iLsa Diagnostic

IDC 20

AUTOMATED LIQUID-BASED CYTOLOGY SLIDE PREPARATION SYSTEM

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1. CYTOLOGY AND iDC 20

Cytology, and more specifically cytopathology, is the specific domain of pathology laboratories.

Cytology is defined as morphological analysis of cells for screening or diagnostic purposes.

Cytology is a fundamental step in the cervical cancer screening process, as it enables detection of precancerous lesions, a pre-requisite to attaining a recovery rate of the order of 100% (before progression to invasive cancer).

Screening tests, particularly for cervical cancer, account for 80% of all cytology evaluations and are referred to **gynaecological specimen testing**. The remaining 20% relates to diagnostic cytology, which covers a range of areas varying from urine cytology, effusion cytology (pleural and peritoneal), endoscopic method cytology, notably brush-cytology (lungs and digestive tract) and all other acts of cytology performed on superficial (breast, thyroid, ganglions, etc.) or deep (pancreas, kidney, liver, etc.) organs by means of fine-needle aspiration. This is referred to as **non-gynaecological specimen testing.**

The main focus of cyto-screening is cervical cancer. A sample is taken by qualified specialists (gynaecologist, general practitioner, nurse or laboratory technician). Following intra-vaginal introduction of a speculum to facilitate access to the cervix, the practitioner uses a brush or a swab to scrape off cervical cells, which are inserted into bottle containing preservative liquid. The bottle is then sent to the cytology laboratory.

The process referred to as liquid-based cytology (LBC) has replaced the conventional Pap smear, which consisted in directly spreading the cells on to a glass slide.

In the laboratory, a set volume of liquid is taken and deposited on a glass slide. This is then stained in preparation for microscopic examination to detect the presence of morphological abnormalities that could indicate a cancerous or precancerous condition. This analysis is conducted by a cytologist (doctor or technician).

Several manual or automatic techniques are involved in effecting smears: they include centrifugation, sedimentation + blotting, filtration and depositing. The advantage of the liquid-based method is that it allows a thin single-cell layer to be obtained.

A further benefit is that, if the cytologist identifies abnormal cells, the same specimen, that is, the suspension may be sent on directly to a laboratory for HPV testing using molecular biology techniques.

iDC 20, a system developed by iLsa, uses a controlled centrifugation process to automate the placement of cells on the slide. iLsa's innovation lies in the integration of an infra-red detection system in the iDC 20 system to **determine cell concentration**, thus providing reproducible, homogeneous, single-cell quality for optimum cell detection and paralleled readability.

iDC 20 can process all types of **gynaecological and non-gynaecological specimens**.

iDC 20 guarantees **total security and zero risk of contamination** (use of disposable tips). **Full traceability** from sample to slide is assured without any risk of operator error.

iDC 20 saves precious time for the technician. It is easy to use; only two hours of training are required.

2. iDC 20 PRESENTATION

Designed by iLsa, iDC 20 is also manufactured at the company's Besançon site. The equipment consumables are produced in iLSA's plastic injection clean-room facility at Saint-Ouen l'Aumône in the Paris area. iDC 20 is certified to CE-IVD standards.

iLsa has the benefit of 30 years of experience and market knowledge. The company is a key player in the in-vitro diagnostics and biotechnology laboratory instrument sector and enjoys partnerships with major distributors with more than 10,000 instruments already installed worldwide.

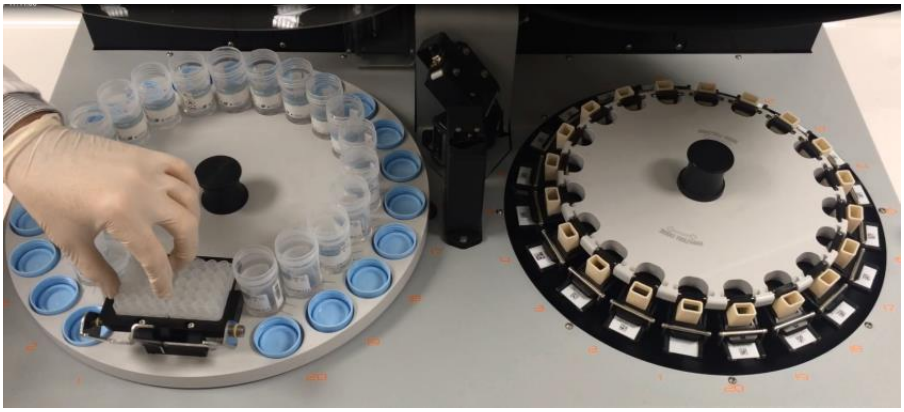
iLsa is certified to ISO 9001 and ISO 13485 (Medical Devices).

a. Overview

iDC 20 is a compact device that automates all operations involved in depositing cells on a glass slide for subsequent analysis. It takes care of identifying both the specimen bottles and the slides. All the operator has to do is to load on to the iDC 20 the sample bottles and the slides, previously placed in individual holders, fit the disposable tips and press the START button.

iDC 20 does all the rest, delivering dry slides that are ready to be stained.

b. iDC 20 - order of operations



1. The specimen bottles and slides, previously identified by bar-code, are loaded on to the machine.
2. iDC 20 automatically reads the bar codes to check the correct match between bottles and slides.
3. A gradient liquid is deposited on the slides. During centrifugation, the density of the liquid causes red blood cells, dust and other matter that could perturb evaluation to be separated out.
4. iDC 20 uses a disposable tip to draw 1 ml of liquid from the sample bottle (following re-suspension). A pressure sensor checks that the sample is correct.
5. iDC 20 places the liquid-filled tip in front of an integrated infra-red sensor to measure turbidity and thus determine cell concentration of the sample.
6. As a function of the concentration, iDC 20 places on the slide the required volume to ensure the correct quantity of cells is present.
7. A first, slow centrifuge is engaged to fix the cells on the slide. This ensures a clear background - no blood, fewer white blood cells, bacteria and less mucus
8. Following supernatant evacuation by the disposable tips, a second, faster centrifugation process fixes the cells definitively to the slide, which is then dried.
9. Slides removed from the iDC 20 are ready for staining.

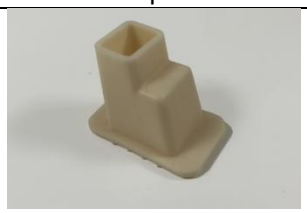
3. ADVANTAGES OF iDC 20

- **High quality slide preparation,** facilitating evaluation: no cell clusters, clear cell separation, no deformation
- **Large rectangular spot that is** homogeneous and reproducible as a result of the fully automated slide preparation operation
- **Single-layer spot** thanks to the infra-red turbidity measurement (cell concentration is automatically calculated)
- **No cross-contamination** (because of the disposable tips)
- Both **gynaecological and non-gynaecological samples** can be handled
- Automation and high throughput (**up to 40 slides per hour**) **frees up the technician's time** for other tasks
- **Total security**: any operating error is detected and flagged up, bar-codes identify and match specimen bottle with slide, bar-codes are read before the sample is taken and distributed. The software meets the requirements of standard 62304.
- Full traceability: all data is stored and accessible in a useable Excel file
- Ergonomic design makes it **extremely easy to use** (tablet touch-screen): only 2 hours of training are required for users
- It may be fitted with an optional **GSM device** to provide a remote and real-time consumption read-out, thus facilitating consumables stock management and also automatic stock replenishment.

Technical Specifications :

Weight	75 Kg
Size	90 cm x 60 cm x 40 cm
Capacity	20 Specimen bottles
Power	110-240 volts - 150 Watts
CE Mark	IVD CE
Software	Touchpad with software inside

Consumables :

Consumables	Ref	Packaging
 Tips	216-483	1600 Tests
 Centrifuge cup	216-486 B	1600 Tests
 Slide	216-601	72 slides polysine
 Specimen Bottles	216-105	Specimen bottles
 cervex brush	216-104	500 Brushs

iLsa Diagnostic

Cytology

Success of a new technology

iDC shaker Agitator with vertical movement

iDC shaker

Agitator for specimen bottles to separate heap of cells and to dissolve mucus, sources of defects of spreading by a vertical agitation.

Compact device with opening by the top. The iDC shaker can shake 40 specimen bottles simultaneously.
Two trays are available for specimen bottles of diameters 26 and 36 mm
Very effective to obtain a homogeneous and fluid smear
Easy to use : one single button to start …. That's it
Fast : only 2 minutes of agitation
Adaptable to various size of specimen bottles

Weight	45 kg
Size	38 cm x 44 cm x 34 cm
Capacity	40 specimen bottles
Power	110-230 volts - 150 Watts
CE Mark	CE
Type of specimen bottle	Ø 36 mm or Ø 26 mm

Vertreten durch:

LAT - Labor- und Analysten-Technik GmbH
Heinkelstraße 4
DE - 30827 Garbsen
+49 5131 4845200
info@latonline.de

Scientific Instruments