Anexa nr. 39 Analizator biochimic automat 300 teste, Cod 150220

Specificarea tehnică solicitată	Specificarea tehnică deplină ofertata, model **Selecta Mach5** (Elitech Group/Olanda)
Analizator biochimic, automat 300 teste, cu sistem de Cod 150220 Descriere Analizator automat destinat analizelor biochimice. Sistem analitic automat cu calculator integrat sau exterior (procesor, monitor, tastatura+mouse) Tip de lucru continuu Tip sistem randoom acces Capacitatea (teste/oră) ≥ 300 (teste fotometrice, fără modulul ISE) Posibilitatea efectuării analizelor urgente obligatoriu Tipul dispozitivului staționar Tip probă Ser și plasmă, urină sînge integru / hemolizat CSF (lichid cefalo-rahidian) Tip diluare automat Sistem de spălare total automat (cuvă, ac, sistem de dozare) obligatoriu Program control al calității obligatoriu Compartiment reactivi cu răcire Rotor cu cuve pentru reacție cu încălzire cu termostat la 37 °C Rotor cu cuve pentru reacție de tip reutilizabil obligatoriu, (indicați ciclurile posibile de reutilizare) Regimuri de măsurare Cinetic Mono și bi-cromatic Imunoturbidimetrc Controlul cantității de reagent rămas Semnalizare lipsă reagent și probă Sistemul de dozare Reagenții Utilizarea a minim 2 metode: mono și bireagent Volumul reagentului programabil cu pasul 1 µl Sistemul de dozare Cu sensor de obstacol Alimentarea 220 V, 50 Hz	Analizator biochimic, automat 300 teste, cu sistem de Cod 150220 Descriere Analizator automat destinat analizelor biochimice cu sistem deschis de reactivi. Sistem analitic automat cu calculator integrat (procesor, monitor, tastatura+mouse), *pag. 4 Selectra Mach5 Brochure* Tip de lucru continuu - **CONTINUOUS REAGENT AND SAMPLE** **LOADING, pag. 4 Selectra Mach5 Brochure** Tip sistem randoom acces – da pag.4 **Selectra Mach5 Brochure.** Capacitatea (teste/oră): 340 to 680 photometric TPH/m2 (teste fotometrice, fără modulul ISE), 4 **Selectra Mach5 Brochure;** Posibilitatea efectuării analizelor urgente da – STAT capability - **pag. 4 Selectra Mach5 Brochure** Tipul dispozitivului staționar – da, benchtop, **pag. 4 Selectra Mach5 Brochure** Tip probă Ser și plasmă, urină – da, **pag. 4 Selectra Mach5 Brochure** sînge integru / hemolizat - **pag. 4 Selectra Mach5 Brochure;** CSF (lichid cefalo-rahidian) - **pag. 4 Selectra Mach5 Brochure;** Tip diluare automat: **automatic onboard dilution, pag. 4 Selectra Mach5 Brochure** Sistem de spălare total automat (cuvă, ac, sistem de dozare da Program control al calității, da Compartiment reactivi cu răcire, da Rotor cu încălzire pentru probe cu termostat la 37 grade C Cuvă pentru probe reutilizabil da, (indicați ciclurile posibile de reutilizare) – 10000 cicluri Regimuri de măsurare Cinetic da, **pagina 188 din Manual de utilizare 8.4.2 Tests screen - General page Mode - The available test methods:** **Kinetic: A continuous measurement of the reaction rate (dAbs/m).** Mono și bi-cromatic da, **pagina 191 din Manual de utilizare 8.4.4 Tests screen - Measurement page Wavelength 1 and Wavelength 2 - Select the wavelength(s) to be used in the calculation of absorbance results. For bichromatic tests, two wavelengths must be selected. If only Wavelength 1 is entered, a monochromatic test is done.** Imunoturbidimetrc da, pag. **pagina 1 din instructiunile de utilizare atasate pentru (CRP IP, ANTI-STREPTOLYSIN O), METHOD & PRINCIPLE Latex-enhanced immuno-turbidimetry – End Point** Controlul cantității de reagent rămas da Semnalizare lipsă reagent și probă da Sistemul de dozare Reagenții Utilizarea a minim 2 metodici: mono și bireagent Volumul reagentului programabil cu pasul 1 µl, da Sistemul de dozare Cu sensor de obstacol, da Alimentarea 220 V, 50 Hz, da

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra Mach5. Make Work Flow

14/01/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra Mach5: Basic Application Specialist Training

14/01/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra Mach5: Basic Troubleshoot Training

03/04/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			Selectra						
DM000306836	ANALIZATOR BIOCHIMIC AUTOMAT		SELECTRA MACH5	6004-301	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000110	17-05-2021

EU Declaration of Conformity

ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

declares under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of:

- Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *In vitro* diagnostics medical devices ("IVD Regulation")
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS2 Directive"), including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances ("RoHS3").

It is certified that this product is registered in accordance with the requirements of above-mentioned EU Regulations/Directives and carries the CE-marking.

Catalogue number	Description	GTIN
6004-301	Selectra Mach5	0 3661540 60054 8

Product	**Multiple clinical chemistry analyzer IVD, laboratory, automated**
SRN	**TBD**
Risk Class	**A**
GMDN code	**56676**
Accessories	**See Annex**

Product classification
As per Article 48, section 10 the products are categorized as class A device ("self-declaration").

Conformity assessment procedure
In accordance with:

- Article 18 of the IVD Regulation
- Article 4 of the RoHS2 Directive

Spankeren, January 2021

M.A.S.V.E. Verdaasdonk
Managing Director

EU Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010, AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	UL
	IEC 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-051:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring.	
	IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
	UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1. General requirements	UL
EMC	IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	DEKRA
	IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA

Annex – List of IVD accessories

Catalogue number	Description	GTIN
3201-019	Precision Test Solution	0 3661540 60042 5
6004-338	Drying Block Set	0 3661540 60470 6
6004-351	Cuvette rotor set (3 pieces)	0 3661540 60043 2

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

***Edit* -** Edit the test parameters of the selected test. You cannot edit a test if it is mentioned in a worklist. Reagents may remain loaded.

***Delete* -** Delete the selected test. You can only delete tests that are not being used elsewhere in the system. If the deleted test was linked to a calibrator or control, it will automatically be unlinked. If the deleted test was included in a panel, it will be removed from the panel.

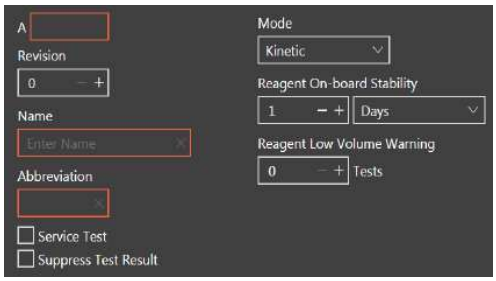
***Accept* -** Confirm the changes in all test configuration pages.

***Cancel* -** Discard the changes in all test configuration pages.

See also:
'Importing data' on page 5-46
'Exporting data' on page 5-47
'System Parameters screen' on page 8-36

8.4.2 Tests screen - General page

Fields



Test Code - A three-digit code that represents the test in the analyzer software. The character in front of the code indicates the creator, Predefined tests are identified by a digit or by D (distributor) or S (service). User-defined tests are identified by A (administrator).

***Revision* -** The version number of the test, with a maximum of 9.

***Name* -** The test name, with a maximum of 20 characters. This name appears in screens and reports. When this page shows the word 'closed' after the name of the test, the test is predefined and cannot be fully edited at administrator (or lower) user level.

***Abbreviation* -** A unique abbreviated test name, with a maximum of 4 characters. This name is used in lists, on buttons and in other places where space is limited.

***Service Test* -** When selected, the test is not included in communications with an optional LIS (the test cannot be requested from the LIS and no results are passed to the LIS when the test is requested manually). This option is used for tests that have no diagnostic function but are scheduled for servicing and maintenance of the system.

***Suppress Test Result* -** When selected, the test results are ignored. They are excluded from reports and are not sent to the LIS.

***Mode* -** The available test methods:

- ***Kinetic***: A continuous measurement of the reaction rate (dAbs/m)
- ***Two-Point***: Difference between two specified points (dAbs)
- ***End-Point***: Measurement at the end of the reaction (Abs)

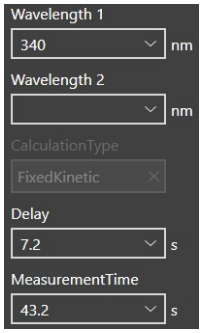
***Reagent On-board Stability* -** Reagent usage period, in days or hours, after loading on the rotor. Maximum is 90 days.

See also:
'Calibrators screen - General page' on page 8-22
'Calibrators screen - Lot page' on page 8-22
'Z - Duplicate Difference Limit Error' on page 7-9

8.4.4 Tests screen - Measurement page

The fields shown in this page depend on the selected test ***Mode*** in the ***General*** page.

Kinetic and Two-Point tests



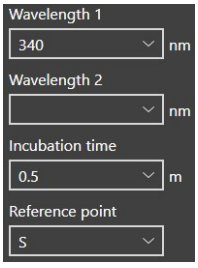
Wavelength 1 **and** ***Wavelength 2*** **-** Select the wavelength(s) to be used in the calculation of absorbance results. For bichromatic tests, two wavelengths must be selected. If only ***Wavelength 1*** is entered, a monochromatic test is done.

Mode **-** The test mode selected in the ***General*** page.

Delay **-** Select the delay (in seconds) between pipetting the sample (or the last reagent in case of multi-reagent tests) and the first measurement.

Measurement Time **-** Select the minimum duration (in seconds) covered by the measurement (from the time specified by ***Delay*** to the last measurement).

End-Point tests



Wavelength 1 **and** ***Wavelength 2*** **-** Select the wavelength(s) to be used in the calculation of absorbance results. For bichromatic tests, two wavelengths must be selected. If only ***Wavelength 1*** is entered, a monochromatic test is done.

Incubation Time **-** Select the time between pipetting the sample (or the last reagent in case of multi-reagent tests) and the measurement.

Reference Point **-** Measurement point used as baseline in the calculation of the result. S means the point just **before** sample is added, R2/R3/R4 means just **before** reagent 2/3/4 is added. If you want to calculate using the point **after** addition of the last ingredient, select ***Mode Two-Point***.

selectra MACH

ANTI-STREPTOLYSIN O

ASLO
ASLO-0250
R1 : 2 x 25 mL
R2 : 1 x 6 mL
Cal : 1 x 1 mL
☛ASLO-5025 R1 : 25 mL
☛ASLO-6006 R2 : 6 mL
☛ASLO-4001 Cal : 1 mL

CE

PIMAC-ASLO-EN-V3 (04/2023)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of anti-streptolysin-O in human serum and plasma samples on Selectra Mach Series analyzers.

The calibrator is intended for the calibration of the reagent.

These *in vitro* diagnostic devices are for professional use only.

CLINICAL SIGNIFICANCE [1]

Streptolysin-O (SLO) is a toxin produced by ß-hemolytic streptococci of groups A, C and G.
Determination of SLO antibodies (ASLO or ASO) is used to help diagnose complications following a group A streptococcal infection such as rheumatic fever or acute glomerulonephritis.

LIMITATION OF USE

Confirmation of streptococcal infection requires two determinations separated by one to two weeks.[2]
The simultaneous determination of anti-streptodornase antibody is recommended to improve diagnostic specificity [1]
The quantitative assay of anti-streptolysin-O alone can not be used to diagnose a disease or a specific pathology.
The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE

Latex-enhanced immuno-turbidimetry – End Point.

When anti-streptolysin O antibodies are present in the sample, they combine with recombinant streptolysin O-coated latex beads. These complexes agglutinate leading to an increase of turbidity measured at 546 nm.

☛COMPOSITION

Reagent 1: R1
Buffer, pH 8.2
Preservative
Reagent 2: R2
Latex particles coated with recombinant streptolysin O, pH 8.2
Preservatives
Calibrator: Cal
Lyophilized calibrator prepared from human serum.
The value is lot-specific.

MATERIALS REQUIRED BUT NOT PROVIDED

- IRCT-0046 RHEUMATOLOGY CONTROL I
- IRCT-0047 RHEUMATOLOGY CONTROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

☛PRECAUTIONS OF USE AND WARNINGS

- The reagent **R1** is classified as hazardous :

WARNING : May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

- The reagent **R2** is classified as hazardous :

DANGER : May damage fertility. May damage the unborn child. Wear protective gloves/protective clothing/eye protection/face protection. Do not handle until all safety precautions have been read and understood. IF exposed or concerned: Get medical advice/attention.

Obtain Safety data sheet (SDS) before use for a proper handling.
- The reagent contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Each unit of human blood used in the manufacture of the calibrator was tested and found to be negative/non-reactive for the presence of HbsAg, HCV and HIV1/2.

The methods used were FDA-approved or CE compliant. Nevertheless, since the risk of infection cannot be fully excluded these products must be handled as potentially infectious. In case of exposure, follow the guidelines of the competent health authorities.
- Take precautions when handling broken glass vials as sharp edges can injure the user.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Do not interchange reagent vials from different kits.

STABILITY

Reagent / Calibrator:
Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
Reagent:
On board stability : 8 weeks.
Calibrator:
The calibrator should be immediately and tightly capped to prevent contamination and evaporation
Stability of calibrator after reconstitution:
Calibrator is stable for 1 month when stored at 2-8 °C or 3 months at -20°C.

PREPARATION

Reagent:
The device is ready to use. Before installing, homogenize the reagent bottles by successive inversions.

Calibrator:
Carefully open the bottle avoiding loss of lyophilizate.
Add exactly 1 mL of distilled or deionized water.
Carefully close the vial and dissolve the contents completely by occasional gentle stirring avoiding the formation of foam.
Keep at room temperature for 10 minutes before use.

PRODUCT DETERIORATION

Reagent:
- The reagent R1 is a clear liquid. R2 is a milky liquid.
- Any presence of particles or turbidity would be a sign of deterioration.
Calibrator:
- Calibrator should be clear after reconstitution. Cloudiness would indicate deterioration.
Reagent / Calibrator:
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the device container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimen[3]
- Serum
- Plasma (Lithium heparin)
- Using any other specimen type should be validated by the laboratory.
Warnings and precautions
According to Good Laboratory Practice, sampling should be performed prior to the administration of drugs.
Storage and stability [3]
- Samples with presence of fibrin should be centrifuged before testing.
- 2 days at room temperature
- 8 days at 2-8°C
- 6 months at -20°C

REFERENCE VALUES [1,4]

Serum/plasma	IU/mL
Children	≤ 240
Adults	≤ 250

ASO levels are age-dependent and change with geographic location and with the local frequency of streptococcal infections.

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

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INSTALLATION AND USE

Consult Selectra Mach operator manual.
Special Programming instructions: Programming special instructions is mandatory when some combinations of tests are performed together on the analyzer. Refer to Instructions For Use of WASH SOLUTION A & WASH SOLUTION B for adequate programming (See PIMAC-WASH).

PROCEDURE

For importing the test parameters, an import file is available on request.
Please contact your local distributor for details.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION

ANTI-STREPTOLYSIN O CALIBRATOR is traceable to the WHO's "1st International Standard for ASO".
The value, specific for each lot is indicated on the vial label and in the value sheet (PITV-ASLOCa) available on the website: www.elitechgroup.com
The value is determined and validated by ELITech Clinical Systems SAS on ELITech Clinical Systems Analyzers using ELITech Clinical Systems ANTI-STREPTOLYSIN O reagent.

Calibration frequency : 4 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL

It is recommended that quality control sera such as RHEUMATOLOGY CONTROL I and RHEUMATOLOGY CONTROL II should be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

20 - 1000 IU/mL
Samples having greater concentrations will automatically be diluted 1:5 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 2000 IU/mL
Do not report results outside this extended range.

- Hook effect

No hook effect up to 2000 IU/mL.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

LoD : 10 IU/mL
LoQ : 20 IU/mL

- Precision

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented below.

		Mean	Within-run	Total
	n	IU/mL	CV (%)	
Level 1	80	97	2.5	6.0
Level 2	80	195	1.7	4.4
Level 3	80	418	1.0	4.5

- Correlation

A comparative study has been performed between ANTI-STREPTOLYSIN O reagent on a Selectra Mach5 analyzer and a similar commercially available system on 72 human serum samples.
The sample concentrations ranged from 21 to 943 IU/mL.
The results are as follows :
Correlation coefficient : (r) = 0.998
Linear regression: y = 0.985 x + 0 IU/mL.

- Limitations/Analytical interferences

- Studies have been performed to determine the level of interference from different compounds.
The following anti-streptolysin O levels were tested: 100 IU/mL and 400 IU/mL.
A no significant interference is defined by a recovery ≤± 10% of the initial value.
Conjugated bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L).
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L).
Hemoglobin: No significant interference up to 500 mg/dL
Triglycerides: No significant interference up to 3000 mg/dL. (33.9 mmol/L).

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[5]

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[6-7]

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device.
For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

BIBLIOGRAPHY

1. Pasteur CERBA. Guide des examens spécialisés, 5th Edition, (2007).

2. Wu, A. H. B., Clinical guide to laboratory tests, 4th Ed., (W.B. Saunders eds.), (2006), 1528.

3. Guder, W.G., *et al., Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples.* (2002). WHO/DIL/LAB/99.1 Rev.2.

4. Kaplan, E.L., *et al*., Pediatrics, (1998), **101**, 86.

5. Berth, M. & Delanghe, J., *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
6. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
7. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

☛SYMBOLS

Symbols used on our documentation are defined on ISO-15223-1 standard, except for some presented in the symbols glossary available on the ELITech Website. (Symbols glossary).

TECHNICAL ASSISTANCE:

Contact your local distributor or ELITech Clinical Systems SAS
(ccsupport@elitechgroup.com).

ELITech Clinical Systems SAS
Zone Industrielle - 61500 SEES FRANCE
www.elitechgroup.com

selectra MACH

CRP IP

ICRP
ICRP-M230
R1 : 2 x 26 mL
R2 : 1 x 9 mL

CE

PIMAC-ICRP-EN-V1 (12/2020)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of C-reactive protein in human serum and plasma samples on Selectra Mach Series analyzers.

This *in vitro* diagnostic reagent is for professional use only.

CLINICAL SIGNIFICANCE [1-3]

C-reactive protein (CRP) is a non-specific protein of the acute phase of the inflammation process. Present at very low concentrations in healthy persons, CRP concentration is increased in numerous pathologies such as infections, inflammatory diseases or trauma, myocardial infarction and tumors.
In clinical practice, CRP is indicated to help in the diagnosis and follow-up of an infection or an acute or chronic inflammation.

LIMITATION OF USE

- Not intended for an evaluation of cardiovascular risk (CRP < 10 mg/L).
- The quantitative assay of C-reactive protein alone can not be used to diagnose a disease or a specific pathology.
- The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE

Immuno-turbidimetry - End Point.

The formation of CRP / anti-CRP antibody complexes is started by the addition of the antiserum to the sample in presence of an accelerator. These complexes agglutinate leading to an increase of turbidity measured at 340 nm.

COMPOSITION

Reagent 1: R1
Buffer, pH 7.43
Accelerator
Sodium azide < 0.1 % (w/w)
Reagent 2: R2
Buffer, pH 7.43
Polyclonal anti-human CRP antibody (goat)
Sodium azide < 0.1 % (w/w)

MATERIALS REQUIRED BUT NOT PROVIDED

- ICRP-0043 CRP IP CALIBRATOR SET
- IRCT-0046 RHEUMATOLOGY CONTROL I
- IRCT-0047 RHEUMATOLOGY CONTROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS

- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- The reagents contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Consult Safety Data Sheet (SDS) for a proper handling.
- Do not interchange reagent vials from different kits.

STABILITY

Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
On board stability : 8 weeks.

PREPARATION

The device is ready to use.

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the reagent container may impact on product performance. Do not use the reagent if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimens required [2]
- Serum
- Plasma (lithium heparin)
- Using any other specimen type should be validated by the laboratory.

Warnings and precautions
Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.
Storage and stability [4]
- 11 days at room temperature.
- 2 months at 2-8°C.
- 3 years at -20°C.

REFERENCE VALUES [2-3]

Serum/plasma	mg/dL	mg/L
Adults	≤ 1.0	≤ 10

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

INSTALLATION AND USE

Consult Selectra Mach operator manual.
Programming of special washes : Use of special wash steps is mandatory when some combinations of tests are performed together on the analyzer. For more information on required special wash steps, please refer to instructions for use PIMAC-WASH.

PROCEDURE

The application is included in the 2D barcode on this insert.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION

Calibrators from CRP IP CALIBRATOR SET are traceable to ERM-DA474/IFCC reference material.
Calibration frequency : 4 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL

It is recommended that quality control sera such as RHEUMATOLOGY CONTROL I and RHEUMATOLOGY CONTROL II be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

4.0-190.0 mg/L (0.40 - 19.00 mg/dL)
Samples having greater concentrations will automatically be diluted 1:5 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 860.0 mg/L (86.00 mg/dL).
Do not report results outside this extended range.

- Hook effect

No hook effect up to 860.0 mg/L (86.00 mg/dL)

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- Limit of Detection (LoD) and Limit of Quantification (LoQ)

LoD : 0.3 mg/L (0.03 mg/dL)
LoQ : 2.0 mg/L (0.20 mgld/L)

- Precision

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented in the following table.

		Mean		Within-run	Total
	n	mg/L	mg/dL	CV (%)	
Level 1	80	5.7	0.57	5.8	16.7
Level 2	80	39.7	3.97	3.8	7.1
Level 3	80	125.8	12.58	2.3	5.2

- Correlation

A comparative study has been performed between CRP IP reagent on a Selectra Mach5 analyzer and a similar commercially available system on 80 human serum samples.
The sample concentrations ranged from 4.1 to 196.5 mg/L (0.41 - 19.65 mg/dL).

The results are as follows :
Correlation coefficient : (r) = 0.992
Linear regression: y = 0.982 x + 0.6 mg/L (0.06 mg/dL).

- Limitations/Analytical interferences

- Studies have been performed to determine the level of interference from different compounds.
The following C-reactive protein levels were tested: 6 mg/L and 40 mg/L.
No significant interference is defined by a recovery ≤± 2.4 mg/L of the initial value at CRP concentration of 6 mg/L and ≤± 15 % of initial value at CRP concentration of 40 mg/L.
Hemoglobin : No significant interference up to 500 mg/dL.
Turbidity : No significant interference up to 400 mg/dL of triglycerides equivalent (5 mmol/L).
Unconjugated bilirubin : No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated bilirubin : No significant interference up to 29.5 mg/dL (505 µmol/L).

- Do not use turbid samples.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[5]

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[6-7]

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

BIBLIOGRAPHY

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2. Sanhai, W.R., *et al*., *Cardiac and Muscle Disease*. Clinical Chemistry: Theory Analysis, Correlation, 5th Ed., Kaplan, L.A., Pesce, A.J., (Mosby, Inc. eds.), (2010), 677 and appendix.
3. Wu, A.H.B., Clinical guide to laboratory tests, 4th Ed., (W.B. Saunders eds.), (2006), 190.
4. Guder, W.G., et al., *Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples*. (2002). WHO/DIL/LAB/99.1 Rev.2.
5. Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
6. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
7. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

SYMBOLS

Symbols used are defined in ISO 15223-1 standard, except those presented bellow :

CONT	Content
R1	Reagent 1
R2	Reagent 2
☛	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE:

Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

ICRP

Place for 2D barcode

ELITech Clinical Systems SAS
Zone Industrielle - 61500 SEES FRANCE
www.elitechgroup.com

Clinical Systems

selectra

MACH 5

Make work flow

ELITechGroup

EMPOWERING IVD

Selectra **Mach®5**

An innovative benchtop solution to match your laboratory's needs now and into the future

- Quality and sturdiness – synonymous with the Selectra brand
- Maximum efficiency through consolidation of routine and special testing
- The accuracy required to help clinicians provide the best patient outcomes
- Economical benchtop solution

Now, how can Selectra Mach®5 add additional value for your clinical chemistry laboratory?

Choose your next benchtop system wisely

When choosing the right solution for your clinical chemistry laboratory, features that directly impact your laboratory's productivity will be critically important.

You will look for the best option to complete your workload with the existing or even less resources.

Simply making side by side comparisons of published technical specifications does not provide the critical information for your unique situation.

An integrated approach, that combines the critical productivity elements in a benchtop system, provides the additional insight required to make your work flow.

An integrated approach to benchtop system efficiency: The Benchtop System Workflow Index™

Efficient workflow depends on much more than a system's published specifications

Benchtop System Workflow (BSW) Index is a different way to compare the overall efficiency of benchtop systems using published specifications

The higher the BSW Index™, the more efficient the workflow in your laboratory

$$\frac{\text{SAMPLE CAPACITY \%}^{1} \times \text{ONBOARD MENU CAPACITY \%}^{2} \times \text{TPH}_{CALC}{}^{3}}{100} = \textbf{BSW INDEX}$$

1 Sample Tray Capacity divided by the capacity needed to perform your daily workload.

2 Onboard Menu Capacity divided by the capacity needed to load your complete routine test menu.

3 Calculated theoretical Tests Per Hour performing your typical daily workload.

How the BSW Index works

The BSW Index assesses the overall workflow in a lab by incorporating three productivity elements of the benchtop system.

In short, it is a measure of benchtop speed ("calculated Tests Per Hour") combined with measurements of benchtop-staff interactions during instrument operating time.

The higher the BSW Index, the more efficient the workflow in your laboratory

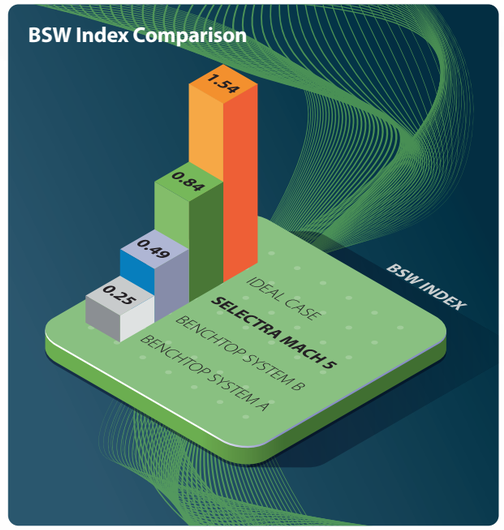
Let's look at the following scenario:

A routine clinical chemistry laboratory needs a new benchtop clinical chemistry system. Demand is expected to grow to 300 samples/day, requiring a menu of 40 parameters[3], with an average of 12 tests/sample. The laboratory is operational 12 hours/day.

A "top 3" of benchtop systems is selected, based on published specifications meeting the current and future productivity needs: Selectra Mach5, Benchtop system A and Benchtop system B.

To determine which system will be most efficient, the BSW Index for all 3 systems is calculated.

Conclusion: for this laboratory, the Selectra Mach5 would be the best fit.



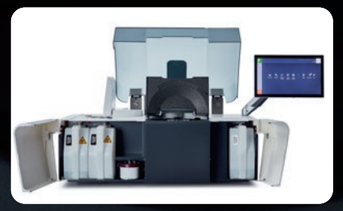
The values for the Ideal Case and the 3 selected instruments are displayed in the table below:

Top 3 selected Benchtop Systems:	SELECTRA MACH5	SYSTEM A	SYSTEM B	IDEAL CASE[1]
SAMPLE CAPACITY	83	40	50	110 (C[2])
ON BOARD REAGENT CAPACITY[3]	68	50	100	100 (B)
CALCULATED TPH (based on cycle time values)	314	270	216	300
BSW INDEX	0.84	0.25	0.49	1.54

1. The Ideal Case is calculated by selecting the maximum score for each efficiency element, from all the instruments used in the comparison, and the desired throughput (in this case 300 Tests Per Hour).
2. Instrument C has the most optimal sample capacity but, because of insufficient throughput, did not make the short list.
3. Reagent positions required for the selected menu for non-ELITech Systems are based on publicly available information. For the Selectra Mach5, 70 reagent positions are required for the selected test menu.

Make work flow with Selectra Mach®5. A new approach to benchtop system efficiency

Other key features of the Selectra Mach®5



System completeness: Unlike many other systems, Selectra Mach®5 has everything included in the system, minimizing footprint. A built-in computer system including touchscreen monitor enabling better cyber security. An integrated supply of system liquid, simplifying system handling for the operator, or, in other words, optimizing human-system interventions.

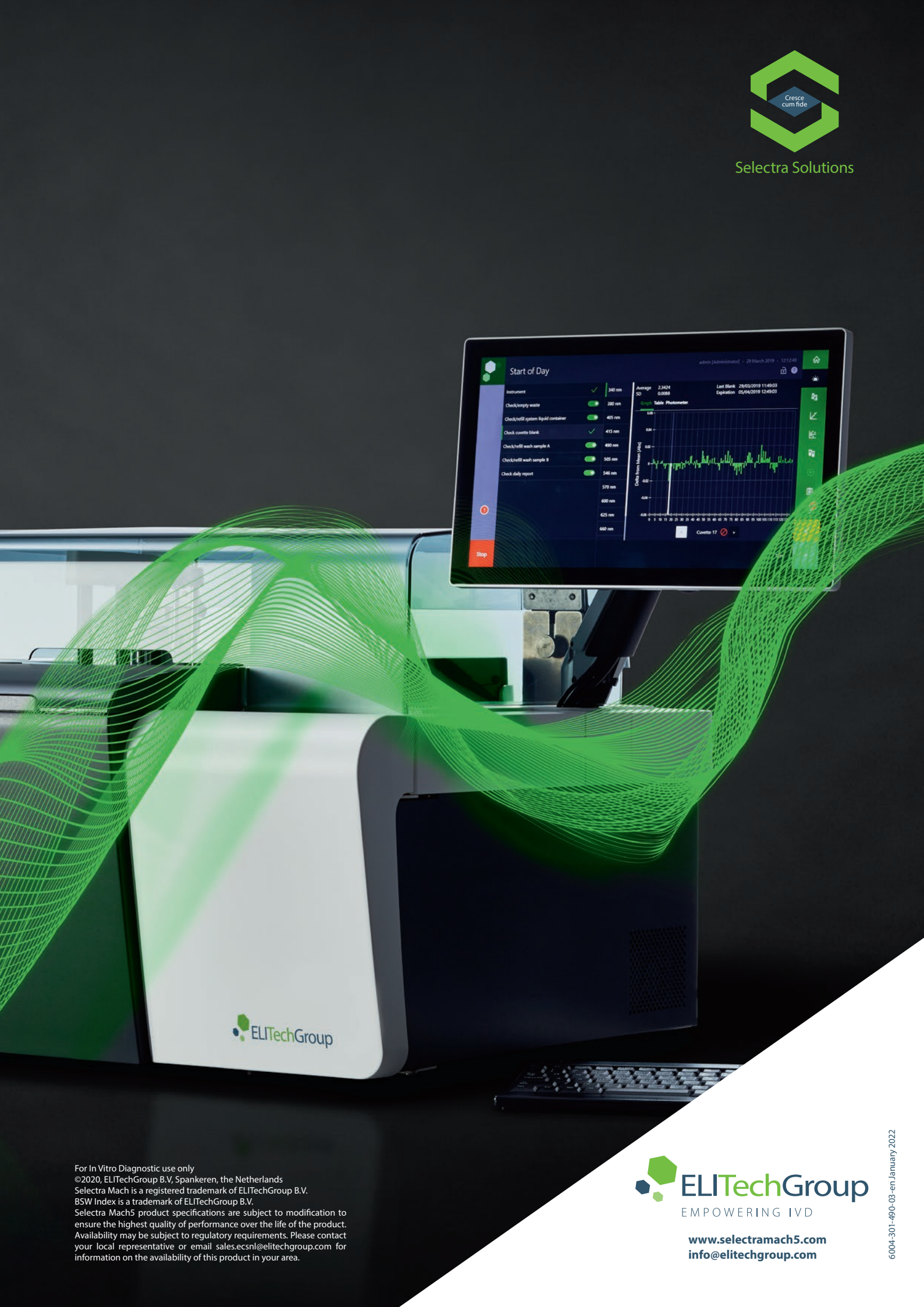
Water usage: Selectra Mach5 has an onboard water capacity of 10L and typically uses up to 2.5L/h. The system is designed to perform efficiently, therefore both the water and waste containers can be replaced without interrupting the analytical process.

Photometric module: The unique photometers of Selectra Mach5 are LED-based and have a significantly longer life span than the halogen lamp in lamp-based photometers used in many other clinical chemistry systems. Moreover, the LED photometric cartridge technology provides more flexibility and adaptability for future assay developments, as up to 16 individual LED photometer cartridges with a specific wavelength can be accommodated (12 included as standard).

GENERAL SPECIFICATIONS

INSTRUMENTS	
SYSTEM	Fully automated, random access, benchtop clinical chemistry system with STAT capability
COUNTRY OF ORIGIN	Netherlands
DIMENSIONS	105 cm (w) x 70 cm (d) x 65 cm (h)
WEIGHT	110 Kg
OPERATING ENVIRONMENT	Between 15-32 °C; 30-85 % relative humidity (non condensing); and up to 3,000 m above sea level
INTEGRATED PLATFORM	Instrument with inbuilt PC, software, reagents, calibrators, controls and consumables
ANALYSIS MODES	Quantitative, Semi-Quantitative and Qualitative
ASSAY TYPES	Quantitative Kinetic Rate, Fixed Point Rate, End Point; Semi-quantitative; and Qualitative (cut-off)
ASSAY TECHNOLOGIES	Colorimetric (UV-Visible spectra), Turbidimetric
TEST MENU	
PROGRAMMABLE TESTS	1,000
ON BOARD REAGENT CAPACITY	Up to 65 Bar Code Readable (BCR) positions, cooled at 8 ± 4 °C
ON BOARD TEST CAPACITY	At least 39 Parameters when using ELITechGroup system reagents
SYSTEM REAGENT MENU	At least 40 CE marked system reagents
USE OF THIRD PARTY REAGENTS	Yes, capability of running third party assays not available from ELITechGroup
WORK FLOW	
PRIMARY TUBE SAMPLING	Primary- tube diameter ranging from 12 to 16 mm and a height ranging from 75 to 100 mm
CONTINUOUS REAGENT AND SAMPLE LOADING	Yes, samples and reagents, via dedicated sample and reagent access covers (maximum pause time for sample of 2 minutes)
ON BOARD SAMPLE CAPACITY	85 sample positions. 65 BCR and 20 auxiliary positions (inner ring)
THROUGHPUT RANGE (PHOTOMETRICS)	250 to 500 photometric TPH
THROUGHPUT /M²	340 to 680 photometric TPH/m^2
TIME TO FIRST RESULT (PHOTOMETRICS)	< 5 minutes when using ELITech system reagents (assay dependent)
STAT LOADING	Utilising pause function, so no interruption to tests already in progress
AUTOMATIC REPEAT TESTING	Yes, automatic onboard dilution of out of range results
WALK AWAY TIME	Up to 4 hours using ELITechGroup system reagents
VALIDATED SAMPLE TYPES	Serum, Plasma, Whole Blood and Urine (assay dependent)
SAMPLE INTEGRITY	Sample clot detection
SAMPLE AND REAGENT IDENTIFICATION	Inbuilt BCR for risk free loading of samples and reagents
SYSTEM CONTROL	
OPERATING SYSTEM	Windows 10 based operating system
USER COMMANDS	15.6 inch capacitance Touch and Swipe screen, resolution 1366 x 768 pixels and widescreen (16:9) aspect ratio
APPLICATIONS	Automatically downloaded from 2D barcode on IFU with handheld BCR
CONTROL AND CALIBRATOR DATA	Automatically downloaded from 2D barcode on IFU with handheld BCR
STATUS DISPLAY	Instrument status, time for completion are displayed in real time
START UP PROCEDURE	System can be programmed for automated start up outside routine hours to prevent interruptions to workflow
SHUT DOWN PROCEDURE	System can be programmed for automated shut down outside routine hours to prevent interruptions to workflow
STORAGE CAPACITY	256 GB solid state hard disk
OPERATOR SAFETY	
ACCESS WHEN OPERATING	Cover open /closed detection. Transparent instrument cover, so moveable parts are visible during operation
MAIN COVER	Open/Closed detection
SAMPLE COVER	Open/Closed detection
REAGENT COVER	Open/Closed detection
CUVETTE ROTOR COVER	Open/Closed detection
NOISE EMISSION	Balanced noise criterium at NCB-58; Sound pressure 58 dB(A)max. when in use
REGULATORY COMPLIANCE	
IVD MEDICAL DEVICES	CE-marked in accordance with EU IVD Regulation 2017/746
ROHS	CE-marked in accordance with EU Directive 2011/65/EU
SAFETY	Tested and certified according to: IEC 61010-1:2010 (incl. AMD1:2016), IEC 61010-2-010:2014, IEC 61010-2-051:2015, IEC 61010-2-101:2015
ELECTROMAGNETIC COMPATIBILITY	Tested and certified by DEKRA according to: IEC 61326-1:2012, IEC 61326-2-6:2012

CE



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