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1. What is the brand name of your company's hematology and/or coag analyzer?

iSED ELITE

HiBand, HiFISH, CytoPower (combined product)

Lyphochek Coagulation Control

2. What is the latest version of your named analyzer?

iSED ELITE was launched in 2023

Latest version v8.4.1 in 2025

N/A

3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.

registered with FDA in 2023

HiBand: CE mark, 2001, FDA 510(k), 2001, Health Canada, 2008
HiFISH: CE mark, 2005, FDA 510(k), 2005, Health Canada, 2008

FDA Class II, 510(k) exempt; CE marked

4. What are the dimensions of the named product?

13.78" x 10.63" x 14.17"

35.5" x 39.4" x 35.5"

N/A

5. What is the intended use or primary function of the product?

Automated erythrocyte sedimentation rate analyzer

Digital slide scanning and computer-aided analysis for karyotyping and FISH

Lyphochek Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.

6. What types of specimen/sample does the product employ?

EDTA whole blood

Blood, bone marrow, amniotic fluid, CVS, urine, and more

Lyophilized, human-plasma control

7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?

Erythrocyte sedimentation rate

Cancer and genetic aberrations

Activated Partial Thromboplastin Time (APTT), Antithrombin III (AT III), Fibrinogen, Prothrombin Time (PT), Thrombin Time (TT)

8. Under ideal conditions, what is the time to first result; how are the test results made available?

Time to first result is 3 minutes and 20 seconds; subsequent results are available within 20 seconds and reported in mm/hr

Scan takes a few minutes. Results are typically available in real-time, while scanning.

This is dependent upon the instrument being used.

9. What are the product's maximum capacity and throughput under ideal conditions?

20 samples can fit onboard and 180 ESR tests can be performed per hour

ASI's trayloader capacity is 99 slides with the possibility to add and replace trays while the system is scanning, making it a continuous scanner.

N/A

10. Briefly describe any automation or connectivity features or options that pertain to the product.

iSED ELITE offers fully automated ESR testing with sample mixing, aspiration, analysis, and result transmission to the LIS done performed automatically once a sample is loaded

Automatic cell detection and classification for karyotyping and FISH analysis. Complete remote access solution, enabling HIPAA-compliant review, analysis, and sign-off cases from any location. Integrated with the laboratory information system.

This control is supported by the Unity interlaboratory quality control data management system.

11. What is the typical training time for the product?

Less than one day

Typical installation and training take less than a week. ASI collaborates with the lab pre- and post-installation to verify smooth integration with lab workflow.

No training is required; material is run as a patient sample.

12. What types of technical support are available?

ALCOR Scientific Technical Support is available live during business hours and the lines are monitored off hours

Both remote and onsite technical support.

Technical support is available by phone or email. Individualized customer support is provided as needed.

13. What capabilities, features, or accessories distinguish this product from others on the market?

iSED ELITE is the most efficient ESR solution for busy labs because it has completely automated labor-intensive traditional ESR testing with a fully automated process and standardized workflow. Using photometric rheology, results are generated within 20 seconds and correlated to the Westergren method.

End-to-end digital karyotyping and FISH solution including scanning and analysis for any sample or probe. High accuracy of computer-aided karyotyping and FISH signal pattern identification. Possibility to use the same platform for scanning and analysis of brightfield and fluorescent pathology specimens (i.e., H&E, IHC, FISH).

Lyophilized independent, human-plasma control, assayed for precision in coagulation tests (PT, APTT, Fibrinogen, Antithrombin III, Thrombin Time). Normal/abnormal levels included. Stable, easy-to-store format. Extended open-vial stability reduces QC costs, enhances value for frequent testing.

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1. What is the brand name of your company's hematology and/or coag analyzer?	Liquichek Sedimentation Rate Control	CellaVision DM and DC series analyzers	T-TAS 01
2. What is the latest version of your named analyzer?	N/A	CellaVision DC-1 - 2020	US 2020
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class I, 510(k) exempt; CE marked	CE Mark 2019; FDA 510(k) 2020	FDA 510(k), 2020; CE Mark, 2018; PMDA, 2021
4. What are the dimensions of the named product?	N/A	14.6" x 11.0" x 15.4"	9.7" x 12.6" x 14.2"
5. What is the intended use or primary function of the product?	Liquichek Sedimentation Rate Control is intended for use as a quality control to monitor the precision of erythrocyte sedimentation rate (ESR) laboratory testing procedures.	Differential count of white bloodcells (WBC), characterization of red blood cell (RBC) morphology, and platelet estimation.	Assessment of total platelet function in clinical laboratories
6. What types of specimen/sample does the product employ?	Liquid, human whole blood based quality control	Peripheral whole blood samples typically flagged by a cell-counter indicating an abnormal morphology	Whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Erythrocyte sedimentation rate (ESR)	Automated cell-locating device for cell location and identification of RBC, WBC, or platelets for in-vitro use. Verification of results by human operator	Primary hemostasis dysfunction and known anti-platelet medication
8. Under ideal conditions, what is the time to first result; how are the test results made available?	This is dependent on the instrument being used.	Approximately 2-6 minutes per slide depending on analyzer	10-minute runtime; results displayed to included monitor
9. What are the product's maximum capacity and throughput under ideal conditions?	N/A	10-30 slides/h for complete differential (100 WBC+RBC+PLT) depending on analyzer	Up to 12 samples per hour
10. Briefly describe any automation or connectivity features or options that pertain to the product.	This quality control is supported by the Unity interlaboratory quality control data management system.	Automatically locates and captures high-quality images of cells. Review of blood smears can be local or remote.	Automated chip detection/identification. Optional barcode reader for sample identification. 2 levels of automated electronic QC
11. What is the typical training time for the product?	No training is required; material is run as a patient sample.	1 day	Half day
12. What types of technical support are available?	Technical support is available by phone or email. Individualized customer support is provided as needed.	First line support by local distribution partners	M-F 8-8 Eastern time. On site as necessary
13. What capabilities, features, or accessories distinguish this product from others on the market?	An independent, bilevel, human whole blood control designed to monitor the precision of erythrocyte sedimentation rate testing procedures. Assayed for over 20 automated and manual methods, including Westergren and Wintrobe.	Automates and simplifies the process of performing blood cell differentials in low-volume laboratories and improves collaboration with colleagues and morphology experts at other sites.	Physiologic flow conditions to mimic the <i>in vivo</i> environment. A single test for a global picture of primary hemostasis.

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1. What is the brand name of your company's hematology and/or coag analyzer?

Abacus

Abacus

Quantra System

2. What is the latest version of your named analyzer

Abacus 5, 2013 US; 2009 NON US

Abacus 3CP, 2013 US; 2013 NON US

2019

3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.

TUV CE mark, 2009; FDA 510(k), 2013

TUV CE mark 2013; FDA 510(k), 2013

FDA 510(k)

4. What are the dimensions of the named product?

18"x16"x20"

14"x12"x19"

19.3(h) x 14.2 cm(w) x 11.9 cm(d)

5. What is the intended use or primary function of the product?

Diagnosis, patient monitoring

Diagnosis, patient monitoring

Indicated for the evaluation of blood coagulation properties are desired. (Cardiovascular, trauma, liver transplant, and orthopedic)

6. What types of specimen/sample does the product employ?

Whole blood

Whole blood

Whole blood

7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?

Anemia, leukocytosis, platelet disorders, infections, chronic diseases etc

Anemia, platelet disorders, infections, chronic diseases etc

Coagulopathies

8. Under ideal conditions, what is the time to first result; how are the test results made available?

Approx 1 minute

Approx 1 minute

Less than 5 minutes. Results are displayed on an intuitive dial display and transmitted into the EHR via common middleware applications.

9. What are the product's maximum capacity and throughput under ideal conditions?

60tests/h

60tests/h

N/A

10. Briefly describe any automation or connectivity features or options that pertain to the product.

The Abacus 5 Hematology Analyzer can be connected to an autosampler, which automates the process of sample loading.

Optional external barcode reader, built-in thermal printer module

Data automatically transfers into LIS/EHR via common middleware applications (Data Innovations, RALS, Telcor). Analyzer automatically performs internal QC every 8 hours.

11. What is the typical training time for the product?

4 to 8 hours

4 to 8 hours

1 day

12. What types of technical support are available?

Software updates, preventive maintenance, online resources (user manuals, troubleshooting guides)

Software updates, preventive maintenance, online resources (user manuals, troubleshooting guides)

Phone, email, and on-site support

13. What capabilities, features, or accessories distinguish this product from others on the market?

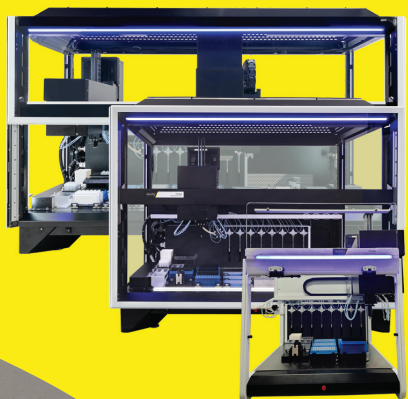
Offers reliable performance with a long-lifetime diode laser, diagnostic flagging, and cap recognition. Its user-friendly design includes a large touch screen, barcode reader, and multilingual menu. Efficient with 26 parameters, 60 tests/hour throughput, and a 100,000-result database. Compact, cost-efficient, and low-maintenance. Ideal for space-restricted labs.

The Abacus 3CP is a compact, 60 tests/hour, 3-part WBC differential analyzer with cap-piercing and open-tube sampling modes. It features a large color touchscreen with an intuitive interface. Ideal for small labs, satellite clinics, and doctor's offices seeking reliable, accurate, and easy-to-use equipment.

Proprietary SEER ultrasound technology directly measures the clot stiffness over time. Rapid time to results and intuitive dials display enable efficient goal-directed transfusion decisions. Novel PCS parameter reflects both platelet count and platelet functionality.



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