Anexa nr. 6 la Formularul Specificații tehnice
Lot nr. 6 Analizator biochimic, automat 400 teste

Specificarea tehnică solicitată	**Specificarea tehnică deplină ofertata**, model **Selecta Mach5** (nr. catalog 6004-301)
Descriere Analizator automat destinat analizelor biochimice cu sistem închis de reactivi. Sistem analitic automat cu calculator exterior (procesor, monitor, tastatura + mouse, imprimanta) Tip de lucru continuu Tip sistem randoom acces cu cititor de coduri de bare pentru reactivi cu cititor de coduri de bare pentru probe Capacitatea (teste/oră) ≥ 400 (teste fotometrice) Modul ISE optional Posibilitatea efectuării analizelor urgente Obligatoriu Tipul dispozitivului staționar Tip probă Ser plasmă urină sânge integru CSF (lichid cefalo-rahidian) lichide biologice Tip diluare automat de la 1 pană la 100 Sistem de spălare total automat (rotor/cuva de reactie, sistem de dozare reactivi si proba) Obligatoriu Program complex de control al calității Obligatoriu Compartiment reactivi cu răcire ≥ 40 celule Compartiment probe ≥ 80 celule Rotor/Cuva de reacție pentru probe cu încălzire la 37°C reutilizabil ≥ 80 celule Sistem fotometricsursa de lumina LED/Halogen gama fotometrica de la 0 până la 3 A. lungimi de unda a filtrelor fotometrice cel puțin de la 340 până la 670nm Regimuri de măsurare Cinetic Obligatoriu Mono și bi-cromatic Obligatoriu Imunoturbidimetrc Obligatoriu Semnalizare lipsă reagent și probă Obligatoriu Sistemul de dozare Reagenții Utilizarea a minim 2 metodici: mono și bireagent Volumul reagentului programabil cu pasul 1 µl detectia automata a cheagurilor de sange Obligatoriu "brațe" pentru dozare reagenti ≥1 "brațe" pentru dozare probe ≥1 Sistemul de dozare Cu senzor de obstacol posibilitatea conectării accesului la distanta (remote acess prin programe ex. TeamViewer /AnyDesk / Radmin) Obligatoriu Posibilitatea programării controalelor și calibratorilor prin acces la distanta in decurs de maxim o ora de la solicitare Obligatoriu Posibilitatea oferirii suportului tehnic prin acces la distanta in decurs de maxim o ora de la solicitare Obligatoriu Dimensiuni lățime ≤ 1450 mm adâncime ≤ 770 mm înălțime ≤ 1260 mm Conectare la LIS protocoale HL7 si ASTM Obligatoriu Alimentarea 220 V, 50 Hz Baterie / UPS Minim 30 min. Adițional să fie inclus și tot ce este necesar pentru funcționalitatea lui: accesorii care necesită unire la canalizare și apeduct (sistemă de ionizare a apei, rezervor de apă); Obligatoriu Accesorii livrate împreună cu analizatorul biochimic calculator (procesor) monitor cu diagonala minim 19 inch tastatura mouse imprimanta Cerințe adăugătoare Analizator trebuie să fie dotat cu stație pentru purificarea apei, UPS și imprimanta pentru tipărirea rezultatelor, deservirea tehnică inclusă în contract pe toată perioada exploatării analizatorului. Stație pentru curățare a apei trebuie să fie prezentată cu costul setului de mentenanță anuală (filtre). Note: Oferta de preț trebuie să includă reactivii necesari pentru testele indicate, soluțiile QC și calibrare Cantitatea soluțiilor propuse trebuie să asigure efectuarea procedurilor de control al calității și calibrare, ori de câte ori este necesar.	Descriere Analizator automat destinat analizelor biochimice cu sistem inchis 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.** cu cititor de coduri de bare pentru reactivi cu cititor de coduri de bare pentru probe – da, **SAMPLE AND REAGENT IDENTIFICATION, pag. 4 Selectra Mach5 Brochure.** Capacitatea (teste/oră): **250 tests/hour for dual reagent tests 500 tests/hour for mono-reagent tests**, **Selectra Mach5_User Manual, A.1 Technical specifications;** Modul ISE optional Posibilitatea efectuării analizelor urgente da – **STAT capability - pag. 4 Selectra Mach5 Brochure** Tipul dispozitivului staţionar – da, benchtop, **pag. 4 Selectra Mach5 Brochure** Tip probă: Ser, plasmă, urină, sânge integru, CSF, lichide biologice – da, **pag. 4 Selectra Mach5 Brochure.** Tip diluare automat de la 0 pană la 100: **Selectra Mach5_User Manual, A.2.3.3 Dilution; automatic onboard dilution, pag. 4 Selectra Mach5 Brochure;** Sistem de spălare total automat (rotor/cuva de reactie, sistem de dozare reactivi si proba) - **Wash station Fully automated with overflow level detector, Selectra Mach5_User Manual, A.1.1.4 Measurement system;** Program complex de control al calității Obligatoriu – da, **QC rules: Westgard, Basic, Separation; Selectra Mach5_User Manual, A.2.3.2 QC rules;** Compartiment reactivi cu răcire **Up to 65 Bar Code Readable (BCR) positions, cooled at 8 ± 4 °C**, *Mach5 prospect, pag. 4* Compartiment probe: 85 sample positions, *Mach5 prospect, pag.4* Rotor/Cuva de reacție pentru probe cu încălzire la 37°C - **Selectra Mach5_User Manual;** Reutilizabil, **85 sample positiona, Mach5 prospect**. Sistem fotometricsursa de lumina **LED based photometer, Selectra Mach5_User Manual, A.1.1.4 Measurement system;** gama fotometrica de la **0 până la 3 Abs**., **Selectra Mach5_User Manual, A.1.1.4 Measurement system;** lungimi de unda a filtrelor fotometrice: **340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800nm - Selectra Mach5_User Manual, A.1.1.4 Measurement system;** Regimuri de măsurare Cinetic Obligatoriu - **Selectra Mach5_User Manual, 8.4.2 Tests screen - General page;** Mono și bi-cromatic Obligatoriu – **da, pag 8-9 Selectra Mach5_User Manual;** Imunoturbidimetrc – **da (IFU atasat);** Semnalizare lipsă reagent și probă – **da, Selectra Mach5_User Manual;** Sistemul de dozare Reagenții Utilizarea a 2 metodici: **mono-reagent tests si dual reagent tests - A.1 Technical specifications, Selectra Mach5_User Manual;** Volumul reagentului programabil cu pasul 1 µl - **da, Selectra Mach5_User Manual, A.1.1.4 Measurement system;** detectia automata a cheagurilor de sange – **Clot detection, A.1.1.2 Technical specifications, Selectra Mach5_User Manual;** "brațe" pentru dozare reagenti - 1, Reagent arm and probe, **Selectra Mach5_User Manual;** "brațe" pentru dozare probe – 1, Sample arm and probe, **Selectra Mach5_User Manual;** Sistemul de dozare Cu senzor de obstacol – **da, colision detection, Selectra Mach5_User Manual;**

Furnizorul va asigura: Transmiterea către spital documentația completă privind conectarea analizatorului la sistemul informatic (H3 SIA AMS/AMP) și să asigure suportul tehnic necesar echipei desemnate de spital sau firmei de software care realizează efectiv conectarea. Instruirea personalului. Mentenanța preventivă și corectivă gratuită pe toată durata de 4 ani atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare). Seturile de mentenanță și piesele de schimb gratuite pe toată durata de 4 ani atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă). Toate consumabilele necesare gratuite pe toată de 4 ani atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă), dacă acestea nu au fost incluse în oferta inițială. Timpul de intervenție în caz de defect: maximum 24 ore de la solicitarea telefonică. Preț pentru reactivi nemodificat pentru toată perioada de de 4 ani. Perioada de valabilitate pentru reagenții livrați: La momentul livrării: Minim 6 luni, dar nu mai puțin de 80% din termenul total de valabilitate. Să se indice timpul de stabilitate a reactivilor după deschidere. Termenele mai mari vor fi considerate un avantaj. Operatorul Economic va include în oferta prețul dispozitivului medical și prețurile pentru fiecare test considerând: - Efectuarea controlului calității pentru fiecare test în fiecare zi lucrătoare. - Efectuarea calibrării ori de cate ori va fi necesar (în baza rezultatului controlului calității). - Toate piesele si kiturile de mentenanță necesare bunei funcționării pe întreaga perioada a contractului de de 4 ani. - Sistemul de filtrare (stație purificare apa) și toate filtrele necesare pentru funcționarea stației de purificare al apei pe toată perioada contractului.- UPS (Sursa neîntreruptibilă de alimentare) și costurile acumulatoarelor necesare pe toata perioada contractului. - Calculator (PC), monitor, tastatura, mouse cu garanție deplină și înlocuire în caz de defectare. - Toate consumabilele, inclusiv: soluții de spălare, soluții de buffer, electrozi/modul ISE, cuve/rotor pentru reacție, lămpi și tot spectrul de consumabile necesare bunei funcționări pentru efectuarea tuturor testelor solicitate de IMSP. - Toate serviciile de mentenanță preventivă și corectivă necesare bunei funcționări pe perioada contractului. Respectiv, se vor lua în calculul toate cheltuielile care ar putea apărea în întreaga perioada a contractului.	posibilitatea conectării accesului la distanta (remote acess prin programe ex. TeamViewer /AnyDesk / Radmin) - da Posibilitatea programării controalelor și calibratorilor prin acces la distanta in decurs de maxim o ora de la solicitare Obligatoriu Posibilitatea oferirii suportului tehnic prin acces la distanta in decurs de maxim o ora de la solicitare Obligatoriu Dimensiuni: **105 cm (w) x 70 cm (d) x 65 cm (h),** *Mach5 prospect.* Conectare la LIS protocoale HL7 si ASTM – **da, Selectra Mach5_User Manual;** Alimentarea **100 - 240 Vac ±10%, 50/60 Hz, Selectra Mach5_User Manual;** Baterie / UPS Minim 30 min - DA. Este inclus tot ce este necesar pentru funcționalitatea analizatorului biochimic. Accesorii livrate împreună cu analizatorul biochimic: calculator incorporat cu tastatura, mouse, imprimanta. Analizatorul nu necesita statie de purificare apa. Cerințe adăugătoare Analizator va fi dotat cu și imprimanta pentru tipărirea rezultatelor, deservirea tehnică inclusă în contract pe toată perioada exploatării analizatorului. Note: Oferta de preț include reactivii necesari pentru testele indicate, soluțiile QC și calibrare Cantitatea soluțiilor propuse va asigura efectuarea procedurilor de control al calității și calibrare, ori de câte ori este necesar. GBG va asigura: Transmiterea către spital documentația completă privind conectarea analizatorului la sistemul informatic (H3 SIA AMS/AMP) și să asigure suportul tehnic necesar echipei desemnate de spital sau firmei de software care realizează efectiv conectarea. Instruirea personalului. Mentenanța preventivă și corectivă gratuită pe toată durata de 4 ani atât pentru analizator cât și pentru dispozitivele auxiliare livrate. Seturile de mentenanță și piesele de schimb gratuite pe toată durata de 4 ani atât pentru analizator cât și pentru dispozitivele auxiliare livrate. Toate consumabilele necesare gratuite pe toată de 4 ani atât pentru analizator cât și pentru dispozitivele auxiliare livrate. Timpul de intervenție în caz de defect: maxim 24 ore de la solicitarea telefonică. Preț pentru reactivi nemodificat pentru toată perioada de de 4 ani. Perioada de valabilitate pentru reagenții livrați: La momentul livrării: Minim 6 luni, dar nu mai puțin de 80% din termenul total de valabilitate. Timpul de stabilitate a reactivilor după deschidere – **maxim 90zile**, **Selectra Mach5_User Manual;** Oferta include in prețul dispozitivului medical și prețurile pentru fiecare test considerând: - Efectuarea controlului calității pentru fiecare test în fiecare zi lucrătoare. - Efectuarea calibrării ori de cate ori va fi necesar (în baza rezultatului controlului calității). - Toate piesele si kiturile de mentenanță necesare bunei funcționării pe întreaga perioada a contractului de de 4 ani. - UPS (Sursa neîntreruptibilă de alimentare) și costurile acumulatoarelor necesare pe toata perioada contractului. - Calculator (PC), monitor, tastatura, mouse cu garanție deplină și înlocuire în caz de defectare. - Toate consumabilele, inclusiv: soluții de spălare, soluții de buffer, electrozi, cuve/rotor pentru reacție, lămpi și tot spectrul de consumabile necesare bunei funcționări pentru efectuarea tuturor testelor solicitate de IMSP. - Toate serviciile de mentenanță preventivă și corectivă necesare bunei funcționări pe perioada contractului. Respectiv, se vor lua în calculul toate cheltuielile care ar putea apărea în întreaga perioada a contractului.

X, x - Concentration High Error / Concentration Low Error

The test result is above the configured concentration range (X) or below the analytical sensitivity (x).

Actions:

- In case of an X flag, rerun the test with a diluted sample, by tapping ***Dilute***. If the ***Automatic Re-run*** option is set for this flag (***Flag Customization*** screen) and if the system state allows processing, the test will be automatically diluted (based on the configured dilution ratio) and processed.
- Check the concentration ***Limits*** in the test configuration (***Tests*** screen - ***Result Calculation*** page).

See also:
'Tests screen - Result Calculation page' on page 8-12

Y, y - Reference Panic High Limit Error / Reference Panic Low Limit Error

The test result is above the configured upper panic limit (Y) or below the configured lower panic limit (y).

Actions:

- Immediate action is required in treatment of the patient.
- If the result is incorrectly labeled as 'panic', then check the ***Reference ranges [units]*** for the ***Panic*** field in the test configuration (***Tests*** screen - ***Result Calculation*** page) and rerun the test.

See also:
'Tests screen - Result Calculation page' on page 8-12

Z - Duplicate Difference Limit Error

The difference between the results of a replicated test is too high.

Possible cause:

- Contamination in the sample or reagent.
- Incorrect test parameter.

Actions:

- Check the sample and reagent for visual contamination.
- Repeat with new or fresh reagent.
- Check the limit parameter of the ***Duplicate Difference*** in the test configuration (***Tests*** screen - ***Processing*** page).

See also:
'Tests screen - Processing page' on page 8-7

- Insufficient Sample Error

Pipetting is not possible due to insufficient sample.

Possible causes:

- The sample tube is empty.
- The sample tube is not loaded.
- The sample tube is not in the correct sample position.
- Air bubbles are preventing aspiration.
- The liquid detection system is malfunctioning.

M, m - High Absorbance Limit Violation / Low Absorbance Limit Violation

The test result was above the configured upper absorbance limit (M) or below the configured lower absorbance limit (m).

Action:

- In case of an M flag, rerun the test with a diluted sample, by tapping ***Dilute***. If the ***Automatic Re-run*** option is set for this flag (***Flag Customization*** screen) and if the system state allows processing, the test will be automatically diluted (based on the configured dilution ratio) and processed.
- Check the ***Absorbance Limits*** in the test configuration (***Tests*** screen - ***Abs Check*** page).
- Check the ***Reagent Blank Absorbance Limits*** in the test configuration (***Tests*** screen - ***Calibration*** page).

See also:
'Tests screen - Abs Check page' on page 8-10
'Tests screen - Calibration page' on page 8-14

N+, N- - High Reference Limit Violation / Low Reference Limit Violation

The test result was above (N+) or below (N-) the applicable reference range (male, female or pediatric). This is a 'normal use' flag.

Possible cause:

- Patient concentration outside defined ranges.
- Incorrect reference ranges (if flagged for multiple patients).

Action:

- Optional: if result is suspicious, then repeat test to confirm.
- Correct the ***Reference ranges [units]*** for the fields ***Male***, ***Female*** or ***Pediatric*** in the test configuration (***Tests*** screen - ***Result Calculation*** page).

Info

This error is not shown if Y, y - ***Reference Panic High Limit Error*** or ***Reference Panic Low Limit Error*** also occurred.

See also:
'Tests screen - Result Calculation page' on page 8-12

R- - Insufficient Reagent

The test was not performed due to an empty or missing reagent bottle. Once the problem is resolved, interrupted tests will be scheduled with the next sample run.

Possible causes:

- Empty bottle.
- No proper aspiration possible.
- Missing reagent bottle.
- The liquid detection system is malfunctioning.

Actions:

- Fill or (re)place the reagent bottle. Carefully remove any bubbles or foam with a disposable pipette.
- Check if the reagents are in the correct rotor positions.
- Rinse the probes and let dry.
- Contact your supplier's Support Department.

See also:
'Rinsing the probes' on page 6-7

Print All **-** Print all test results for all completed samples.

Summary Report **-** Print a summary of the test results for a particular date range, according to the ***Summary Report Template*** setting in ••• ***> Configure > Report > Print***. The default date range is today.

Resend to LIS **-** Resend the results for the selected sample to the LIS. You must be signed in at the supervisor or administrator level.

Repeat **-** Request a repeat for the selected sample and test. Only available if the corresponding sample is still on the sample rotor.

Info

Do not forget to start processing after requesting a ***Repeat*** or ***Dilute***.

Dilute **-** Request a repeat with diluted sample for the selected sample and test. Only available if ***Rerun Dilution*** has been configured in the ***Processing*** page of the test, and if the corresponding sample is still on the sample rotor.

Accept **-** Accept the selected result. Only available for the supervisor, if the result is available and flagged.

Reject **-** Reject the selected result. Only available for the supervisor, if the result is available and flagged.

Cancel Test **-** Cancel a pending test for the selected sample. Only available for tests that are in progress or were paused.

View Test **-** Shows the test parameters.

Calibration **-** Shows the last calibration and/or control results (if applicable) for the selected test.

See also:
'Evaluating patient results' on page 5-38
'Patient Sample [ID] [Test] Details dialog' on page 4-31

4.4.7.1 Patient Sample [ID] [Test] Details dialog

This dialog shows the detailed results for the selected measurement of a test on a sample. This dialog appears after double clicking (tapping twice) the graph in the right-hand pane in the ***Patients*** page of the ***Results*** screen.

Table 4-2: System state symbols

Symbol	Description
	Internal system liquid insufficient, system will pause.
	Empty system. Maintenance task being performed.
	Reagent rotor cover and/or sample rotor cover are open. Close the cover(s) before starting to process tests.
	Main cover open. Close the cover when the maintenance task is completed.
	Cuvette rotor cover open. Close the cuvette rotor cover and the main cover when the maintenance task is completed.
	Printer problem.
	Clot detected in the sample probe at the sample rotor position indicated.
	Disconnected. No connection with the system is detected and its state is unknown.
	System is recovering data. Wait until the system is ready for use.
	***Power Save*** state. The system is inactive. The reagent rotor is cooled, the rest of the system is not powered to save energy.
	LIS disconnected.
	LIS connected.

Symbols are displayed on (or next to) the item they apply to.

Table 4-3: Processing and notification symbols

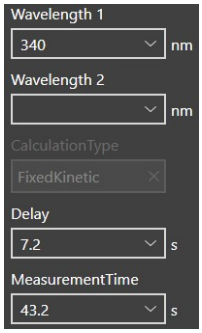
Symbol	Description
	Task completed and unloaded / Status Ok / Status correct / Accepted.
	Expiration date extended.

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



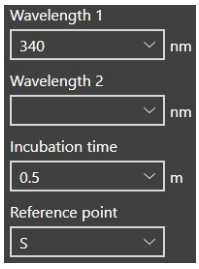
Wavelength 1 **and** ***Wavelength 2*** **-** Select the wavelength(s) to be used in the calculation of absorbance results. For bichromatic tests, two wavelengths must be selected. If only ***Wavelength 1*** is entered, a monochromatic test is done.

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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EMPOWERING IVD

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.

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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

1. Johnson, A.M., *Amino Acids and Proteins*. Tietz Fundamentals of Clinical Chemistry, 6th Ed, Burtis, C.A. & Ashwood, E.R., Bruns, D.E., (W.B. Saunders eds), (2008), 286.
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.
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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

A.2.3.2 QC rules

Westgard rules

When the Westgard option is selected, the high and low limits are automatically set from the standard deviation that is entered by the user.

The Westgard rules are violated if one or more of the following conditions apply:

- 1 control result is more than 3 standard deviations from the target.
- The last 2 control results are more than 2 standard deviations from the target in the same direction (+ or –).
- The last 4 control results are more than 1 standard deviation from the target in the same direction (+ or –).
- The last 10 control results are all located either on the '+' or the '–' side to the target.

The Westgard rules are not violated in any other case.

Basic rules

When the basic option is selected, a low and high limit can be set. If the result is outside these limits, a flag is raised.

Separation rules

Separation checks if the control result has a minimal distance from the fixed cut-off or calibrator result. If the result is too close, a flag is raised.

See also:
'Controls screen - General page' on page 8-27
'Controls screen - Lot page' on page 8-28

A.2.3.3 Dilution

The 'sample predilution' option is used for samples that would normally fall outside the measurable absorbance, concentration or calibration range. The sample is prediluted by the system, using diluent available on the rotor.

The 'rerun dilution' option is a post-dilution available for a flagged test result. If requested, the test is repeated with diluted sample. Dilution options and ratios are defined in the test configuration settings.

It is possible to dilute a calibrator into one or more diluted calibrator levels.

Info

In this manual and in the analyzer software, the dilution ratios are given as parts of the sample to parts of the resulting solution. Thus, a dilution ratio of 1/5 means 1 part of the sample diluted with 4 parts of diluent, resulting in 5 parts of solution.

Example

A test uses a calibrator with 5 standards, for concentrations 0, 10, 20, 50 and 100. Measuring a sample with a concentration of 200 would mean that the actual concentration cannot be obtained by interpolation on the calibration curve. In this case, predilution of the sample with a factor of 1/5 brings the concentration within the calibrator range. The measured concentration (40) is corrected with the predilution factor to obtain the actual concentration which is shown on screen (uncorrected concentrations are not shown).

***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.

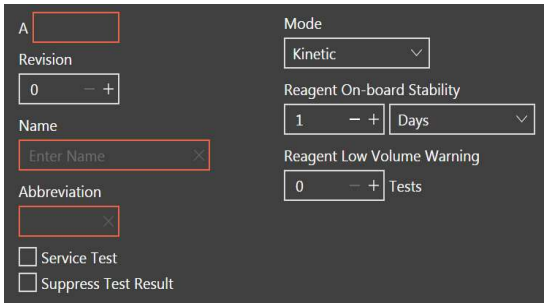
***Accept* -** Confirm the changes in all test configuration pages.

***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.

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

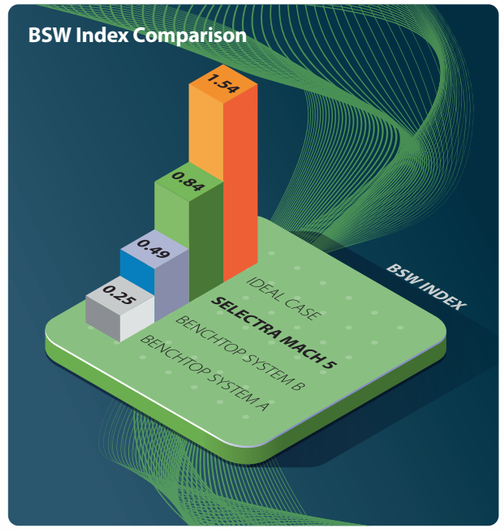
Let's look at the following scenario:

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.



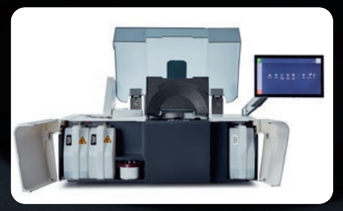
The values for the Ideal Case and the 3 selected instruments are displayed in the table below:

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

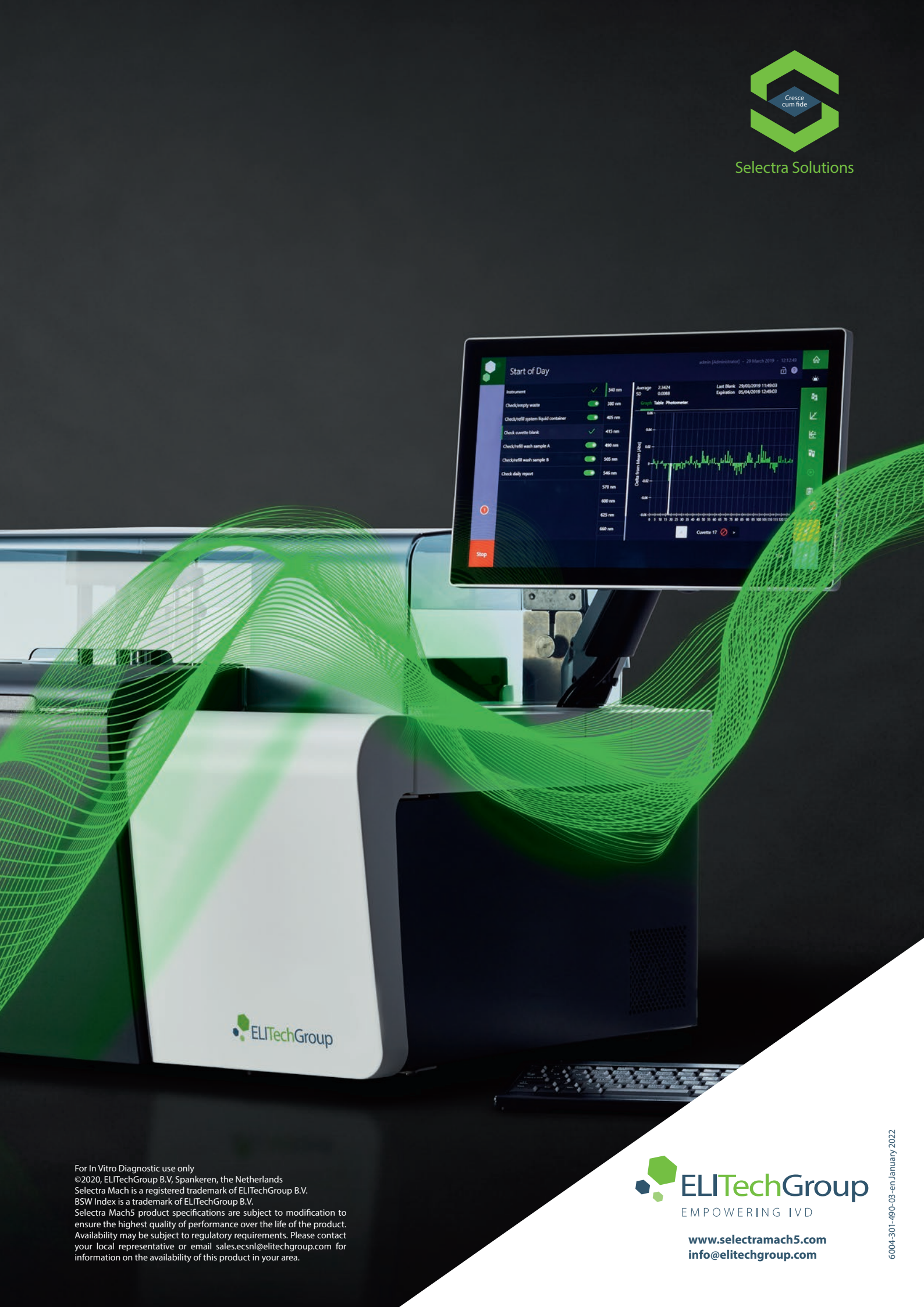
WORK FLOW	
PRIMARY TUBE SAMPLING	Primary- tube diameter ranging from 12 to 16 mm and a height ranging from 75 to 100 mm
CONTINUOUS REAGENT AND SAMPLE LOADING	Yes, samples and reagents, via dedicated sample and reagent access covers (maximum pause time for sample of 2 minutes)
ON BOARD SAMPLE CAPACITY	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



ELITechGroup
EMPOWERING IVD

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info@elitechgroup.com

6004-301-490-03-en January 2022

A.1.1.3 Reagent system

Reagent rotor	30 to 80 positions on 5 replaceable segments (6 or 16 positions each) Segments with 6 positions are for barcode readable reagent containers with a capacity of 90mL Segments with 16 positions are for 13 barcode readable containers (30 mL), 2 barcode unreadable containers and 1 barcode unreadable bottle (10 mL)
Reagents containers or bottles	Wedge shaped containers: 90 mL Rectangle shaped containers: 30 mL Round bottles: 10 mL Adapter allowed for small bottles in large positions
Volumes per test	Reagent 1: 50 - 370 µL Reagents 2, 3 and 4: 10 - 349 µL
Refrigeration	7 ± 3 ºC Ambient temperature 15 - 25 ºC
Probe	Level detection Collision detection Heater with temperature sensor
Pipetting capacity	400 µL (increments of 1 µL)

A.1.1.4 Measurement system

Cuvette rotor	Replaceable rotor with 128 positions
Optical path length	5 mm
Total volume range (sample and reagent)	110 to 400 µL
Wash station	Fully automated with overflow level detector
Cuvette rinsing	4 x 500 µL system liquid
Light source	LED based photometer
Photometers	16, each measuring absorbance at a single wavelength
Wavelengths	340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800 nm
Central wavelength accuracy	± 2 to ± 15 nm, depending on the wavelength
Measuring range	0 to 3.0 Abs.

A.1.1.3 Reagent system

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Refrigeration	7 ± 3 ºC Ambient temperature 15 - 25 ºC
Probe	Level detection Collision detection Heater with temperature sensor
Pipetting capacity	400 µL (increments of 1 µL)

A.1.1.4 Measurement system

Cuvette rotor	Replaceable rotor with 128 positions
Optical path length	5 mm
Total volume range (sample and reagent)	110 to 400 µL
Wash station	Fully automated with overflow level detector
Cuvette rinsing	4 x 500 µL system liquid
Light source	LED based photometer
Photometers	16, each measuring absorbance at a single wavelength
Wavelengths	340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800 nm
Central wavelength accuracy	± 2 to ± 15 nm, depending on the wavelength
Measuring range	0 to 3.0 Abs.

CISPR 11 Class A	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case it may be necessary to take measures to mitigate the interference. The system is tested and certified by UL according IEC 61010-1:2010 (incl. AMD1:2016), IEC 61010-2-010:2014, IEC 61010-2-051:2015 and IEC 61010-2-101:2015. The CB-certificate is available upon request.

Info

The approvals listed here refer only to the instrument and operator console, not to additional devices. For the approvals for these devices, see the corresponding manuals.

A.1.2 Requirements

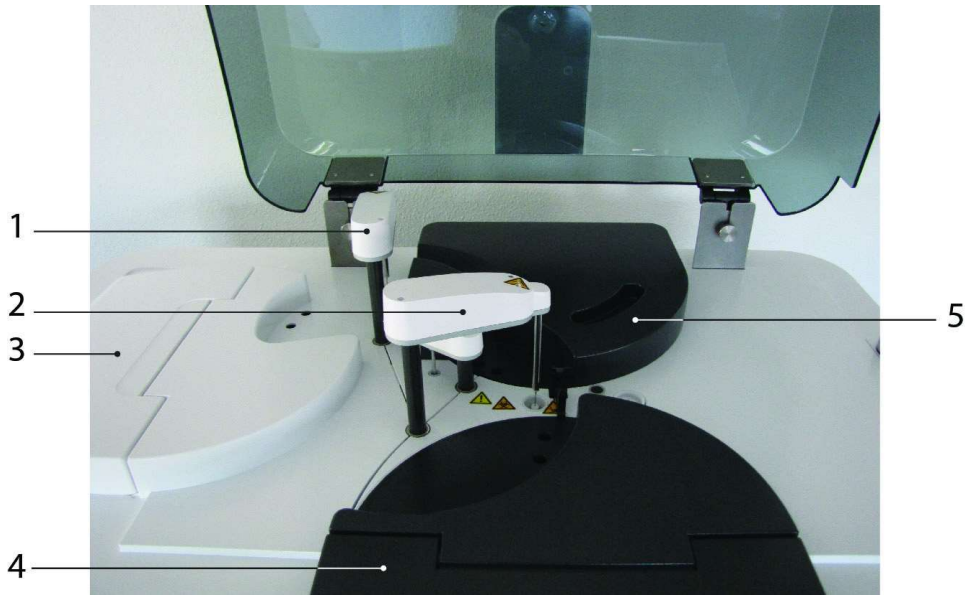
A.1.2.1 Power requirements

Mains inlet	1 x IEC60320/C13 input connector
Line Voltage	100 - 240 Vac ±10%
Line Frequency	50/60 Hz
Max. Power Consumption	700 VA
Overvoltage category	II (in accordance with IEC 61010-1)
Main fuses	2 x 10 A, time delay, high breaking capacity, 250 Vac

A.1.2.2 Environmental requirements

Ambient temperature	15 to 32 ºC (59 to 90 ºF)
Relative humidity	30 - 85%, non-condensing
Operating environment	Indoor use
Maximum altitude	3000 meter / 10.000 feet
Pollution degree	2 (in accordance with IEC 664)
Degree of protection	IP X0

3.3 Reagent and sample probes



1	*Reagent arm and probe*	*4*	*Sample rotor cover*
2	*Sample arm and probe*	*5*	*Cuvette rotor cover*
3	*Reagent rotor cover*		

Fig.3-3 Reagent and sample probes

The Selectra Mach5 has one reagent probe [1] and one sample probe [2]. When aspirating reagent or sample, the probe is lowered through one of the openings in the reagent cover [3] or sample cover [4]. The reagent or sample is then dispensed into a cuvette through the opening in the cuvette rotor cover [5]. After dispensing the reagent or sample, the probes are cleaned with system liquid at the rinsing stations.

A.1 Technical specifications

A.1.1 System specifications

A.1.1.1 Performance

Maximum throughput	250 tests/hour for dual reagent tests 500 tests/hour for mono-reagent tests
Programmable tests	Maximum 1000, depending on the system configuration
Sample processing	Random access
Quality control	6 per parameter
Noise emission	Balanced noise criterium at NCB-58 Sound pressure 58 dB(A) max. when in use

See also:
'Accuracy and precision' on page A-7

A.1.1.2 Sample system

Sample rotor	65 positions for barcode readable sample tubes, on 5 replaceable outer segments (each 13 positions) 20 positions for barcode unreadable calibrators, controls, blanks, special fluids and pediatric cups, on non-replaceable special sample segment
Sample tubes	Diameter: 12 - 16 mm Height: 75 - 100 mm; 75 mm in non-replaceable special sample segment
Sample cups	As recommended and supplied by ELITechGroup B.V.
Probe	Level detection Collision detection Clot detection Heater with temperature sensor
Pipetting capacity	1 - 30 µL (increments of 0.1 µL)

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

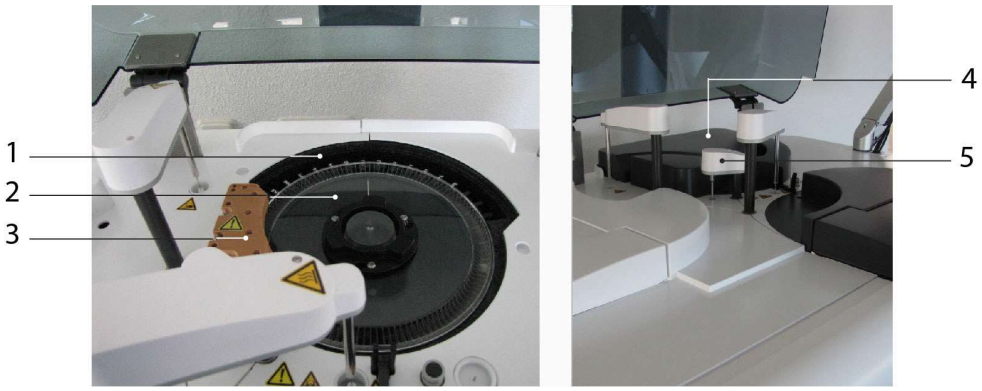
Selectra Mach5. Make Work Flow

14/01/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

3.2 Cuvette rotor



1	*Photometer units*	*4*	*Cuvette rotor cover*
2	*Cuvette rotor*	*5*	*Mixer*
3	*Cuvette wash station*		

Fig.3-2 Cuvette rotor

The cuvette rotor [2] contains 128 cuvettes. The measuring volume must be between 110 and 400 µl. The cuvette rotor is heated from below and has an insulated cover [4]. The cuvette rotor temperature is kept at 37 °C. The mixer [5] ensures that the reaction mixture in the cuvettes is well mixed.

The cuvette rotor rotates to bring each sample into the measurement position. Light from the photometer LED [1] passes through the cuvette. After the last measurement, the cuvette is washed and dried by the cuvette wash station [3]. The waste is disposed in a waste container.

A.2.3.2 QC rules

Westgard rules

When the Westgard option is selected, the high and low limits are automatically set from the standard deviation that is entered by the user.

The Westgard rules are violated if one or more of the following conditions apply:

- 1 control result is more than 3 standard deviations from the target.
- The last 2 control results are more than 2 standard deviations from the target in the same direction (+ or –).
- The last 4 control results are more than 1 standard deviation from the target in the same direction (+ or –).
- The last 10 control results are all located either on the '+' or the '–' side to the target.

The Westgard rules are not violated in any other case.

Basic rules

When the basic option is selected, a low and high limit can be set. If the result is outside these limits, a flag is raised.

Separation rules

Separation checks if the control result has a minimal distance from the fixed cut-off or calibrator result. If the result is too close, a flag is raised.

See also:
'Controls screen - General page' on page 8-27
'Controls screen - Lot page' on page 8-28

A.2.3.3 Dilution

The 'sample predilution' option is used for samples that would normally fall outside the measurable absorbance, concentration or calibration range. The sample is prediluted by the system, using diluent available on the rotor.

The 'rerun dilution' option is a post-dilution available for a flagged test result. If requested, the test is repeated with diluted sample. Dilution options and ratios are defined in the test configuration settings.

It is possible to dilute a calibrator into one or more diluted calibrator levels.

Info

In this manual and in the analyzer software, the dilution ratios are given as parts of the sample to parts of the resulting solution. Thus, a dilution ratio of 1/5 means 1 part of the sample diluted with 4 parts of diluent, resulting in 5 parts of solution.

Example

A test uses a calibrator with 5 standards, for concentrations 0, 10, 20, 50 and 100. Measuring a sample with a concentration of 200 would mean that the actual concentration cannot be obtained by interpolation on the calibration curve. In this case, predilution of the sample with a factor of 1/5 brings the concentration within the calibrator range. The measured concentration (40) is corrected with the predilution factor to obtain the actual concentration which is shown on screen (uncorrected concentrations are not shown).

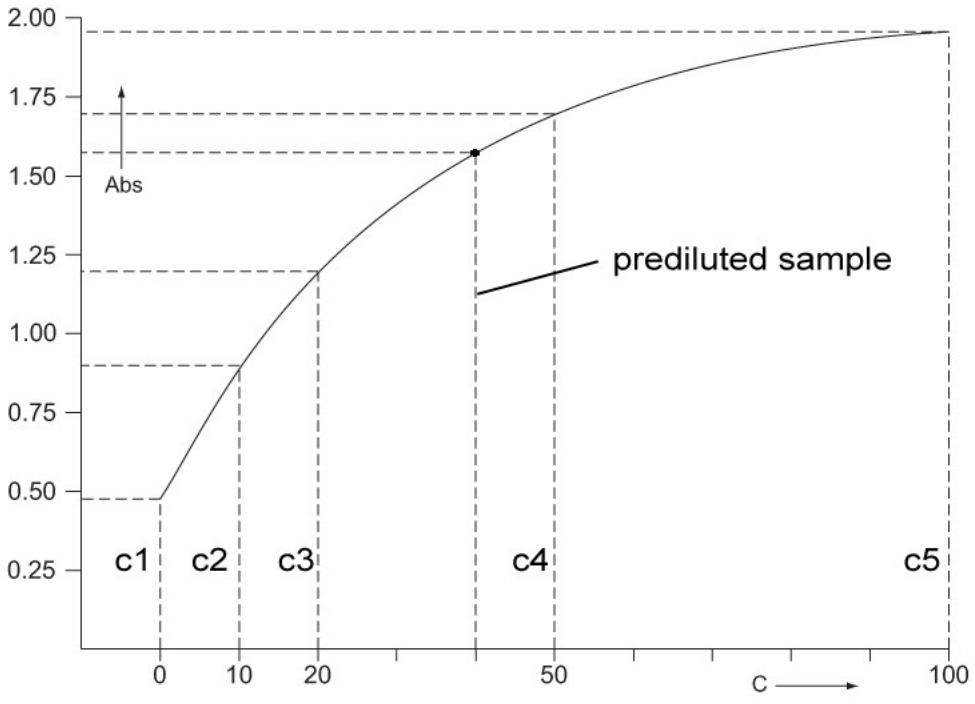


Fig.A-4 Interpolation on a calibration curve

***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.

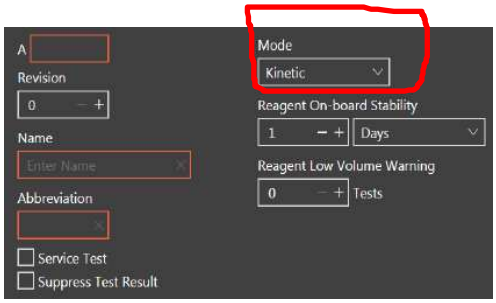
***Accept* -** Confirm the changes in all test configuration pages.

***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.