagent set for the determination of vitamin B1 (thiamine) and B6 (pyridoxal 5'-phosphate)
Method	LC-MS
Sample material	EDTA whole blood
Shelf life	4 years from date of production
Storage	2-8 °C / -20 °C
Product number	3158
Contents	96 tests
Calibrator included?	No, can be ordered additionally

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3168	Vitamin B1 & B6 LC-MS II Calibrator Set	2 x 6 x 500 µl
3159	Vitamin B1 & B6 LC-MS Control Low Level	10 x 500 µl
3160	Vitamin B1 & B6 LC-MS Control Normal Level	10 x 500 µl
3161	Vitamin B1 & B6 LC-MS Control High Level	10 x 500 µl



Water LC-MS/UPLC/HPLC Grade
0.055 μ S/ 18.2 M Ω

REF 2195

CONT 1000 ml

LOT 56120122

15-25 °C

2026-01-31



instruchemie****
Zwet 26, 9932AB, Delfzijl, The Netherlands



IVD

HPLC, UPLC & LC-MS grade

Application

Demineralized water for the use in HPLC, UPLC and LC-MS systems

Shelf life

0,5 years from date of production

Storage

15-25 °C

Product number

2195

Contents

1 liter



Colorimetric Method

Application	Reagent set for the determination of zinc without deproteinization step
Method	Colorimetric
Sample material	Serum, heparin plasma or urine
Shelf life	4 years from date of production
Storage	15-25 °C
Product number	3106
Contents	50-250 tests
Calibrator included?	Yes

Corresponding calibrator(s) and control(s)

Product no.	Description	Contents
3031	Zinc Serum Control Low Level	1 x 3 ml
3032	Zinc Serum Control High Level	1 x 3 ml
3033	Zinc Urine Control Low Level	1 x 3 ml
3034	Zinc Urine Control High Level	1 x 3 ml



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